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.

301773

Licensee	
1. Midwest Imaging Diagnostic, Inc., Ltd. (MIDI) 2. 111 Wellington Place Cincinnati, OH 45219	3. License Number 34-26753-01 4. Expiration Date October 31, 2001 5. Docket or Reference No. 030-34230

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (except generators, xenon-133, and aerosols)	B. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (except generators, xenon-133, and aerosols).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 111 Wellington Place, Cincinnati, Ohio.

11. Radiation Safety Officer: Harold T. Pretorius, M.D., Ph.D.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 34-26753-01
Docket or Reference Number: 030-34230

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
A. Harold T. Pretorius, M.D., Ph.D.	10 CFR 35.100 and 35.200 (except generators, xenon-133, and aerosols)

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. Letter received October 10, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 10/14/96

By Richard T. Weber
Materials Licensing Branch, Region III

COPY

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:

S2
16

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: MIDWEST IMAGING DIAGNOSTIC/INC/LTD.
   Received Date: 960826
   Docket No: 3034230
   Control No.: 301773
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED?
   Amount: $1,700.00
   Check No.:

3. COMMENTS

Signed Maria Pearson
Date 8/27/96

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

1. Fee Category and Amount: $1400 7C

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

3. OTHER

Signed JC
Date 9/4/96

96 AUG 29 PM 4:25

Log Aug 15 III
Remitter
Check No. 420 (Acct No. 0839-847)
Amount $1400
Fee Category 7C
Type of Fee APP
Date Check Rec'd 9/17/96
Date Completed
By JC

SEP 23 1996

Check reassigned for #420 Returned 9/17/96

Log Aug 15 III
Remitter
Check No. #2000 Refund
Amount $1400 $20,300
Fee Category 7C
Type of Fee APP
Date Check Rec'd Aug 29 1996
Date Completed Sept 4, 1996
By JC

Midwest Imaging Diagnostics Incorporated, Limited (MIDI)
111 Wellington Place
Cincinnati, Ohio 45219 Telephone: (513) 579-1054

U.S. Nuclear Regulatory Commission
Attn: Sandra Kimberly
mail stop T9E10
Washington DC 20555

Dear Ms Kimberly:

Enclosed is a check for $1400 for application for a Nuclear Regulatory Commission license to use medical radioisotopes in a physician's office. We previously sent a check for $21,700, which we were told by the licensing reviewer, Mr. Charles Gill, was not necessary since our operation do not fall in the broad license category. We understand that our earlier check for $21,700 will therefore be voided or returned.

Sincerely,

H. Thomas Pretorius, M.D., Ph.D.
Medical Director, MIDI

Dr. Pretorius,
Enclosed is your August 23, 1996, check in the amount of $21,700. We are returning ~~it~~ to you for voiding.

MIDWEST IMAGING DIAG:
INCORPORATED, LTD.
111 WELLINGTON PLACE
CINCINNATI, OHIO 45219

AA905 APP TC
Aug 15 III

August 23, 1996

PAY TO THE ORDER OF U.S. Nuclear Regulatory Commission $ 21,700.00

Twenty-one thousand seven hundred and no/100 DOLLARS

The Provident Bank
CINCINNATI, OHIO

FOR

:042000424: 0839-847" 3017

NARLAND N33

AUG 26 1996

NRC FORM 313 (10-94)
10 CFR 30, 32, 33, 34, 35, 36, 39 and 40

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

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

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, 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

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

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

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

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

Midwest Imaging Diagnostic Incorporated, Limited (MIDI)
111 Wellington Place
Cincinnati, OH 45219

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

Midwest Imaging Diagnostic Incorporated, Limited (MIDI)
111 Wellington Place
Cincinnati, OH 45219

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Ahmad A. Najafi, Ph.D.

TELEPHONE NUMBER

(714) 824 2018

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.

RECEIVED
AUG 26 1996
REGION III

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE

HAROLD T. PRETORIUS MD, MEDICAL DIRECTOR

SIGNATURE

DATE

Aug 23, 1996

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
					PM 8/23/96 301773

APPROVED BY | DATE

NRC FORM 313 (10-94)

5. Radioactive Material

Radioactive Material	Amount	
a. Radiopharmaceuticals used for uptake, dilution, and excretion studies (35.100)	As needed	
b. Radiopharmaceuticals, generators, and reagent kits used for imaging and localization studies (35.200)	As needed	
c. Other than byproduct material (not listed in Part 35)	F-18	800 mCi
	I-123	10 mCi
	I-124	10 mCi
	In-111	5 mCi
	Tl-201	100 mCi
	Co-57	100 mCi
	Co-56	10 mCi
	N-13	400 mCi
	Ge/Ga-68	200 mCi
	Ga-67	100 mCi
	C-11	200 mCi

6. Purpose(s) for which licensed Material will be used

Radioactive Material	Amount	Purpose
a. Radiopharmaceuticals used for uptake, dilution, and excretion studies (35.100)	As needed	Medical use
b. Radiopharmaceuticals, generators, and reagent kits used for imaging and localization studies (35.200)	As needed	Medical use
c.	As needed	Medical use

7. Individual(s) responsible for radiation safety program and their training experience.

Until another qualified person is employed Harold T. Pretorius, M.D., Ph.D. (Board Certified Nuclear Medicine Physician) Medical Director of the center will be responsible for the radiation safety program (see attached resume).

8. Training requirements of radiation workers and ancillary personnel in restricted areas.

To obtain approval to begin work with radioactive materials at Midwest imaging Diagnostic Incorporated, Limited (MIDI) the person has to have either an approved and verifiable training and experience working with radioactive materials, or have at least 20 hours of supervised work and training which includes:

a. General handling of radioactive materials

b. Physical decay

c. Radiation protection

d. How to handle a spill

e. How to handle an emergency

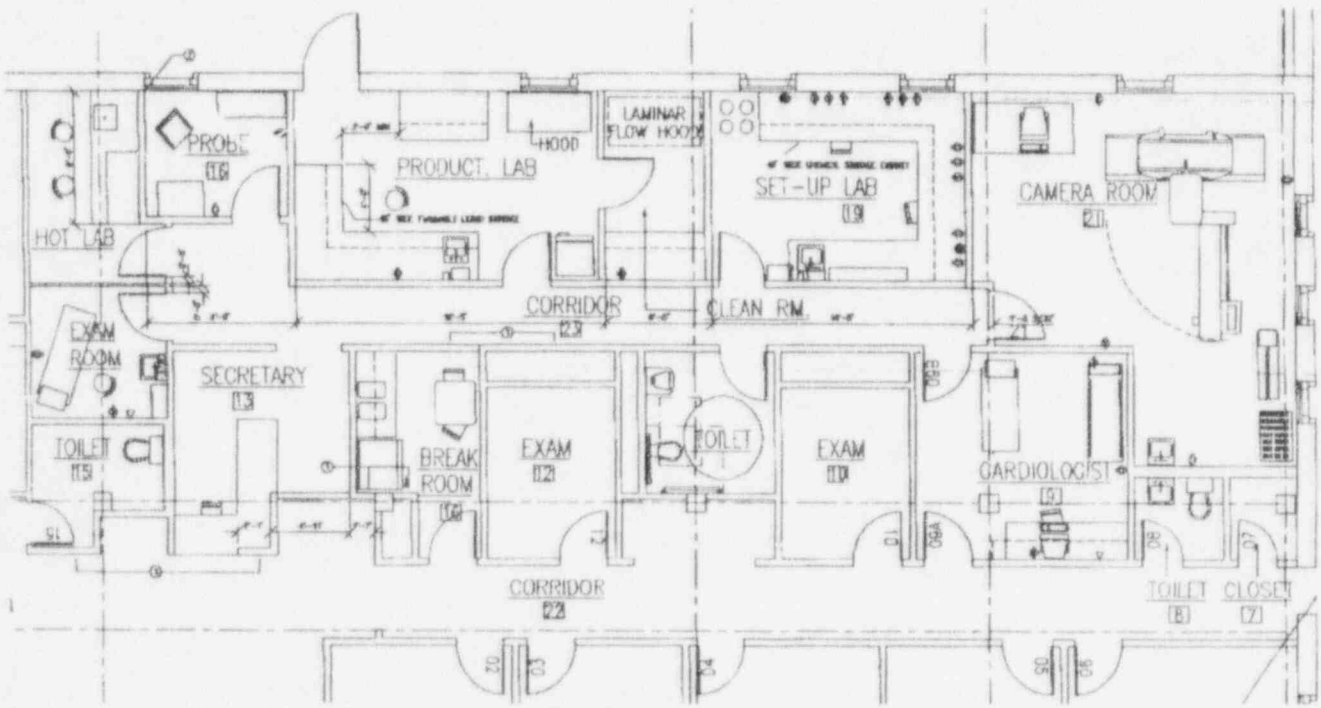
9. Facilities and equipment's.

9.1. Building and Facilities

The MIDI occupies part of the upper level (approximately 2000 square feet) of the two floor Diagnostic Center. The outside wall of the building, in addition to the floor of the facility are consist of at least 4.5 inch concrete. The other parts of the building house Diagnostic Radiology, Magnetic Resonance Imaging, Ultrasound, and Patient Registration.

All radioactive materials are received and kept, and dispensed in the Hot Lab.

One sink, and one L Shield is available in the Hot Lab. Figure below shows the floor plan of the center with the equipment layout.



b. Equipment Listing

Major equipment to be used in the center are listed below with manufacturer, model number, for location please see the floor plan in the previous page.

(1) Two Ludlum survey meter model # 14C/44-6 one including 44-6 thin wal GM detector and the other pancake GM detector, with Cs-137 check source.

(2) NRC Integrating survey meter model # ADM-300A.

(3) A complete facility monitoring system including a. Five integrated gamma Detectors b. Two digital wide range gamma monitors c. Special in-line stack monitor d. Control system for the detectors.

(4) Two L Shield model # HC-101, One hundred lead Bricks, and two syringe shields.

(5) Two radioisotope calibrator, ionization chamber, Atomlab 100 Model number 086-265 with reference source set including Cs-137, Ba-133, and Co-57.

(6) High Pressure Liquid Chromatograph, Waters model 510 pump, Waters model U6K injector, Waters model 410 differential refractometer , UV, and radioactivity detector s and Waters computer interface module.

(7) Gas Chromatograph, Hewlett Packard 6890 Series 2, Flame ionization detector.

(8) Two analytical balance, model # PG-502 and AG-104, range 0-300 g, readability 0.1 mg.

(9) Oven, Isotemp 655F model # 13-247-750F, temperature range ambient to 300° C.

(10) Gamma-ray spectrometer, Canberra Accuspec, Detector - 3" x 3" NaI(Tl) well, MCA computer card - Intel System 120.

(11) Computer, general purpose, IBM PS 2 Network. Use - word processing, business systems, technical computation, archives.

(12) Biological safety cabinet (laminar airflow hood), Labconco model 35210-00, HEPA filtered to Class 100. Use - Aseptic component preparation. Location - Processing and testing laboratory.

(13) Two digital dosimeters model # 06-502

(14) 6' Constant bypass radioisotope fume hood model # 72822-00

9.2 Survey Instrumentation Calibration

Survey instruments are send to manufacturer for annual calibration.

9.3 Dose Calibrator Calibration

I. Daily Constancy Check

In the absence of any radioactive sources, adjust background knob until a zero reading is obtained.

Place the Cs-137 source in the dose calibrator.

Push the Tc-99m, I-131, I-123, Tl-201, and set the proper range F-18 and record the readings at each setting..

Compare the value to the previous readings for the source.

Variations greater than ± 5% from the calculated source activity indicate need for adjustment and/or repair.

II. Quarterly Dose Calibrator Linearity

a. Linearity Check by Tc-99m Decay Method

Prior to each measurement during this test, select proper range and isotope settings on dose calibrator module. Also check the background and zero levels on the module and adjust if necessary.

Using long-handled tongs, place the Tc-99m source in the ionization chamber of the dose calibrator to be tested.

Measure the activity over a 72-hour period and record the results.

b. Linearity Check by Concentric Lead Sleeve Method

Prior to each measurement during this test, select proper range and isotope settings on dose calibrator module. Also check the background and zero levels on the module and adjust if necessary.

Record the readings of a Tc-99m source with different sleeves.

The measured activity at each time during the 72-hour test must be within ± 10% of the calculated activity (corrected for decay).

After application of the lead sleeve calibration factors, the measured activity for each lead sleeve must be within ± 10% of the calculated activity (corrected for attenuation).

If the dose calibrator fails either of these tests, repair or replace as appropriate

III. Quarterly Dose Calibrator Accuracy

Using appropriate range and isotope settings on the dose calibrator module, measure and record the activity of at least two of the sources.

Accounting for decay, calculate the activity of the source at the time of the measurement.

To pass the accuracy test, the measured activities from readings must agree with the calculated activities to within ± 10% for each source.

If the dose calibrator fails the accuracy test, the instrument must be repaired or replaced.

IV. Quarterly Dose Calibrator, Geometric Independence

Inject 1 mL of ^{18}F into a 30 mL vial.

Adjust background and zero settings for the range to be used. Check to see that proper isotope selection (F-18) has been made. Place the vial in the ionization chamber. Assay the vial using the lowest possible range setting.

Remove the vial from the calibrator and inject 1 mL of normal saline into the vial. Assay the vial.

Repeat the additions of saline and reassay the vial at total volumes of 4 mL, 8 mL, 10 mL, 20 mL and 25 mL. Decay correct each measurement to a common time.

Select 10 mL as the reference volume.

Divide the assay of the reference volume by the assay of each other volume. The quotient is the volume correction factor.

An assay correction must be made for volume deviations that result in corrections greater than ± 5%.

9.4 Personal Monitoring Program

All personnel will be wearing TLD Ring and Film dosimetry badges provided and developed by Radiation Detection Company, 162 Wolfe Rd., P.O. Box 3414, Sunnyvale, CA 94088

10. ELEMENTS OF THE RADIATION SAFETY PROGRAM

10.1 Responsible person or Radiation Safety Officer duties are:

- responsible for managing the radiation protection program
- identifies radiation safety problems
- initiates, recommends and verifies completion of corrective actions
- ensures compliance with pertinent regulations and license conditions
- investigates all incidents involving radioactive material
- reviews occupational radiation exposures and investigates as necessary
- ensures appropriate training for radiation workers and ancillary personnel whose duties may require to work or frequent a restricted area
- maintains radioactive material license and amends as needed

2. ALARA (page 8)

3. Leak Test (page 9)
We developed leak test procedures for your review appended as ATT 10.3

4. Safe use of pharmaceuticals (page 10)
We developed procedures for the safe use of pharmaceuticals for your review appended as ATT 10.4.

5. Spill procedures (page 11)
We developed spill procedures for your review appended as ATT 10.5.

6. Ordering and receiving radioactive material (page 13)
We developed a procedure for ordering and receiving radioactive material for your review appended as ATT 10.6.

7. Opening Packages (page 14)
We developed a procedure for opening radioactive materials packages for your review appended as ATT 10.7.

8. Unit dose usage
We will establish and implement the model procedure as described in reg. guide 10.8 Rev. 2 for unit dose usage.

9. Multidose vial use
We will establish and implement the model procedure as described in reg. guide 10.8 Rev. 2 for multidose vial use.

10. Molybdenum concentrations
We will establish and implement the model procedure as described in reg. guide 10.8 Rev. 2 for measuring and recording Mo concentration.

11. Area survey procedures (page 15)
We developed survey procedures for your review appended as ATT 10.11.

12. Air concentration control
We do not intent to use radioactive gas.

13. Other procedures as needed.

14. Waste disposal (page 17)
We developed a procedure for waste disposal appended in ATT 10.14.

ATTACHMENT 10.2

ALARA PROGRAM

We, the management MIDI, are committed to keeping individual and collective doses as low as reasonable achievable. It is the responsibility of everyone, management, radiation workers, and the Radiation Safety Officer to operate within the ALARA guidelines. The ALARA philosophy is meant to strike a balance between the cost of radiation protection and the health benefit derived from that protection.

In practice, to operate within ALARA guidelines is to promote sound safety procedures in the clinic through training, continuing education and information about the radiation workplace. In addition, the workplace environment is monitored to control contamination and minimize doses.

Administratively, we will perform a periodic review of the radiation safety program, including such considerations as occupational doses and changes in procedures and safety measures.

ATTACHMENT 10.3

LEAK TESTING SEALED SOURCES

GENERAL

1. Leak tests on sealed sources are performed by the Radiation Safety Officer or qualified individuals designated by him.

2. The Leak Test Record identifies the radionuclide, the activity on a specified date, and the physical form of the sealed source.

3. A sealed source is one in which the radioactive material is encapsulated to prevent leakage.

4. Any sealed source is exempt from leak testing if it contains less than 100 uCi of beta or gamma emitting material.

5. Disposable gloves are worn when leak testing sealed sources. For larger sources, the radiation exposure is monitored with an appropriate survey meter.

LEAK TEST AND ANALYSIS

1. A separate wipe sample for each source is used. Accessible surfaces of the source are wiped with a suitable medium such as filter paper, tissue paper, or cotton swap.

2. Each wipe is numbered or otherwise identified to correspond to the source being wiped..

3. The leak test wipe is assayed in an appropriate counting instrument, such as a NaI crystal with a scaler or a GM survey meter, sufficiently sensitive to detect 0.005 uCi. The counting geometry is standardized and the detection efficiency of the counting system is verified.

4. Raw data from the counting system is recorded on the Leak Test Record and the estimated activity in uCi is calculated for each wipe sample.

5. If the wipe sample activity is 0.005 uCi or greater, it will be withdrawn from use to be repaired or discarded. The appropriate regulatory agency such as the NRC or Agreement State is notified as required.

ATTACHMENT 10.4

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear protective clothing such as a labcoat in areas where radioactive material is used.
2. Wear disposable gloves when handling radioactive material.
3. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
4. Do not eat, drink, smoke, or apply cosmetics in designated areas where radioactive material is used or stored.
5. Do not store food or drink in designated areas where radioactive material is used or stored.
6. Wear your dosimeters, including a finger TLD, during elution of generator, and preparation, assay, and injection of radiopharmaceuticals.
7. Dispose radioactive waste only in specifically designated waste containers.
8. Never pipette by mouth.
9. Survey generator, kit preparation, and injection areas for contamination at the end of the day. Decontaminate if necessary.
10. Identify containers containing radioactive material, syringes, and unit doses with appropriate information such as name of compound, radionuclide, date, and activity.
11. Store and transport radioactive material in shielded containers.

ATTACHMENT 10.5

EMERGENCY PROCEDURES

GENERAL

During the course of routine operations, radioactive material may be spilled, causing contamination of the "Hot Lab.", imaging room, personnel, or equipment. Immediate and correct action during such an emergency can greatly prevent any further spread of contamination.

Medical attention takes precedence over radiological or other concerns in the case of a serious injury. Inform medical personnel if there is the possibility of contamination.

MAJOR SPILLS

Major spills are defines as contamination of large surface areas, external or internal contamination of personnel, and excessive radiation exposure to personnel.
Take the following steps to respond:

STEP	PROCEDURE
1	**CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2	**PREVENT SPREAD OF CONTAMINATION:** Cover the spill with absorbent paper but don't try to clean it up. To prevent spread of contamination, limit movement of contaminated personnel and prevent persons from entering contaminated area.
3	**SHIELD THE SOURCE:** If possible, shield source by returning stock vials to their shields, but only if it can be done without further contamination or without a significant increase in radiation exposure.
4	**CLOSE THE ROOM:** Leave the room and secure the area to prevent entry.
5	**CALL FOR HELP:** Notify the Radiation Safety Officer
6	**PERSONNEL DECONTAMINATION:** Monitor personnel for contamination. Decontaminate personnel by removing contaminated clothing and thoroughly flushing contaminated skin, followed by gently washing with mild soap and luke-warm water.
7	**REPORT:** The Radiation Safety Officer completes an incident and decontamination report.

ATTACHMENT 10.5
EMERGENCY PROCEDURES
(continued)

MINOR SPILLS

Minor spills are those that contaminate small areas or equipment. Take the following steps to respond:

STEP	PROCEDURE
1	**NOTIFY:** Notify all persons in the area that a spill has occurred.
2	**PREVENT SPREAD OF CONTAMINATION:** Cover the spill with absorbent paper to prevent spread of contamination.
3	**CLEAN UP:** Wearing disposable gloves, carefully clean up the spill with absorbent paper. Collect contaminated absorbent paper and other contaminated material in a plastic bag and dispose of it in a radioactive waste container.
4	**SURVEY:** Survey the area around the spill with an appropriate instrument. Similarly, check your hands, clothing and shoes for contamination. Perform follow up measurements and decontaminate as necessary.
5	**REPORT:** Report the incident to the Radiation Safety Officer.

ATTACHMENT 10.6

ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Radiation Safety Officer ensures that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. For routinely used material, a standing (or blanket) order is placed with the supplier. A record is maintained of that standing order that identifies the radionuclide, chemical form, activity, and shipment dates.

3. For non-routine or occasionally used material, a separate order form identifying the radionuclide, compound, activity and supplier is maintained and checked against the material received.

4. During normal business hours, carriers are instructed to deliver packages containing radioactive material to the (hot lab., RSO, to be determined).

5. During off-duty hours we do not accept packages.

6. If the package is wet or damaged, immediately contact the Radiation Safety Officer. If possible, detain the carrier until it is determined that neither the carrier or his vehicle is contaminated.

ATTACHMENT 10.7

OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Put on disposable gloves.

2. Visually inspect package for any sign of damage. If package is damaged, notify the Radiation Safety Officer before proceeding any further.

3. Check the radiation levels of package surfaces and at one meter for packages labeled with Yellow II and III labels to verify the information on the shipping label. Package surface radiation levels should not exceed 200 mrem/hr. Packages with White I labels should measure less than 0.5 mrem/hr at surface. If higher than expected radiation levels than stated on the labels are found, notify the Radiation Safety Officer.

4. Carefully open the package. Verify contents against the packing list. Check the integrity of the final source container inspecting for breakage of seals, loss of liquid, and discoloration of packing material.

5. If leakage or contamination is suspected, wipe the exterior surface of the final source container to determine levels of contamination; assay and record.

6. Monitor the packing material and packages for contamination and obliterate radiation labels before discarding to regular trash.

7. Check that the shipment does not exceed the possession limit.

ATTACHMENT 10.11

AREA SURVEY PROCEDURES

1. Survey all elution, preparation, and injection areas daily with a survey meter such as GM meter or NaI crystal detector. Perform removable contamination surveys (wipes) in those areas weekly.

2. Survey waste storage areas weekly.

3. Survey all other areas such as laboratories in which small amounts of radioactive material is used monthly.

4. The weekly and monthly survey consists of
   a. a measurement of radiation levels
   b. a series of wipe tests to measure removable contamination

5. Record survey results on survey form (ATT 10.11A) and any corrective actions.

6. For daily surveys where no abnormal findings are found, only the date and the identification of the person performing the survey is recorded.

7. Action levels in dpm/100 cm^2 for surface decontamination:

TABLE 10.11

	P-32, Co-58, Fe-59 Co-60, Se-75, Sr-85 Sr-89, In-111, I-123 I-125, I-131, Ba-133 Cs-137, Yb-169, Au-198	Cr-51, Co-57 Ga-67, Ga-67 Mo-99, Tc-99m Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing, skin	2,000	20,000

ATTACHMENT 10.11A

SURVEY RECORD

Radiation Survey for the month of _____, 19__

Instrument: _____

diagram of facility(ies)

mR/hr or dpm/100cm^2 (circle one)

Location	1	2	3	4	5	6	7	8	9	10	Initial
Date/Bkgd											

ATTACHMENT 10.14
ATTACHMENT 10.14

WASTE DISPOSAL

1. LIQUID WASTE will be disposed of the sewer system in accordance with 10CFR Part 20.303.

2. Mo/Tc-99m GENERATORS will be disposed of by being returned to the manufacturer for disposal.

3. SOLID WASTE will be disposed of by decay-in-storage (physical half-life less than 65 days).

OCT 16 1996

Harold T. Pretorius, M.D., Ph.D.
Radiation Safety Officer
Midwest Imaging Diagnostic, Inc., Ltd.
111 Wellington Place
Cincinnati, OH 45219

Dear Dr. Pretorius:

Enclosed is your NRC Material License Number 34-26753-01 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) 29-9887 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

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

301773

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.: 34-26753-01
Docket No.: 030-34230

Enclosures:
1. License No. 34-26753-01
2. 10 CFR Part 19
3. 10 CFR Part 20
4. 10 CFR Part 35
5. Form NRC-3

DOCUMENT NAME: M:\03034230.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII	C							
NAME	MWEBER:jaw								
DATE	10/14/96								

OFFICIAL RECORD COPY

From: Ahmad A. Najafi, Ph.D.
MIDI
111 Wellington Place
Cincinnati, OH 45219
(714) 824 2018

To: Mr. Michael Weber
USNRC Material Licensing
801 Warren Ville Rd.
Lisle, IL 60532

RE: Additional Information to Control # 301773

Dear Mr. Weber:

Thank you very much for your time and all your helpful suggestions. Enclosed please find the revised copy of our NRC application. I would appreciate a response as soon as you can and is possible.

Sincerely Yours

Ahmad A. Najafi, Ph.D.

5. Radioactive Material

Radioactive Material	Amount	
a. Radiopharmaceuticals used for uptake, dilution, and excretion studies (35.100)	As needed	
b. Radiopharmaceuticals, generators, and reagent kits used for imaging and localization studies (35.200)	As needed	
c. Other than byproduct material (not listed in Part 35)	F-18	800 mCi
	I 123	10 mCi
	I-124	10 mCi
	In-111	5 mCi
	Tl-201	100 mCi
	Co-57	100 mCi
	Co-56	10 mCi
	N-13	400 mCi
	Ge/Ga-68	200 mCi
	Ga-67	100 mCi
	C-11	200 mCi

6. Purpose(s) for which licensed Material will be used

Radioactive Material	Amount	Purpose
a. Radiopharmaceuticals used for uptake, dilution, and excretion studies (35.100)	As needed	Medical use
b. Radiopharmaceuticals, generators, and reagent kits used for imaging and localization studies (35.200)	As needed	Medical use
c.	As needed	Medical use

7. Individual(s) responsible for radiation safety program and their training experience.

Until another qualified person is employed Harold T. Pretorius, M.D., Ph.D. (Board Certified Nuclear Medicine Physician) Medical Director of the center will be responsible for the radiation safety program (see attached resume).

8. Training requirements.

Before a radiation worker begins work with radioactive materials at Midwest imaging Diagnostic Incorporated, Limited (MIDI), the person will be provided with site-specific instruction about areas where radioactive materials are stored, radiological safety procedures appropriate to their respective duties, potential hazards associated with

radioactive material, pertinent regulations and license conditions, appropriate response to emergencies or unsafe conditions, and the ALARA program. In addition all radiation workers will have informal radiation safety training courses in areas such as:

a. General handling of radioactive materials

b. Physical decay

c. Radiation protection

d. How to handle a spill

e. How to handle an emergency

Radiation workers will also participate in an annual refresher training as well as whenever there is a significant change in regulations or license conditions.

Ancillary personnel that may support activities in restricted areas will be informed about radiation hazards and appropriate precautions.

9. Facilities and equipment's.

9.1. Building and Facilities

The MIDI occupies part of the upper level (approximately 2000 square feet) of the two floor Diagnostic Center . The outside wall of the building, in addition to the floor of the facility are consist of at least 4.5 inch concrete. The other parts of the building house Diagnostic Radiology, Magnetic Resonance Imaging, Ultrasound, and Patient Registration. The ground floor plan of the building is shown on the exhibit 1. The MIDI's area is shown with yellow color. More detail of MIDI's area is shown on the exhibit 2.

Principal use of different rooms at MIDI

1. Hot Lab (exhibit 3).

MIDI does not intent to use Generators, and only single patient doses are obtained. All radioactive materials are received and kept, and dispensed in the Hot Lab.

One sink, one L Shield, one Dose Calibrator, and Lead Shielded cabinet is available in the Hot Lab. All radioactive materials will be kept in the Lead Shielded cabinet until use. Patients doses are prepared in this room. The high level radioactive waste such as contaminated syringes and vials used for patient doses are stored in the shielded cabinet. The low level radioactive waste such as contaminated gloves are stored in a box with a radioactive label.

2. Production Lab (exhibit 4).

This room is used for production of F-18 Fluoro-deoxy-glucose (FDG). The production of FDG is performed by an automatic synthesizer which is placed in a shielded area in the fume hood. There is one L Shield, one Dose Calibrator, one refrigerator, two lead boxes, and an analytical Balance in this room. This room is equipped with an area monitor with automatic siren.

3. Clean Room.

This room is used for sterile setting of the components for the synthesizer, in addition to pyrogen and possibly sterility testing of the FDG products. Therefore, very small amount of radioactive material is used in this room.

There is one Laminar Flow Hood, Oven, Incubator, and Sterilizer in this room.

4. Set up Lab.

This room is used for setting up the components for the FDG synthesizer in addition for quality control of the FDG products and other radiopharmaceuticals. Therefore, very small amount of radioactive material will be used in this room.

There is one HPLC, GC, TLC scanner, and a water purifying system in this room.

The other rooms include Camera room which is used for imaging the patients, Exam rooms which are used for examining the patients. The exam room close to the hot lab. is also used for patient administration.

b. Equipment Listing

Major equipment to be used in the center are listed below with manufacturer, model number, for location please see the floor plan in the previous page.

(1) Two Ludlum survey meter model # 14C/44-6 one including 44-6 thin wal GM detector and the other pancake GM detector, with Cs-137 check source.

(2) NRC Integrating survey meter model # ADM-300A.

1

(3) A complete facility monitoring system including a. Five integrated gamma Detectors b. Two digital wide range gamma monitors c. Special in-line stack monitor d. Control system for the detectors.

1

(4) Two L Shield model # HC-101, One hundred lead Bricks, and two syringe shields.

(5) Two radioisotope calibrator, ionization chamber, Atomlab 100 Model number 086-265 with reference source set including Cs-137, Ba-133, and Co-57.

(6) High Pressure Liquid Chromatograph, Waters model 510 pump, Waters model U6K injector, Waters model 410 differential refractometer , UV, and radioactivity detector s and Waters computer interface module.

(7) Gas Chromatograph, Hewlett Packard 6890 Series 2, Flame ionization detector.

(8) Two analytical balance, model # PG-502 and AG-104, range 0-300 g, readability 0.1 mg.

(9) Oven, Isotemp 655F model # 13-247-750F, temperature range ambient to 300° C.

(10) Gamma-ray spectrometer, Canberra Accuspec, Detector - 3" x 3" NaI(Tl) well, MCA computer card - Intel System 120.

(11) Computer, general purpose, IBM PS 2 Network. Use - word processing, business systems, technical computation, archives.

(12) Biological safety cabinet (laminar airflow hood), Labconco model 35210-00, HEPA filtered to Class 100. Use - Aseptic component preparation. Location - Processing and testing laboratory.

(13) Two digital dosimeters model # 06-502

(14) 6' Constant bypass radioisotope fume hood model # 72822-00

9..2 Survey Instrumentation Calibration

Survey instruments are send to manufacturer for annual calibration.

9.3 Dose Calibrator Calibration

I. Daily Constancy Check

In the absence of any radioactive sources, adjust background knob until a zero reading is obtained.

Place the Cs-137 (200 uCi) source in the dose calibrator.

Push the Tc-99m, I-131, I-123, Tl-201, and set the proper range F-18 and record the readings at each setting..

Compare the value to the previous readings for the source.

Variations greater than ± 10% from the calculated source activity indicate need for adjustment and/or repair.

II. Quarterly Dose Calibrator Linearity

Note: This test should at least cover the radioactivity levels equal to the maximum patient dose down to 30 uCi.

a. Linearity Check by Tc-99m Decay Method

Prior to each measurement during this test, select proper range and isotope settings on dose calibrator module. Also check the background and zero levels on the module and adjust if necessary.

Using long-handled tongs, place the Tc-99m source in the ionization chamber of the dose calibrator to be tested

Measure the activity over a period of time and record the results.

b. Linearity Check by Concentric Lead Sleeve Method

Prior to each measurement during this test, select proper range and isotope settings on dose calibrator module. Also check the background and zero levels on the module and adjust if necessary, in addition to reading and following the manufacturer's instruction.

Record the readings of a Tc-99m source with different sleeves.

The measured activity at each time during the 72-hour test must be within ± 10% of the calculated activity (corrected for decay).

After application of the lead sleeve calibration factors, the measured activity for each lead sleeve must be within ± 10% of the calculated activity (corrected for attenuation).

If the dose calibrator fails either of these tests, repair or replace as appropriate

III. Annual Dose Calibrator Accuracy

Using appropriate range and isotope settings on the dose calibrator module, measure and record the activity of at least two of the following sources.

Cs-137	200 uCi
Ba-133	250 uCi
Co-57	5.0 mCi

Accounting for decay, calculate the activity of the source at the time of the measurement.

To pass the accuracy test, the measured activities from readings must agree with the calculated activities to within ± 10% for each source.

If the dose calibrator fails the accuracy test, the instrument must be repaired or replaced.

IV. Dose Calibrator, Geometric Independence

Note: This test is done upon an installation of a new Dose Calibrator or upon any repairs, and it is done on 10, and 3 mL syringes since these are the syringes which are normally used for patient's doses.

Product vial

Inject 1 mL of ^{18}F (1-10 mCi) into a 30 mL vial.

Adjust background and zero settings for the range to be used. Check to see that proper isotope selection (F-18) has been made. Place the vial in the ionization chamber. Assay the vial using the lowest possible range setting.

Remove the vial from the calibrator and inject 1 mL of normal saline into the vial. Assay the vial.

Repeat the additions of saline and reassay the vial at total volumes of 4 mL, 8 mL, 10 mL, 20 mL and 25 mL. Decay correct each measurement to a common time.

Select 10 mL as the reference volume.

Divide the assay of the reference volume by the assay of each other volume The quotient is the volume correction factor.

An assay correction must be made for volume deviations that result in corrections greater than ± 5%.

!0 mL Syringe

Draw 1 mL of ^{18}F (1-10 mCi) into a 10 mL Syringe.

Adjust background and zero settings for the range to be used. Check to see that proper isotope selection (F-18) has been made. Place the syringe in the ionization chamber. Assay the syringe using the lowest possible range setting.

Remove the syringe from the calibrator and draw saline into the syringe and reassay at total volumes of 2, 4, 6, 8, and 10 mL.

Select 4 mL as the reference volume.

Divide the assay of the reference volume by the assay of each other volume. The quotient is the volume correction factor.

An assay correction must be made for volume deviations that result in corrections greater than ± 5%.

3 mL Syringe

Draw 0.5 mL of ^{18}F (1-10 mCi) into a 3 mL Syringe.

Adjust background and zero settings for the range to be used. Check to see that proper isotope selection (F-18) has been made. Place the syringe in the ionization chamber. Assay the syringe using the lowest possible range setting.

Remove the syringe from the calibrator and draw saline into the syringe and reassay at total volumes of 1, 1.5, and 2mL.

Select 1 mL as the reference volume.

Divide the assay of the reference volume by the assay of each other volume. The quotient is the volume correction factor.

An assay correction must be made for volume deviations that result in corrections greater than ± 5%.

9.4 Personal Monitoring Program

A NVLAP-certified dosimetry provider will be used for monitoring radiation. A monthly whole body film monitor will be issued to all radiation workers (individuals that are occupationally exposed). Radiochemist(s) and Med Techs who directly handle radioactive material will be also issued a ring dosimeter.

Other individuals, such as security personnel who deliver packages, secretarial personnel who work in the clinic, or individuals who occasionally are in a restricted area will not normally be issued exposure dosimeters unless deemed necessary by RSO.

The RSO will review all exposure reports quarterly, look for trends, and follow up on any unusual or significant exposures.

10. ELEMENTS OF THE RADIATION SAFETY PROGRAM

10.1 Responsible person or Radiation Safety Officer duties are:

- responsible for managing the radiation protection program
- identifies radiation safety problems
- initiates, recommends and verifies completion of corrective actions
- ensures compliance with pertinent regulations and license conditions
- investigates all incidents involving radioactive material
- reviews occupational radiation exposures and investigates as necessary
- ensures appropriate training for radiation workers and ancillary personnel whose duties may require to work or frequent a restricted area
- maintains radioactive material license and amends as needed

2. ALARA (page 10)

3. Leak Test (page 11)
We developed leak test procedures for your review appended as ATT 10.3

4. Safe use of pharmaceuticals (page 12)
We developed procedures for the safe use of pharmaceuticals for your review appended as ATT 10.4.

5. Spill procedures (page 13)
We developed spill procedures for your review appended as ATT 10.5.

6. Ordering and receiving radioactive material (page 15)
We developed a procedure for ordering and receiving radioactive material for your review appended as ATT 10.6.

7. Opening Packages (page 16)
We developed a procedure for opening radioactive materials packages for your review appended as ATT 10.7.

8. Unit dose usage
We will establish and implement the model procedure as described in reg. guide 10.8 Rev. 2 for unit dose usage.

9. Multidose vial use
We will establish and implement the model procedure as described in reg. guide 10.8 Rev. 2 for multidose vial use.

10. Molybdenum concentrations
We will not use Generators.

11. Area survey procedures (page 17)
We developed survey procedures for your review appended as ATT 10.11.

12. Air concentration control
We do not intent to use radioactive gas and aerosols.

13. Other procedures as needed.

14. Waste disposal (page 19)
We developed a procedure for waste disposal appended in ATT 10.14.

ATTACHMENT 10.2

ALARA PROGRAM

We, the management in MIDI, are committed to keeping individual and collective doses as low as reasonable achievable. It is the responsibility of everyone, management, radiation workers, and the Radiation Safety Officer to operate within the ALARA guidelines. The ALARA philosophy is meant to strike a balance between the cost of radiation protection and the health benefit derived from that protection.

In practice, to operate within ALARA guidelines is to promote sound safety procedures in the clinic through training at orientation, in continuing education during refresher training, and in information when significant changes in procedure or license conditions occur in the radiation workplace.

In addition, the workplace environment is monitored for radiation exposure and contamination control. Results from the monitoring program will be reviewed on a quarterly basis. Any unusual or significant monitoring results will be investigated promptly.

Administratively, we will perform an annual review of the radiation safety program, including such considerations as occupational doses and changes in procedures and safety measures.

ATTACHMENT 10.3

LEAK TESTING SEALED SOURCES

GENERAL

1. Leak tests on sealed sources are performed by the Radiation Safety Officer or qualified individuals designated by him.

2. The Leak Test Record identifies the radionuclide, the activity on a specified date, and the physical form of the sealed source.

3. A sealed source is one in which the radioactive material is encapsulated to prevent leakage.

4. Any sealed source is exempt from leak testing if it contains less than 100 uCi of beta or gamma emitting material.

5. Disposable gloves are worn when leak testing sealed sources. For larger sources, the radiation exposure is monitored with an appropriate survey meter.

LEAK TEST AND ANALYSIS

1. A separate wipe sample for each source is used. Accessible surfaces of the source are wiped with a suitable medium such as filter paper, tissue paper, or cotton swap.

2. Each wipe is numbered or otherwise identified to correspond to the source being wiped..

3. The leak test wipe is assayed in an appropriate counting instrument, such as a NaI crystal with a scaler or a GM survey meter, sufficiently sensitive to detect 0.005 uCi. The counting geometry is standardized and the detection efficiency of the counting system is verified.

4. Raw data from the counting system is recorded on the Leak Test Record and the estimated activity in uCi is calculated for each wipe sample.

5. If the wipe sample activity is 0.005 uCi or greater, it will be withdrawn from use to be repaired or discarded. The appropriate regulatory agency such as the NRC or Agreement State is notified as required.

ATTACHMENT 10.4

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear protective clothing such as a labcoat in areas where radioactive material is used.

2. Wear disposable gloves when handling radioactive material.

3. Use syringe shields for preparation of patient doses and administration to patients except in circumstances such as pediatric cases when their use would compromise the patient's well-being.

4. Do not eat, drink, smoke, or apply cosmetics in designated areas where radioactive material is used or stored.

5. Do not store food or drink in designated areas where radioactive material is used or stored.

6. Wear your dosimeters at all times while at work in MIDI.

7. Dispose radioactive waste only in specifically designated waste containers.

8. Never pipette by mouth.

9. Survey all areas that radioactive materials are used including the preparation areas, and injection areas for contamination at the end of the day. Decontaminate if necessary.

10. Identify containers containing radioactive material, syringes, and unit doses with appropriate information such as name of compound, radionuclide, date, and activity.

11. Store and transport radioactive material in shielded containers.

12. Wipe the storage, preparation, and administration areas weekly for surface contamination.

13. Assay each patient dosage in the dose calibrator before administration. Match the patient, radionuclide, and any other pertinent information to the prescribed dosage. All dosages must be within 10% of the prescribed dosage, except for dosages less than 10 microcuries.

ATTACHMENT 10.5

EMERGENCY PROCEDURES

GENERAL

During the course of routine operations, radioactive material may be spilled, causing contamination of the "Hot Lab.", imaging room, personnel, or equipment. Immediate and correct action during such an emergency can greatly prevent any further spread of contamination.

Medical attention takes precedence over radiological or other concerns in the case of a serious injury. Inform medical personnel if there is the possibility of contamination.

MAJOR SPILLS

Major spills are defines as contamination of large surface areas, external or internal contamination of personnel, and excessive radiation exposure to personnel.
Take the following steps to respond:

STEP	PROCEDURE
1	**CLEAR THE AREA:** Notify all persons not involved in the spill to vacate the room.
2	**PREVENT SPREAD OF CONTAMINATION:** Cover the spill with absorbent paper but don't try to clean it up. To prevent spread of contamination, limit movement of contaminated personnel and prevent persons from entering contaminated area.
3	**SHIELD THE SOURCE:** If possible, shield source by returning stock vials to their shields, but only if it can be done without further contamination or without a significant increase in radiation exposure.
4	**CLOSE THE ROOM:** Leave the room and secure the area to prevent entry.
5	**CALL FOR HELP:** Notify the Radiation Safety Office.
6	**PERSONNEL DECONTAMINATION:** Monitor personnel for contamination. Decontaminate personnel by removing contaminated clothing and thoroughly flushing contaminated skin, followed by gently washing with mild soap and luke-warm water.
7	**REPORT:** The Radiation Safety Officer completes an incident and decontamination report.

ATTACHMENT 10.5
EMERGENCY PROCEDURES
(continued)

MINOR SPILLS

Minor spills are those that contaminate small areas or equipment. Take the following steps to respond:

STEP	PROCEDURE
1	**NOTIFY:** Notify all persons in the area that a spill has occurred.
2	**PREVENT SPREAD OF CONTAMINATION:** Cover the spill with absorbent paper to prevent spread of contamination.
3	**CLEAN UP:** Wearing disposable gloves, carefully clean up the spill with absorbent paper. Collect contaminated absorbent paper and other contaminated material in a plastic bag and dispose of it in a radioactive waste container.
4	**SURVEY:** Survey the area around the spill with an appropriate instrument. Similarly, check your hands, clothing and shoes for contamination. Perform follow up measurements and decontaminate as necessary.
5	**REPORT:** Report the incident to the Radiation Safety Officer.

ATTACHMENT 10.6

ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Radiation Safety Officer ensures that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. For routinely used material, a standing (or blanket) order is placed with the supplier. A record is maintained of that standing order that identifies the radionuclide, chemical form, activity, and shipment dates.

3. For non-routine or occasionally used material, a separate order form identifying the radionuclide, compound, activity and supplier is maintained and checked against the material received.

4. During normal business hours, carriers are instructed to deliver packages containing radioactive material to the (hot lab., RSO, to be determined).

5. During off-duty hours we do not accept packages.

6. If the package is wet or damaged, immediately contact the Radiation Safety Officer. If possible, detain the carrier until it is determined that neither the carrier or his vehicle is contaminated.

ATTACHMENT 10.7

OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Put on disposable gloves.

2. Visually inspect package for any sign of damage. If package is damaged, notify the Radiation Safety Officer before proceeding any further.

3. Check the radiation levels of all packages at surface and at one meter to verify the information on the shipping label. Package surface radiation levels should not exceed 200 mrem/hr. Packages with White I labels should measure less than 0.5 mrem/hr at surface. If higher than expected radiation levels than stated on the labels are found, notify the Radiation Safety Officer.

4. Carefully open the package. Verify contents against the packing list. Check the integrity of the final source container inspecting for breakage of seals, loss of liquid, and discoloration of packing material.

5. Wipe the exterior surface of the final source container to determine levels of contamination; assay and record.

6. Monitor the packing material and packages for contamination and obliterate radiation labels before discarding to regular trash.

7. Check that the shipment does not exceed the possession limit.

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

ATTACHMENT 10.11

AREA SURVEY PROCEDURES

1. Survey all areas such as laboratories in which radioactive material is used daily and record the date and the identification of the person performing the survey.

4. Action levels in dpm/100 cm^2 for surface decontamination and exposure readings in mR/hr:

TABLE 10.11a

Surface Contamination Action Levels, dpm/100 cm^2

The action levels are those that described in table N-1 of Appendix N of Regulatory Guide 10.8

TABLE 10.11b

Exposure Readings Action Levels, mR/hr

1. Unrestricted areas
0.5, not to exceed 2.0 in any one hour, and not to exceed 100 in any one year

2. Restricted areas
5.0

ATTACHMENT 10.11A

SURVEY RECORD

Radiation Survey for the month of _____, 19__

Instrument: _____

diagram of facility(ies)

mR/hr or dpm/100cm^2 (circle one)

Location	1	2	3	4	5	6	7	8	9	10	Initial
Date/Bkgd											

ATTACHMENT 10.14
ATTACHMENT 10.14

WASTE DISPOSAL

1. LIQUID WASTE will be disposed of either by

a. the sewer system in accordance with 10CFR Part 20.2003, or
b. a commercial waste disposal service identified in item 3.

2. SOLID WASTE will be disposed of either by

a. decay-in-storage (physical half-life less than 65 days), or
b. a commercial waste disposal service identified in item 3.

Decay-in-storage only with radionuclide less than 65 days, store for 10 half-lives, and surveyed prior to disposal.

3. A NRC-licensed commercial waste disposal service will be contracted for proper disposal of radwaste.

UNIT #	FLOOR
B-1	BASEMENT
B-1	GROUND
B-2	GROUND
B-3	GROUND
B-4	GROUND
B-1	SECOND

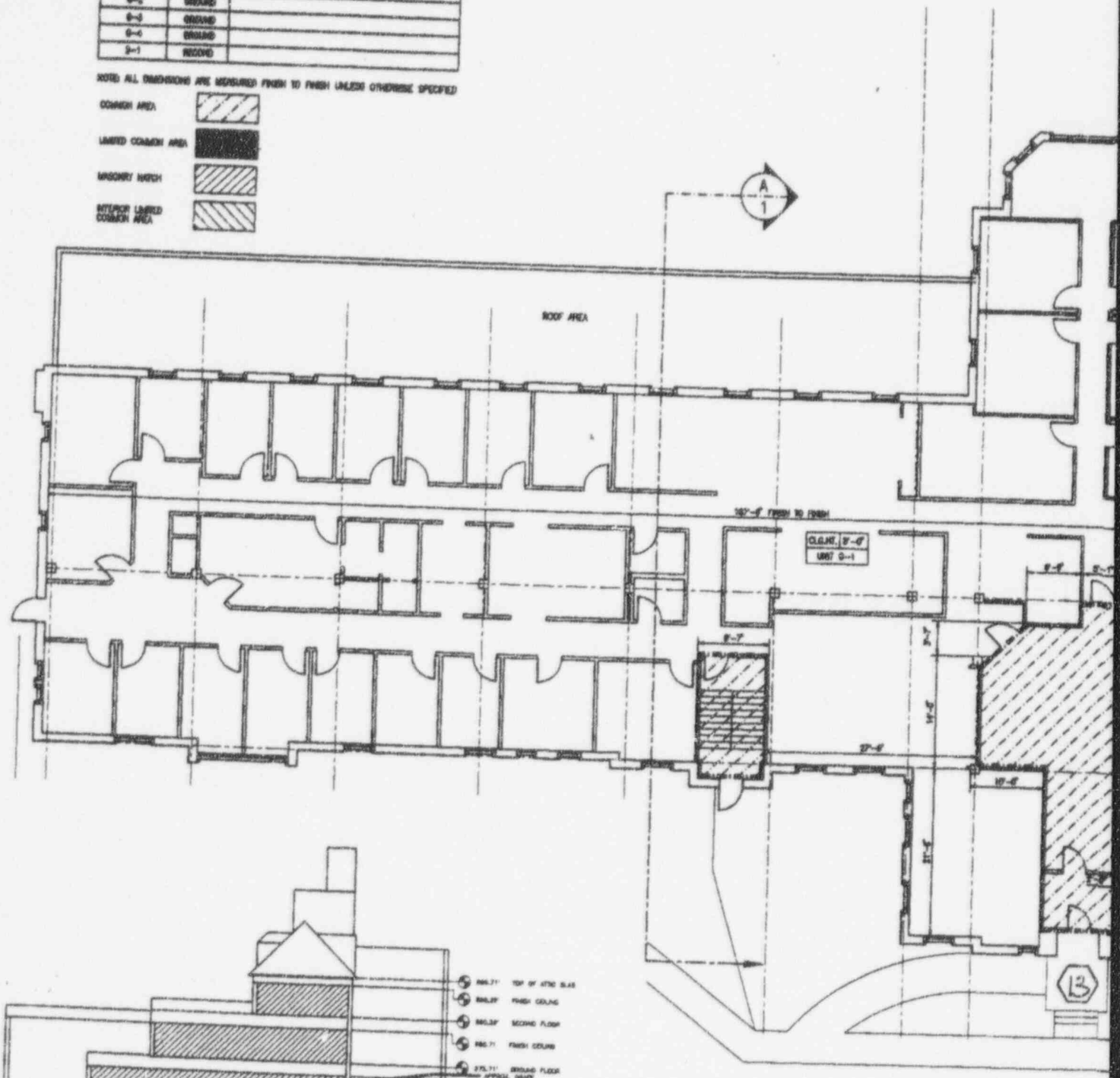
NOTE: ALL DIMENSIONS ARE MEASURED FINISH TO FINISH UNLESS OTHERWISE SPECIFIED

COMMON AREA

LIMITED COMMON AREA

MASONRY INFILL

INTERIOR LIMITED COMMON AREA

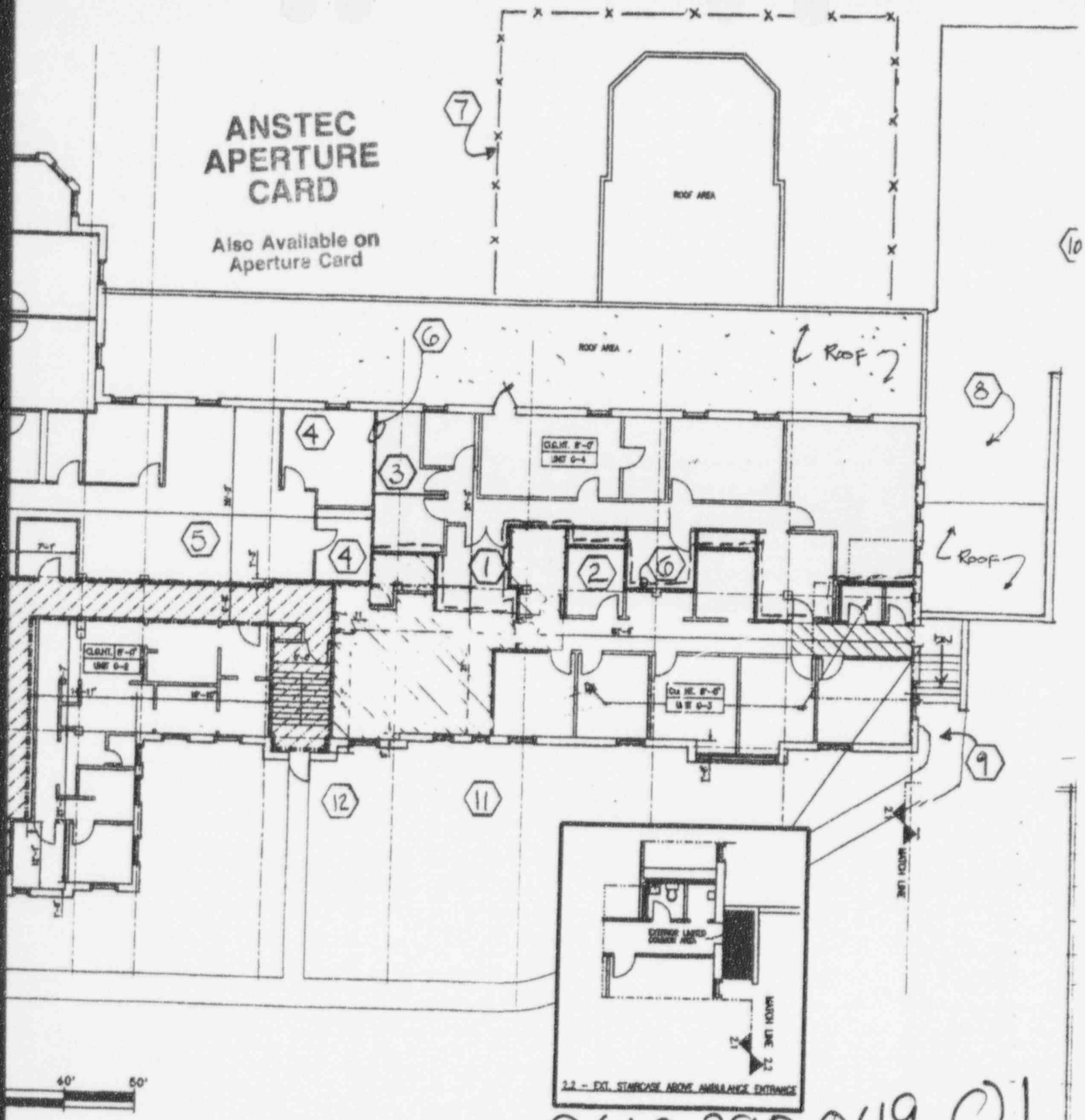


VOLUME SECTION (A)
1/16" = 1'-0"

NOTE: FOR SPECIFIC FINISH CEILING HEIGHTS REFER TO SHEETS A.5-A.7

0 10' 20' 30

Exhibit 1



9610280049-01

1 MIDI Office
2 Dr. Elam's patients room
3. MIDI Hot Lab.
4. Brace Shop Work room
5. Brace Shop
6. Property Line
7. Fence below
8. Basement Entry
9. Sidewalk
10. Driveway
11. Landscaping
12. Emerg. Exit
13. Main Entry

North

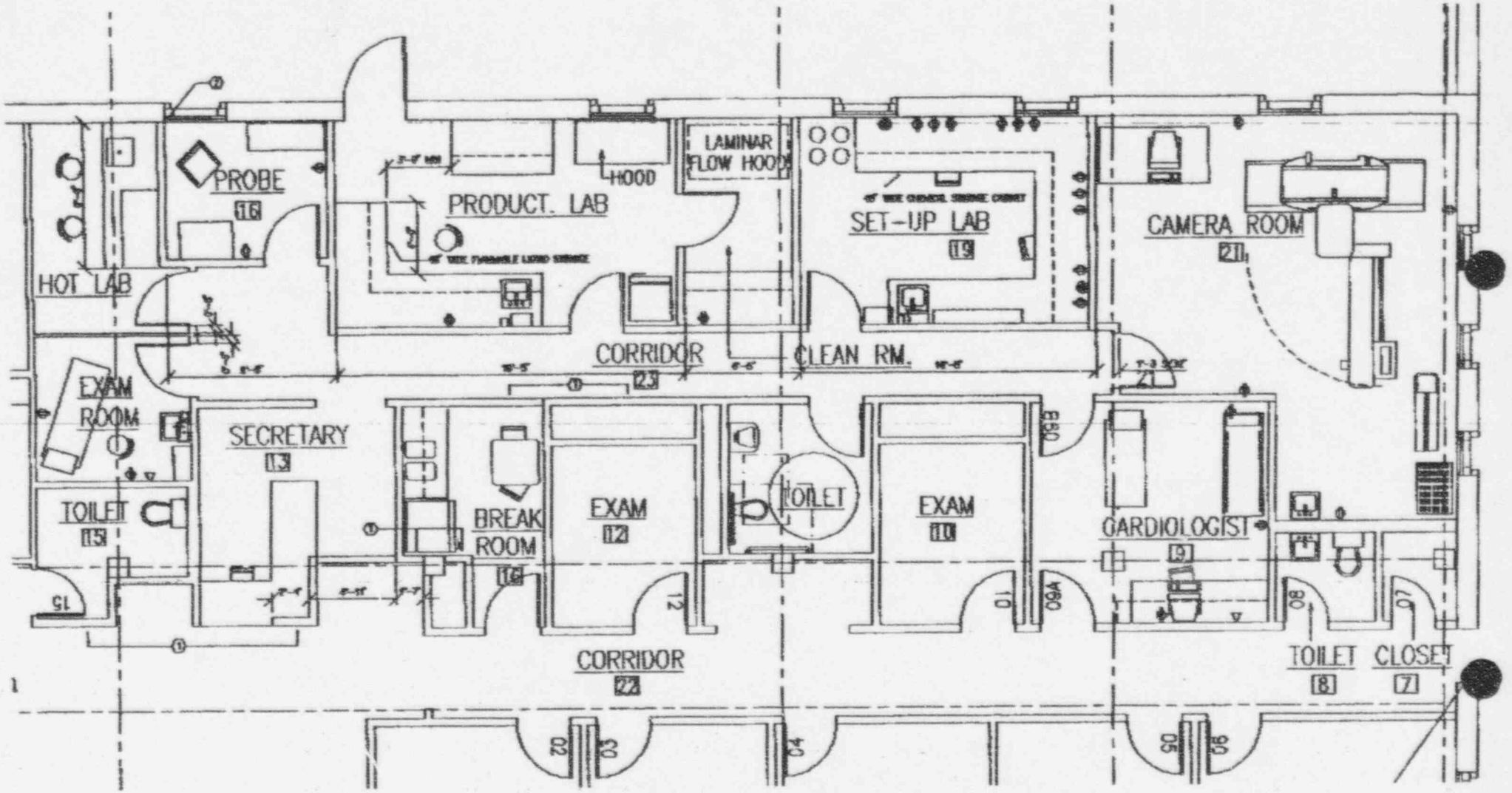

PROBE
16
HOT LAB
PRODUCT. LAB
HOOD
LAMINAR FLOW HOOD
SET-UP LAB
19
CAMERA ROOM
21
CORRIDOR
23
CLEAN RM.
EXAM ROOM
SECRETARY
13
TOILET
15
BREAK ROOM
14
EXAM
12
TOILET
EXAM
11
CARDIOLOGIST
9
CORRIDOR
22
TOILET
8
CLOSET
7

EXHIBIT 2

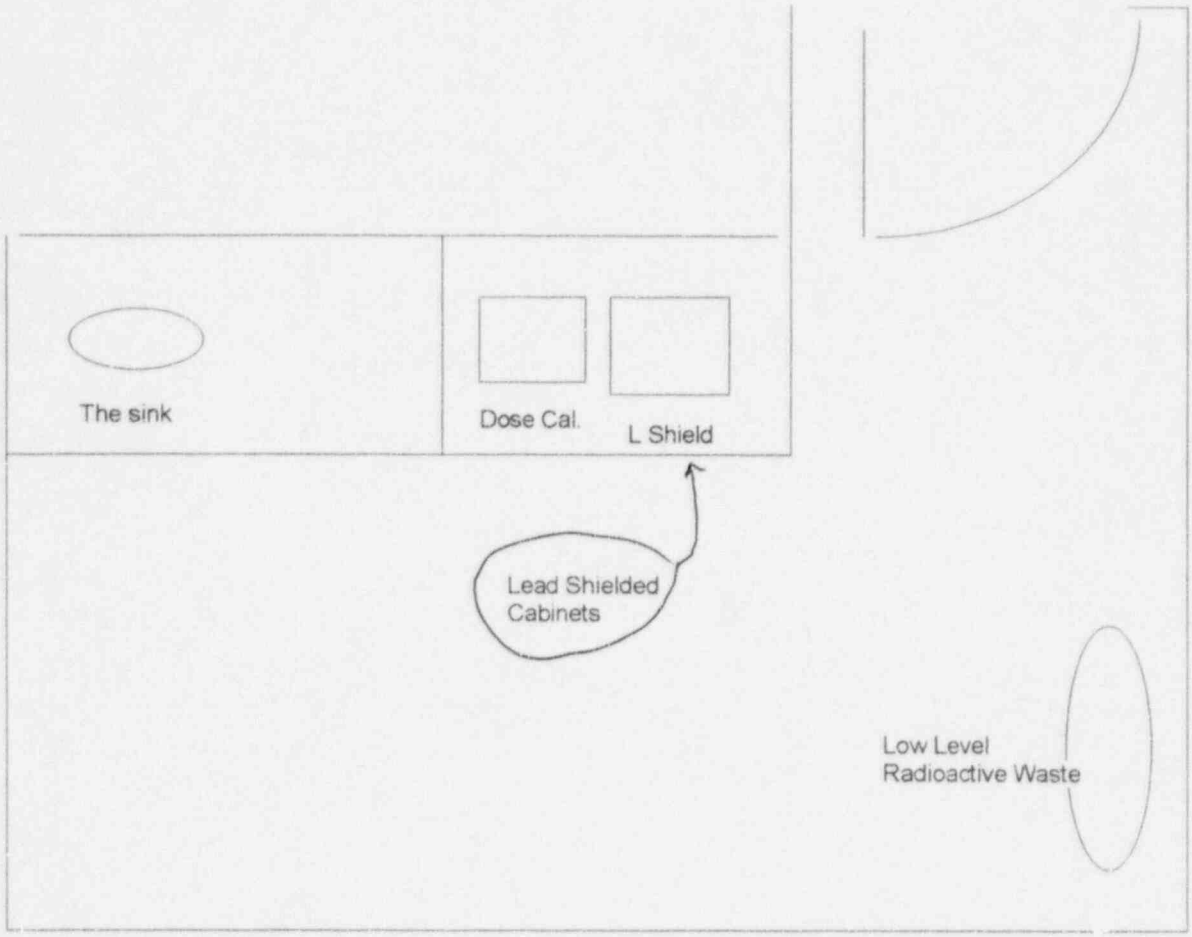


Exhibit 3, The Hot Lab

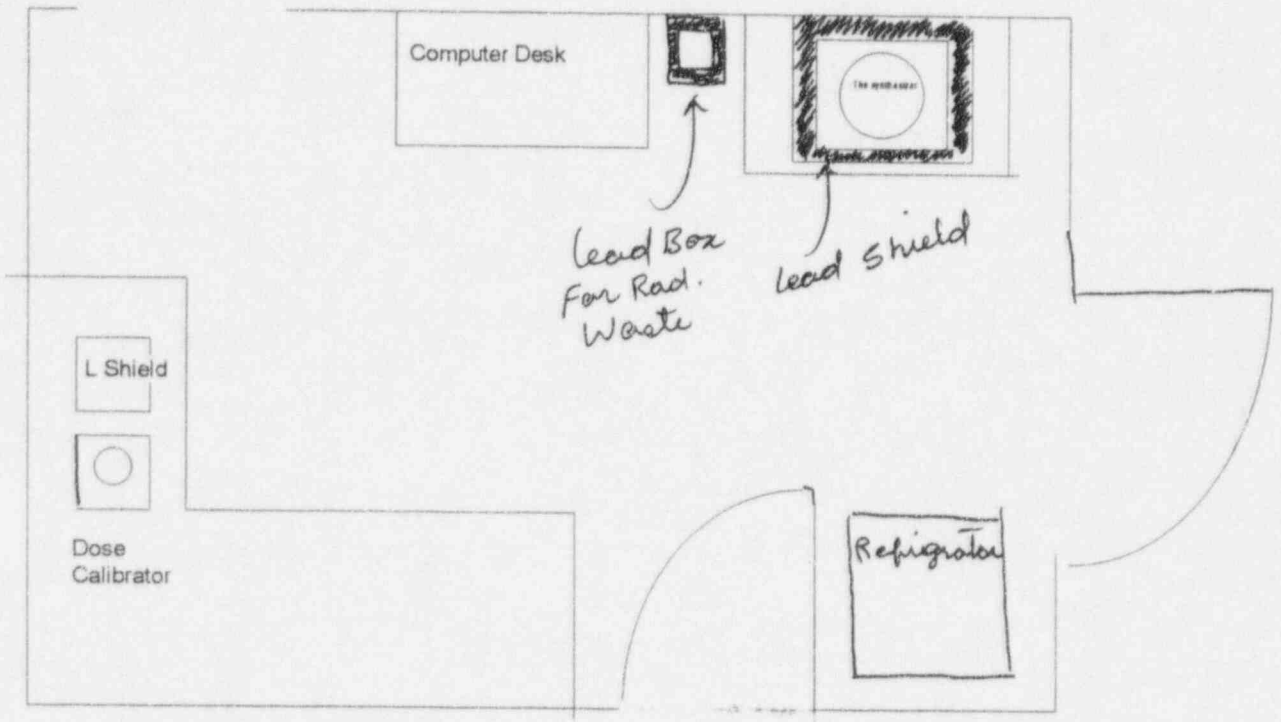


Exhibit 4 Production Lab

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME	DATE
12:45 am	10/8/96

○ VISIT ○ CONFERENCE X TELEPHONE

NAME OF PERSON(S) CONTACTED	ORGANIZATION (OFFICE, DEPT ETC.)	TELEPHONE NO.
Ahmad Najafi, Ph.D.	MIDI	714-824-2018

SUBJECT

New license application - Control No. 301773 - Lic. No. 34-26753-01

SUMMARY

Background:

This application is marked "please expedite." Unfortunately, the application is deficient in many areas, primarily because the applicant did not agree to follow the model procedures in Reg. Guide 10.8.

Phone call:

I went over the deficiencies in great detail w/ Dr. Najafi and one of his colleagues (an HP from Caltech). Dr. Najafi appeared to understand and agree with the issues, and indicated that he would revise the application and send it to RIII ASAP. He also stressed that the license was needed very, very soon.

ACTION REQUIRED

Wait for response.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Michael F. Weber	Michael F. Weber	10/9/96

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-9887 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME	DATE
9:45 am	10/1/96

○ VISIT ○ CONFERENCE X TELEPHONE

NAME OF PERSON(S) CONTACTED	ORGANIZATION (OFFICE, DEPT ETC.)	TELEPHONE NO.
Ahmad Najafi, Ph.D.	MIDI	714-824-2018

SUBJECT

New license application - Control No. 301773 - Lic. No. 34-26753-01

SUMMARY

Background:

This application is marked "please expedite." Unfortunately, the application is deficient in many areas, primarily because the applicant did not agree to follow the model procedures in Reg. Guide 10.8.

Phone call:

I informed Dr. Najafi that the application was deficient in many areas, and that we could proceed in one of two ways: (1) I could write a long deficiency letter and he could respond, etc., etc., which would take a lot of time, or (2) he could resubmit and agree to follow the model procedures. We discussed Reg. Guide 10.8, and Dr. Najafi indicated that MIDI wanted to follow all the NRC requirements, so he would resubmit and agree to follow the model procedures in Reg. Guide 10.8.

Dr. Najafi asked for a copy of Reg. Guide 10.8. His address:

Brain Imaging Center
162 Irvine hall
UCI
Irvine, CA 92697

ACTION REQUIRED

Send Reg. Guide.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Michael F. Weber	M. F. Weber	10/1/96

Midwest Imaging Diagnostics Incorporated, Limited (MIDI)
111 Wellington Place
Cincinnati, Ohio 45219

U. S. Nuclear Regulatory Commission
Nuclear Material Licensing Branch
U.S. NRC Region 3
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Sirs:

Enclosed are copies of licenses which you have requested (through the reviewer, Mr. Charles Gill) documenting qualifications of Dr. Harold T. Pretorius, the Medical Director and Radiation Safety Officer of our firm. Although we do not have a copy of the broad license (at The Christ Hospital in Cincinnati, Ohio) which Dr. Pretorius was previously listed under, Mr. Gill has a copy of this and indicated he was forwarding it to you.

We would like to expedite review of our license application since we have had a nuclear camera delivered and would like to complete its testing amd that of our dose calibrators with the necessary radioisotopes listed on our application. Mr. Gill has informed us that our operation falls within the scope of a private physician's office and we have included a check for $1400 in a separate letter sent to Ms. Sandra Kimberly, mail stop T9E10, Washington D.C., as we were instructed by Mr. Gill.

Thankyou for your assistance.

Sincerely,

H. Thomas Pretroius, M.D.,Ph.D.
Medical Director, MIDI

Call with any questions
(513) 579-1054

CERTIFICATE OF REGISTRATION

Pursuant to the Ohio Revised Code, sections 3701.90 through 3701.99, as amended, and in reliance on statements and representations made by the facility listed below and upon payment of the requisite fee, the Director of Health (the Director) hereby grants a certificate of registration to the facility to receive, possess, use, store, transfer, install, service and or dispose of the radiation sources listed below at the designated source location.

Pursuant to rule 3701-71-01(D) of the Ohio Administrative Code, a registrant is required to notify the Director, in writing, fifteen days prior to making any change which would render the information contained in its application for registration no longer accurate.

A registrant is also required to comply with sections 3701.90 to 3701.98 of the Ohio Revised Code, the rules promulgated thereunder, and with orders of the Director issued pursuant thereto.

Registration Number	Issue Date	Expiration Date
53-A-00026-01	06/06/96	07/31/98

Facility:

MIDWEST NUCLEAR
46 EAST HOLLISTER STREET
CINCINNATI, OH 45219

Source Location:

111 WELLINGTON PLACE
CINCINNATI, OH 45219

REGISTERED SOURCES OF RADIATION:

Co-57 - 100.00 mCi	P-18 - 800.00 mCi	Ga-67 - 100.00 mCi
In-111 - 5.00 mCi	I-123 - 10.00 mCi	Tl-201 - 100.00 mCi
Co-56 - 10.00 mCi	Ge-68/Ga-68 - 200.00 mCi	C-11 - 200.00 mCi
N-13 - 400.00 mCi	I-124 - 10.00 mCi	

INDIVIDUAL ON-SITE RESPONSIBLE FOR RADIATION PROTECTION:

HAROLD T. PRETORIUS, M.D.

The American Board of Nuclear Medicine

Incorporated 1971

Organized with the cooperation of the American Board of Internal Medicine, American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine hereby certifies that

Harold Thomas Pretorius, M.D., Ph.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 & Therapy with unsealed Radionuclides.

CHAIRMAN

SECRETARY

05356
NUMBER

9/10/88
DATE

THE AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

Harold Thomas Pretorius

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY

DESIGNATED A DIPLOMATE CERTIFIED IN

THE SPECIALTY OF

INTERNAL MEDICINE

CHAIRMAN

CHAIRMAN ELECT

SECRETARY-TREASURER

PRESIDENT

VICE PRESIDENT

NUMBER 72769

THE AMERICAN BOARD OF INTERNAL MEDICINE

DATE

SEPTEMBER 16, 1981

FORM 300-7 81

The President, Professors, and Trustees of

New York University

To all persons to whom this writing may come, Greeting:

Be it known, that we, in recognition of the successful completion of the requisite course of study in our

School of Medicine

by virtue of authority granted us by charter of the State of New York do confer upon

Harold Thomas Pretorius

the degree of

Doctor of Medicine

with all the rights, privileges, and immunities thereunto appertaining.

In witness whereof we have caused this Diploma to be signed by the duly authorized officers of the University and sealed with our corporate seal, in the City of New York, June, Nineteen hundred seventy-six.

Peter John Acee
Secretary

[redacted]

John C. Sawhill
President

Frank Bennett, Jr.
Chairman

STATE OF

OHIO

№ 56690

State Medical Board

This Certifies that Harold Thomas Pretorius

having presented to the Ohio State Medical Board satisfactory evidence that he graduated from New York University School of Medicine located in New York, NY on the 1st day of June A.D. 19 76 and holds the degree Doctor of Medicine

is hereby authorized to practice Medicine and Surgery in the State of Ohio in accordance with and subject to the provisions of "An Act to Regulate the Practice of Medicine in the State of Ohio."

Given under the hands and seal of the Ohio State Medical Board at the City of Columbus this 20th day of May A.D. 19 95

HAROLD THOMAS PRETORIUS, MD
Has met the requirements of the law, is duly registered and entitled to practice in The State of Ohio until the expiration date

3 9 4

017294

1 9 9 6

L BOARD OF OHIO
Columbus, Ohio 43266-0315
IDENTIFICATION NUMBER
35-05-6690

CONVERSATION RECORD | TIME | DATE

Deficiency Telephone Call | 2:30pm | 9/4/96

O VISIT O CONFERENCE ⊘ TELEPHONE

O INCOMING
⊘ OUTGOING

MID I letter

NAME OF PERSON(S) CONTACTED OR IN CONTACT | ORGANIZATION (OFFICE, DEPT. ETC.) | TELEPHONE NO.

Harold T. Bretorius, MD, RSO | Midwest Imaging Diagnostic | 513/651-5632 (Also 513/579-1054)

SUBJECT

Deficient New Lic Appl (dtd 8/23/96), Lic # 34-26753-01, Control # 301773 grant

SUMMARY

Dr. Bretorius was the only Dr. to be named on the license & he did not submit his qualifications. Dr. Bretorius agreed to submit his qualifications as added info to control # 301973. I informed him that upon receipt of this information the review would continue. (Private Practice)

ACTION REQUIRED ① Licensee to submit RSO (+ only named Dr.) qualifications.

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

CHARLES F. GILL | Charles F. Gill | 9/4/96

ACTION TAKEN
① Fax of RSO quals arrived 9/4/96 ck, Hardcopy to follow, review can now proceed.

SIGNATURE | TITLE | DATE

H. Thomas Pretorius, M.D., Ph.D., F.A.C.P.
Internal Medicine, Nuclear Medicine, Endocrinology & Metabolism
46 East Hollistor Street Cincinnati, Ohio 45219 Telephone: (513) 651-5632

Attn. Mr. Charles Gill

From: Dr. Harold T. Pretorius

Re: Here are Dr. Harold T. Pretorius certifications for Nuclear Medicine, Internal Medicine, also his license to practice Medicine in the States of Ohio and Kentucky. If you need anything else could you please call at 513-367-5632 or fax us something at 513-651.4074.
Thank you !

The American Board of Nuclear Medicine

Incorporated 1971

Organized with the cooperation of the American Board of Internal Medicine, American Board of Pathology, American Board of Radiology and the Society of Nuclear Medicine hereby certifies that

Harold Thomas Pretorius, M.D. Ph.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 & Therapy with unsealed Radionuclides.

CHAIRMAN

SECRETARY

05356
NUMBER

9/10/88
DATE

THE AMERICAN BOARD OF INTERNAL MEDICINE

INCORPORATED 1936

ATTESTS THAT

Harold Thomas Pretorius

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS HEREBY DESIGNATED A DIPLOMATE CERTIFIED IN THE SPECIALTY OF

INTERNAL MEDICINE

Lyle A. Hilbert
CHAIRMAN

Ira Rezek
CHAIRMAN ELECT

Norton J. Greenberger
SECRETARY-TREASURER

Glenn Bryan, Jr.
PRESIDENT

Irvine H. Wilson
VICE PRESIDENT

Richard Allyn

William H. Blahd

John P. Bolan, Jr.

David Brinton

Paul Calabresi

Clarke C. J. Carpenter

Edward B. Cyriax

Jane F. Desforges

Lawrence E. Early

Harold J. Fallon

John T. Farmer

Alvan R. Feinstein

Eugene W. Fletcher

Maurice Fox

Eugene P. Frenkel

THE AMERICAN BOARD OF INTERNAL MEDICINE

E. W. Hancock

T. Reginald Harris

Edward W. Hook

Richard B. Hornick

Edgar B. Jordan, Jr.

Jack C. Johnston III

William N. Kelley

Peter F. Kohler

Lyle A. Lange

John F. Murray

William D. Odell

Roscoe R. Robinson

Philip D. Schein

Ramona Schreier

Robert W. Schrier

Knight Steele

Morton N. Swartz

Samuel O. Thier

John S. Thompson

Hubbard E. Welch

NUMBER 72769

DATE
SEPTEMBER 16, 1981

31919

Kentucky Board of Medical

Commonwealth of Kentucky

Kentucky Board of Medical Licensure
LIC NO 31919
THIS IS TO CERTIFY THAT
Harold T. Pretorius, M.D.
is duly licensed to practice in Kentucky and has registered for the period through 3-1-97 with the Kentucky Board of Medical Licensure
PRESIDENT
SECRETARY

Harold T. Pretorius, M.D.

is hereby issued this regular license to practice

Medicine

in the State of Kentucky in accordance with and subject to the provisions of the Kentucky Medical and Osteopathic Practice Act as enacted and amended by the General Assembly of Kentucky, and the rules and regulations of the State Board of Medical Licensure issued thereunder.

Given under our hands and the Seal of the State Board of Medical Licensure of Kentucky at Louisville, Jefferson County, on this the 21st *day of* March, 19 96.

Boyce E. Duncan MD
President

STATE OF

OHIO

№ 50690

State Medical Board

This Certifies that Harold Thomas Pretorius

having presented to the Ohio State Medical Board satisfactory evidence that he graduated from New York University School of Medicine located in New York, NY on the 1st day of June A.D. 1976 and holds the degree Doctor of Medicine

is hereby authorized to practice Medicine and Surgery in the State of Ohio, in accordance with and subject to the provisions of "An Act to Regulate the Practice of Medicine in the State of Ohio"

[illegible] the Ohio State

9 4 17294

BOARD OF OHIO
Columbus, Ohio 43266-0315
IDENTIFICATION NUMBER
35-05-6690

HAROLD THOMAS PRETORIUS, MD
Has met the requirements of the law, is duly registered and entitled to practice in The State of Ohio until the expiration date

1 9 9 6

H. Thomas Pretorius, M.D., Ph.D., F.A.C.P.
Internal Medicine, Nuclear Medicine, Endocrinology & Metabolism
46 East Hollister Street Cincinnati, Ohio 45219 Telephone: (513) 651-5632

Attn: Mr. Charles Gill

From: Dr. Harold T. Pretorius

Re: Here is the Curriculum Vitae for Dr. Harold T. Pretorius

1976 - 1977	University of Texas Health Science Center San Antonio, Texas	Medicine Internship

GRADUATE

1976	New York University Graduate School of Arts and Sciences New York City, New York	Ph.D. Microbiology (Biochem-Bosphys)
1976	New York University School of Medicine New York City, New York	M.D.
1974	New York University Graduate School of Arts and Sciences New York City, New York	M.S. Microbiology

UNDERGRADUATE

1970	University of Southern California Los Angeles, California	B.S. Biochemistry

HIGH SCHOOL

1967	West High School Torrance, California	Diploma

PROFESSIONAL EXPERIENCE

1992-Present	Pretorius & Robles, MD's 46 East Holllister Street Cincinnati, Ohio 45219	Endocrinology Private Medical Practice
1995-Present	CinHio Diagnostic Imaging 34-03831-02 authorized user 2139 Auburn Avenue Cincinnati, Ohio 45219	The Christ Hospital Nuclear & Metabolic Imaging Consultant
1994-1995	Cinhio Diagnostic Imaging 2139 Auburn Avenue Cincinnati, Ohio 45219	The Christ Hospital Associate Director Metabolic Imaging
1990-1994	Cinhio Diagnostic Imaging 2139 Auburn Avenue Cincinnati, Ohio 45219	Associate Director Nuclear Medicine & Metabolic Imaging

1989-1992	Harold T. Pretorius 2123 Auburn Avenue Cincinnati, Ohio 45219	Endocrinology Private Medical Practice
1990-Present	University of Cincinnati Medical School 234 Goodman Street Cincinnati, Ohio 45267 39-06903-11	Clinical Assistant Professor 35/0 Endocrinology Div.
	The Jewish Hospital 34-00855-07 3200 Burnet Avenue Cincinnati, Ohio 45229	Attending Physician Department of Med.
1990-Present	Jewish Hospital of Kenwood 8000 Kenwood Road 34-13869-01 Cincinnati, Ohio 45236	Associate Staff Department of Med.
1989-1990	Tuberculosis Clinic Cincinnati, Ohio	Staff Physician
1988-1990	The Christ Hospital 2139 Auburn Avenue Cincinnati, Ohio 45219	Associate Director Nuclear Medicine
1988-Present	The Christ Hospital 2139 Auburn Avenue Cincinnati, Ohio 45219	Attending Physician Endocrinology Division
	Providence Hospital 2446 Kipling Avenue Cincinnati, Ohio 45239	Attending Physician Department of Med.
1987-1988	University of California San Diego Nuclear Medicine Division San Diego, California	Instructor Radiology Department
1986-1987	University of California San Diego Nuclear Medicine Division San Diego, California	Fellow Radiology Department
1985-1986	Desert Samaritan Hospital Tempe, Arizona	Internal Medicine
1985-1986	Mesa Lutheran Hospital Mesa, Arizona	Internal Medicine
1985-1986	Tempe-St. Lukes Hospital Tempe, Arizona	Internal Medicine

1985-1986	Scottsdale Memorial Hospital Scottsdale, Arizona	Internal Medicine
1985-1986	Chandler Memorial Hospital Chandler, Arizona	Internal Medicine
1984-1985	David Grant USAF Medical Center Fairfield, California Internal Medicine	Chief of Endocrinology
1981-1984	USAF Medical Center Keesler Biloxi, Mississippi	Endocrinology Attending Internal Medicine Dept.
1978-1981	National Institutes of Health Bethesda, Maryland	Fellow in Endocrinology
1977-1978	Univ. of Texas, Health Science Center And Audie Murphy VA Hospital San Antonio, Texas	Resident Internal Medicine
1976 1977	Univ. of Texas, Health Science Center And Audie Murphy VA Hospital San Antonio, Texas	Intern Internal Medicine
1970-1976	New York University School of Med. New York City, New York	Medical Scientist Trainee

Professional Certification

American Board of Nuclear Medicine	1988
Subspecialty Board Certification in Endocrinology	1985
American Board of Internal Medicine	1981
National Medical Boards Parts I, 6/72; II, 4/76; III, 3/77	
FLEX	1976

Medical Licenses

State	License Number	Date Issued	Date Expires
Kentucky	31919	3/21/96	3/1/97
Ohio	056690	5/20/88	9/30/96
New York	173654	03/88	
Arizona	15394	6/7/85	Inactive
California	G54425	3/18/85	2/28/97
Louisiana	05942R	1/28/83	Inactive
Virginia	30621	04/79	
Maryland	D23087	2/15/79	Inactive
Texas	E7488	02/77	11/30/96

Professional Societies

American Diabetes Association	Member	1993-present
Cincinnati Chapter	Board Member	1995-present
American Association of Clinical Endocrinology	Member	1991-present
Institute of Clinical PET	Member	1990-present
Ohio State Medical Association	Member	1989-present
Cincinnati Academy of Medicine	Member	1988-present
American Medical Association	Member	1988-present
Society of Nuclear Medicine	Member	1986-present
American College of Physicians	Associate	1977-1981
	Member	1981-1986
	Fellow	1986-present
Southern Medical Society	Member	1981-1991
Maricopa Medical Society	Member	1985-1986
Cincinnati Chamber of Commerce	Member	1990-1991

Honors and Awards

PROFESSIONAL

Oct. 1993-April 5, 1995 Pretorius HT, Principal Investigator, Determination of Myocardial Viability by C-11 Acetate Assessment of Myocardial Oxidative Metabolism, Research Protocol funded in part by The Christ Hospital.

Jan 15,1993-April 5, 1995 Pretorius HT, Principal Investigator, Positron Emission Tomography Investigation of Ovarian Cancer, Research Protocol funded by The Christ Hospital.

Jan 15,1993-April 5, 1995 Pretorius HT, Principal Investigator, Positron Emission Tomography Investigation of Patients with Prostate Carcinoma: Response of Tumor Metabolism to Standard Hormonal Manipulation, Chemotherapy or Radiotherapy (Megavoltage or Brachytherapy), Research Protocol funded by The Christ Hospital.

Jan 11, 1993-April 5, 1995 Pretorius HT, Principal Investigator, Positron Emission Tomography Study of Liver Metastases, Research Protocol funded by The Christ Hospital.

Mar 8, 1993-April 5, 1995 Pretorius HT, Co-Investigator, Positron Emission Tomography Imaging Protocols for Evaluation of Sarcoma, High-Grade Lymphoma, Colon, Breast and Lung Cancer, for Post Chemotherapy, Post Radiation Therapy, or Post Surgery Follow-Up. Monitoring FDG Tumor Metabolism Effects of Standard Methods of Cancer Management by P E T., Research Protocol funded by The Christ Hospital.

1992	Squibb Funded Research Project: Pretorius HT. "Review of the Squibb Rubidium Generator Experience at The Christ Hospital."
1987-1988	Co-investigator (with Dr. William L. Ashburn) University of California San Diego Divisions of Nuclear Medicine and Neurology: SPECT Brain Imaging Research and Multicenter Clinical Protocol in Investigation of Dementia
1986-1988	Participating Investigator (with Dr. Samuel Halpern and Hybritech) University of California San Diego and La Jolla Veterans Administration Medical Center Nuclear Medicine and Oncology Division: Monoclonal Antibody Research and Clinical Protocols.
1983-1987	Clinical Assistant Professor of Medicine Tulane University School of Medicine New Orleans, Louisiana
1985-1986	Postgraduate Fellowship in Neuroendocrinology Tulane University and New Orleans VA Medical Center
1982-1984	Clinical Assistant Professor of Medicine University of South Alabama, Mobile, Alabama
1984-1985	Chief Endocrinology Section, Medicine Department David Grant USAF Medical Center, Travis AFB, Fairfield, California
1982-1984	Principal Investigator Thyroid Carcinoma Research Protocol USAF Medical Center Kessler, Biloxi, Mississippi

POSTGRADUATE

1978-1981	National Institute of Health Clinical Associate, Clinical Endocrinology Branch, Bethesda, Maryland
1977	Accepted for Short Track (two years) Internal Medicine Residency Training with Board Eligibility

GRADUATE

1970 - 1976	National Institute of Health Medical Scientist Trainee Fellowship Grant; New York University
1975	National Biophysical Society Presentation

UNDERGRADUATE

1967 - 1968 Alumni Federation Scholarship
Advanced Placement, Sophomore

SECONDARY

1967 National Merit Scholar
1967 Senior Achievement Award in Science and Mathematics
1967 Vice-President, Senior Class
1967 Salutatorian of Graduating Class

MILITARY STATUS

1967 - 1971 United States Air Force Reserve Officer Training Corps
1971 - 1985 United States Air Force Medical Corps Commissioned Officer
1981 - 1985 Active Duty Service, Grade 04 (Major, USAF)
July 4, 1985 Honorable Discharge

Military Education

1981 - 1988 Advanced Cardiac Life Support Certification
1983 - 1985 Advanced Trauma Life Support Certification

Additional Military Honors and Awards

1987 Runner-up Grollman Award for Abstracts
American College of Physicians, Air Force Society

1981 - 1985 Department of Medicine Management Committee
and Radiation Safety Committee Member
David Grant USAF Medical Center
Fairfield, California

1982 - 1984 Assistant Director of Medicine Residency and Radiation Safety
Committee Member USAF Medical Center Keesler Biloxi, Mississippi

1981 - 1985 Authorized Radioiodide Therapy

1984 United States Air Force National Tennis Team Member

1983 Captain Keesler Air Force Base Tennis Team

1982 - 1985 Air Force Specialty Code 9386ET
(Senior Staff Internal Medicine Specialist in Endocrinology and Medical Education)

1983 Diabetes Mellitus Task Force Assignment for Government Health Services

PUBLICATIONS (Including Abstracts of Particular Significance)

Pretorius HT, Cordero GC, Pomeranz SJ, Ramsingh PS, Pemberton CC, Broderick TM, Williams CC. "Combination of Adenosine and Dobutamine for Cardiac Stress." J Nucl Med 37:Suppl 307P, No. 1426, 1996.

Pretorius HT, Ramsingh KK, Albright RE, Pomeranz SJ, Ramsingh PS, Rolfes RJ. "Significance of a Clinical Grading Scale for FDG-PET in Glioma." J Nucl Med 37 Suppl:263P No. 1177, 1996.

Ramsingh KK, Pretorius HT, Pomeranz SJ, et. al. "PET Measured FDG Metabolism of Breast Cancer Correlates with the Estrogen Receptor Status and with Average but not Aneuploid or Diploid S Phase." Journal of Nuclear Medicine 36 Suppl:83P,A336, 1995.

Pomeranz SJ, Pretorius HT, Ramsingh PS. "Bone Scintigraphy and Multimodality Imaging in Bone Neoplasia: Strategies for Imaging in the New Health Care Climate." Seminars in Nuclear Medicine 1994; 24:188-207.

Pretorius HT, Pomeranz SJ, Ramsingh PS. "Effect of Cardiac Positron Emission Tomography (PET) on Case Management." Radiology 189P Suppl: 255, A867, 1993.

Kipper SL, Gay TA, Dietemeyer JA, Pretorius HT. "Indium-111 Leukocyte Scintigraphy of the Heart in the Prediction of Surgical Complications of Bacterial Endocarditis." Journal of Nuclear Medicine 29 Suppl: 794, A222, 1988.

Lee Y, Flannery K, Pretorius HT, Wilson GA, O'Mara RE. "Radioiodide Doses Split in two or three Fractions Compared to Usual, Single Doses for Thyroid Cancer", Abstract Journal of Nuclear Medicine 29, 1988.

Hoit B, Rashwan M, Pretorius HT, Verba J, Sahn DJ, Bhargava V. "Instantaneous Transmitral Flow Using Doppler and M-Mode Echocardiography: Comparison With Radionuclide Ventriculography." American Heart Journal, 118:308-313, 1989.

Vasquez TE, Rimkus DS, Pretorius HT, Greenspan G. "Intravenous Administration of Morphine Sulfate Hepatobiliary Imaging for Acute Cholecystitis -- A Review of Clinical Efficacy." Nuclear Medicine Communications, 1987.

Vasquez TE, Pretorius HT, Rimkus DS. "Space Medicine -- A Review of Current Concepts." Western Journal of Medicine, 147:292-295, 1987.

Pretorius HT, Kastin AJ, Banks WA. "Binding of Tyr-MIF-1 to Isolated Brain Capillaries." Brain Research Bulletin 147:292-295, 1987.

Vasquez TE, Pretorius HT, Greenspan G. "Radiolabled Sucralfate: A Review of Clinical Efficacy." Nuclear Medicine Communication 8:327-333, 1987.

Ramos-Gabatin A, Pretorius HT. "Radionuclide Turnover Studies on Ectopic Thyroid Glands--Case Report and Survey of the Literature." Journal of Nuclear Medicine 26:258-262, 1985.

Ramacciotti CE, Pretorius HT, Chu EW, Barsky SH, Brennan MF, Robbins J. "Diagnostic Accuracy and Use of Aspiration Biopsy in the Management of Thyroid Nodules." Archives of Internal Medicine 144:1169-1173, 1984.

Saroff HA, Pretorius HT. "The Uniqueness of Protein Sequences: o-Uniqueness and Infrequent Peptides." Bulletin of Mathematical Biology 45:117-138.

Ramacciotti C, Pretorius HT, Line BR, Goldman JM, Robbins J. "Ablation of Nonmalignant Thyroid Remnants by Low Doses of Radioactive Iodine." Journal of Nuclear Medicine 23:483-489, 1982.

Pretorius HT, Katukineni M, Kinsella TJ, Barsky SH, Brennan MG, Chu EW, Robbins J. "Thyroid Nodules after High-Dose External Radiotherapy." Journal of the American Medical Association 247:3217-3220, 1982. Editor selected also as having particular interest for publication in foreign editions of Journal of the American Medical Association.

Pretorius HT, Nandi PK, Lippoldt RE, Keen JH, Pastan I, Edelhoch H, Johnson ML. "Native Clathrin Self-Associates to form a Bimodal and Physiological Collection of Closed Lattices", in "Membranes and Cytoskeleton: Role in Pathological Processes", McNutt NS, Hoffstein S, (eds). Federation Proceedings 40:206-213, 1981.

Pretorius HT, Nandi PK, Lippoldt RE, Johnson ML, Keen JH, Paston I, Edelhoch H. "Molecular Characterization of Human Clathrin." Biochemistry 20:2777 2782, 1981.

Nandi PK, Pretorius HT, Lippoldt RE, Johnson ML, Edelhoch H. "Molecular Properties of the Reassembled Coat Protein of Coated Versicles." Biochemistry 19:5917-5921, 1980.

Pretorius HT, Klein M, Day LA. "Gene V Protein of fd Bacteriophage: Dimer Formation and the Role of Tyrosyls in DNA Binding." Journal of Biological Chemistry 250:9262-9269, 1975.

Bound Volumes

Pretorius HT. DNA-Binding by Gene V Protein of Bacteriophage fd. New York University, Doctor of Philosophy Dissertation, 1976.

Saroff HA, Pretorius HT. Uniqueness Diagrams for the Human Genome Datafile (available on microfiche) cf. Bulletin of Mathematical Biology 45:117-138, 1983.

Book in Progress (see below also for additional works in progress)

Pretorius HT and Pretorius ME, with Leslie, N. Testosterone: Effects on the Brain, Body, Aging, and Sex. (1995-1996)

Abstracts and Limited Circulation Publications

Pretorius HT, Cordero GC, Pomeranz SJ, Ramsingh PS, Pemberton CC, Broderick TM, Williams CC. "Combination of Adenosine and Dobutamine for Cardiac Stress." J Nucl Med 37:Suppl 307P, Abstract 1426, 1996.

Pretorius HT, Ramsingh KK, Albright RE, Pomeranz SJ, Ramsingh PS, Rolfes RJ. "Significance of a Clinical Grading Scale for FDG-PET in Glioma." J Nucl Med 37:Suppl 263P Abstract 1177, 1996.

Kemme T, Flannery K, Pretorius HT, Williams C, Patel K. "Cardiac Perfusion Metabolism Studies with C-11 Acetate-Rapid Split Dose Protocols for Optimal Clinical Use." Posterboard, Institute of Clinical PET International Meeting, Washington, DC, Oct. 1994.

Pretorius HT, Kemme TG, Patel KM. "FDG-PET Distinction of Metastatic and Nonmetastatic Hepatic or Splenic Lesions." Abstract, Institute of Clinical PET International Meeting, Washington, DC, October 28, 1993

Pretorius HT, Patel KM, Ramsingh PS, Pomeranz SJ. "Improved Standard Uptake Value for Clinical Positron Emmission Tomography." Abstract The Institute for Clinical PET International Meeting, October 28, 1993.

Pretorius HT. "Review of the Squibb Rubidium Generator Experience at The Christ Hospital." October 1992 (Part of Squibb data for United States Food and Drug Administration Approval of the Rubidium Generator for Myocardial Perfusion).

Lee Y, Flannery K, Pretorius HT, Wilson GA, O'Mara RE. "Fractioned Radioiodide Doses Compared to Usual, Single Doses for Ablation in Thyroid Cancer", Posterboard, 35th Annual Meeting, June, 1988.

Pretorius HT, Rimkus DS, Dillon WA. "Use of Uptake Kinetics to Improve SPECT IMP Brain Imaging." Abstracts, Society of Nuclear Medicine National Meeting, Toronto, Canada, June, 1987.

Koroscil T, Pretorius HT, Reasner CA, Perlstein R. "Low Dose Radioiodide Therapy of Thyroid Carcinoma." Abstract, Air Force Society of Physicians National Meeting, 1987.

Sodowitz MM, Davies RJ, Pretorius, HT, Vasquez TE. "Indium-III White Blood Cell Studies After Prosthetic Vascular Reconstruction." Presented, Western Regional Vascular Society Meeting, Tuscon, Arizona, January 23, 1987.

Davis R, Pretorius HT. "Hyperparathyroidism in Pregnancy: Review and Case Report of an Associated Follicular Thyroid Carcinoma " Society of Air Force Physicians National Meeting (American College of Physicians Air Force Region), 1986.

Mallette L, Thornby J, Pretorius HT. "Internal Homology in Preproparathyroid Hormone: Four Copies of a Primitive Gene." Abstract 2, American Society for Bone and Mineral Research National Meeting, Washington D.C., June, 1985.

Meuller GL, Pretorius HT, Linde R, "Apparent Acquired Androgen Resistance. Evidence For A New Clinical Syndrome." Abstract, The Endocrine Society, January, 1983.

Ramos-Gabatin A, Freeman T, Pretorius HT. "Fine Needle Aspiration Biopsy Cytology in Toxic Goiter." Abstract 1278, Endocrine Society National Meeting, San Antonio, Texas, June, 1983.

Pretorius HT, Robles RM, McClellan SI. "Serum TSH in Outpatients in the Southern United States: A High and Sex-Biased Abnormality Rate." Abstract 30, Society of Air Force Physicians National Meeting (American College of Physicians Air Force Region), Colorado Springs, Colorado, March, 1984.

Bellinger RL, Pretorius HT, Gabatin AR, Vacek JL. "Correlation of Total Cardiac Contraction Time with Thyroid Status." Abstract 28, Society of Air Force Physicians National Meeting (American College of Physicians Air Force Region), Colorado Springs, Colorado, March, 1984.

Pretorius HT, Blum ME, Horan M, Hill G. "Early Phase of Iodide Metabolism: A Sensitive Measure of Thyroid Status." Endocrine Session II, Air Force Society of Physicians National Meeting (American College of Physicians Air Force Region), San Antonio, Texas, March, 1983.

Pretorius HT, Valentin-Stone PE. "Glucose Tolerance Tests, Glycosylated Hemoglobin, and High Density Lipoprotein in Patients with Suspicion of Diabetes Mellitus." Endocrine Session I, Air Force Society of Physicians National Meeting (American College of Physicians Air Force Region), San Antonio, Texas, March, 1983.

Ramos Gabatin A, Pretorius HT, Watzinger W, Caruth C. "The Importance of Fine Needle Aspiration Biopsy Cytology in the Diagnosis and Management of Thyroidal and Non-Thyroidal Neck Masses: An Update." Plenary Session II, Air Force Society of Physicians National Meeting (American College of Physicians Air Force Region), San Antonio, Texas, March, 1983.

Orrison WW, Watridge CB, Gabatin AR, Pretorius HT, Floyd JF. "Dynamic Computed Tomographic Scanning of the Pituitary Gland." Radiological Society of North America National Meeting, Chicago, 1983.

Rehe GT, Pretorius HT. "Scheuermann's Kyphosis: A Common Developmental Abnormality Presenting as Acute Back Pain." Abstract, Air Force Society of Physicians National Meeting (American College of Physicians Air Force Region), Sacramento, California, March, 1982.

Reasner CA, Pretorius HT. "Use of Iodine-131 Retention in the Treatment of Thyroid Cancer." Abstract, Air Force Society of Physicians National Meeting (American College of Physicians Air Force Region), Sacramento, California, March, 1982.

Ramacciotti C, Pretorius HT, Line BR, Goldman J, Robbine J. "Ablation of Postsurgical Thyroid Remnants with 30 mCi Doses of I-131." European Thyroid Association, Pisa, Italy, September, 1981.

Saroff HA, Pretorius HT. "The Uniqueness of Protein Sequences." Federation of the American Society for Experimental and Biological Sciences International Meeting, St. Louis, Missouri, 1981, Federation Proceeding 40, Abstract 786, 1981.

Pretorius HT, Klein M, Day LA. "Salt Dependence of fd Gene 5 Protein Dimer Formation: Properties of Tyrosyl and Thiol Groups in Monomers, Dimers, and DNA-Protein Complexes." Abstract FAMG5, Philadelphia, Pennsylvania, Biophysical Journal 15, February 18-21, 1975.

Hearse DJ, Webber WW, Pretorius HT. "Multiple N- Acetyltransferases and their Relation to Drug Toxicity." American Journal of Human Genetics 22, Abstract 15a-16a, 1970.

Pretorius HT in "Tricks of the Trade." Emergency Medicine, October, 1978.

Manuscripts Not Published or In Progress

Rolfes RJ, Georgian-Smith D, Pretorius, HT, Ramsingh PS, Pomeranz SJ, et al. Department of Defense Grant Submitted and Christ Hospital IRB approved Protocol for Investigation of Breast Carcinoma by FDG-PET or FDG-SPECT collaborating with University of Cincinnati and The Christ Hospital Biomedical Statistics and Radiology Departments 1995.

Pretorius HT, Barron M, Patel K. "Quantitative Assesment of Myocardial Vasodilator Response to Adenosine in Patients with and without Coronary Artery Disease." Resident Research Project, 1992.

Pretorius HT, Ramsingh PS, Pomeranz SJ. "Positron Emission Tomography Investigation of Coronary Angiography Patients." Principal Investigator. Research study approved December 29, 1992 - 1995 at The Christ Hospital.

Pretorius HT, Ramsingh PS, Pomeranz SJ. "Positron Emission Tomography Investigation of Ovarian Carcinoma." Principal Investigator. Research study approved January 15, 1993 - 1995 at The Christ Hospital.

Pretorius HT, Ramsingh PS, Pomeranz SJ. "Positron Emission Tomography Study of Liver Metastases." Principal Investigator. Research study approved January 11, 1993 - 1995 at The Christ Hospital.

Pretorius HT, Ramsingh PS, Pomeranz SJ, Patel K. "Positron Emission Tomography Investigation of Patients with Prostate Carcinoma: Response of Tumor Metabolism to Standard Hormonal Manipulation, Chemotherapy, or Radiotherapy (Megavoltage or Brachytherapy)." Principal Investigator. Research Study approved January 15, 1993 -1995 at The Christ Hospital.

Pomeranz SJ, Ramsingh PS, Pretorius HT. "Positron Emission Tomography (PET) Imaging Protocols for Evaluation of Sarcoma, High-Grade Lymphoma, Colon, Breast, and Lung Cancer, For Post Chemotherapy, Post Radiation Therapy, or Post Surgery Follow-up. Monitoring FDG Tumor Metabolism and Effects of Standard Methods of Cancer Management by PET." Investigator, Research Study at The Christ Hospital.

Seeger TL, Pretorius HT, Popp. "Phase III Clinical Study: The Comparison Current Diagnostic Modalities to the Radioimmunoguided surgery (RIGS) System Using I-125 CC49 Monoclonal Antibody for Patients with Primary Adenocarcinoma of the Colon and Rectum." Participating Investigator, Research Study at The Christ Hospital, 1993-1995.

Pretorius HT. Protocol for I-124 Therapy of Thyroid Cancer and Hyperthyroidism. Principal Investigator (approved at The Christ Hospital but awaiting isotope availability and IND to initiate patient studies), 1991.

Pretorius HT, Lukes S. "Total Body and Neck Retention of I-131 after Radioiodine Therapy: Dependence on I-131 Source and Dietary Iodine." Work in progress.

Pretorius, HT Protocol for Diagnosis and Therapy of Hepatic Metastases with Radioiodine-labelled Lipiodol (completed but awaiting availability of labeled Lipiodol).

Pretorius HT, Rimkus DS, Ruhm D, and Verba J. "Effect of a Passive Motion Device on Muscle Blood Flow Measured by Digital Computer Analysis of Xenon Clearance." Fellowship Research Project.

Pomeranz SJ, Heidt RS, Ramsingh PS, Pretorius HT. "Use of Magnetic Resonance (MR) in Assessment of Etiologic Contribution of Acroioclavicular Joint Disease to Subacromial Arch Stenosis and Clinical Impingement Syndrome." Scientific Paper Submitted for the 79th Annual Meeting of the Radiological Society of North America.

Pomeranz SJ, Heidt RS, Funk DA, Shybut GT, Pretorius HT, Ramsingh PS "Nonchondromalacic Anterior Knee Pain - Radiographic MR Syndromes and Pitfalls in Evaluation." Scientific Paper Submitted for the 79th Annual Meeting of the Radiological Society of North America.

Pretorius HT, Pomeranz SJ, Wolf RK, Ramsingh PS, Patel KM. "Optimal Positron Emission Tomography (PET) Use in the Spectrum of Thoracic Neoplasms." Scientific Paper Submitted for the 79th Annual Meeting of the Radiological Society of North America.

Pretorius HT, Pomeranz SJ, Ramsingh PS, Drake DF, Desai A. "Positron Emission Tomography (PET) Imaging of Metabolic Correlates in 'Stunned' Myocardium." Scientific Paper Submitted for the 79th Annual Meeting of the Radiological Society of North America.

Cordero GC, Pretorius HT. "Cerebral PET and MRI Findings in Autopsy Proven Primary Amyloidosis." Manuscript in preparation.

Pretorius HT, Ford S.Jr. "Use of a Multicrystal High Count Rate Scintillation Camera with Stacking Collimators to Monitor Individual Metastatic Lesion Response to Iodine-131 Therapy of Thyroid Carcinoma." Manuscript in preparation.

Pretorius HT, Rorick MH. "Cerebral PET in Mitochondrial Encephalopathy." Manuscript in preparation.

Pretorius HT, Tan TX. "The Cerebral Metabolic Fraction, Average Basal Ganglia to Cerebral Cortical Ratio, Cortical to Cerebellar and Temporal to Cerebellar Ratiios: Quantitative Measures of Cerebral Function Suitable for Analysis of PET or SPECT Images." Resident Research Project.

Summary of Professional Career Highlights

Tom Pretorius (always known by his middle name, which matched his father's first name) decided to become a doctor at the age of four years when he began studying anatomy charts in an Encyclopedia. By starting elementary school a year early and finishing his BS (at the University of Southern California) in three years, Tom Pretorius was accepted to medical school by age 19 years and began in 1970 at The New York University School of Medicine.

Although Tom felt that the MD-Ph.D program at NYU was one of the best coordinated in the country, it had exceptionally high standards. In fact, Tom Pretorius was one of only two candidates to actually complete the program in the prescribed six years. Over 800 candidates had applied for the full tuition funded National Institutes of Health Medical Scientist Trainee program and over the average of eight years it took to complete the program well over 20 candidates were accepted into his "year" and less than half of these ever completed it.

Dr. Pretorius'es graduate thesis involved DNA-protein interaction, one of the hottest scientific topics of the last 25 years. The fd bacteriophage (also called M13) which he studied soon became the first living organism to have its entire DNA sequence defined and thereafter became one of the fundamental building blocks for genetic engineering.

The work included in Dr. Pretorius'es first publication, in the Journal of Biological Chemistry, was sufficient for at least three publications (in the opinion of his research advisor, which is one of the ways to escape from graduate school). It was based on expertise in a wide range of biochemical and biophysical methods including:

Analytical Gravimetry (special microbalances)

Analytical Ultracentrifugation, using equilibrium gradient density or nonequilibrium gradient or nongradient techniques

Chemical kinetics monitored by radiolabeled filter binding assay or scintillation counting, automated micropH analysis, or UV or Fluorescence Assay,

Electron Microscopy, including heavy metal shadowing

Electron Spin Resonance Spectral Analysis

Equilibrium Dialysis Methods

Laser Light Scattering and turbidity analysis,

Spectroscopy including Fluorescence emission and absorption spectra,
Circular dichroism spectroscopic and difference spectroscopic methods,
Ultraviolet spectra including far and near UV and UV difference spectra,
Magnetic Resonance Spectral Analysis

Molecular Sieving and Affinity Chromotography Analysis
Including Sephadex, Sepharose, Agarose, BioGel, selective pore size glass beads, DNA cellulose, alumina, thin layer and column, and Whatman paper

Multicomponent Nonlinear Computer Regression Analysis

Precision densimetry (including density measure to eight significant figures)

Polyacrylamide gel electrophoresis using both slabs and discs

Refractometric analysis

Specific chemical modification and purifications of both DNA and protein.

Dr. Pretorius'es prethesis research experience included the basics of mamallian cell culture, in which he also took a tutorial, as well as minicomputer

technology including the basics of computer machine language. Dr. Pretorius took a tutorial at the Rockefeller University under Dr. W. Gibbons, who used this method to deduce the structure of the antibiotic, gramicidin, a fundamental discovery bearing on the theory of ion pores in cell membranes.

It will not be surprising to those familiar with the above methods that Dr. Pretorius often "slept" in the laboratory during his medical school days. He also had ample opportunity to spend nights awake in the hospital during his subinternship at the Bellevue Hospital. He did his medicine clerkship on the ward where the cardiac enzymes were described and as a medical student listened to his first lecture in Nuclear Medicine given by the man who discovered the cardiac enzyme based method for diagnosis of myocardial infarction. Both topics were of interest (and still are).

After selection for the short track (two instead of three years) in Internal Medicine Training, Dr. Pretorius did a three year fellowship (the usual Clinical Fellowship is only two years) in Endocrinology and Metabolism at the National Institute of Health. Though not known for this work, one of the first experiments establishing the basic concept that a high glucose level (as in Diabetes) effects molecular structure was performed at Dr. Pretorius'es suggestion. This experiment showed that glucose altered the binding of the hormone thyroxine to thyroid binding prealbumin.

Dr. Pretorius was the first to isolate the protein of the coated pit, clathrin, from human brain. This protein is fundamental in the process of receptor mediated endocytosis, by which cells incorporate proteins, hormones, and other specific substances such as cholesterol. Dr. Pretorius'es work established that the protein itself defined the basic molecular size and structure of clathrin coated pits, even in the absence of its lipid bilayer membrane.

Working with Dr. Harry Saroff, Dr. Pretorius analyzed all then available human protein sequences and developed the concepts of o-Uniqueness and i-Uniqueness of protein sequences. When first presented in abstract form at the Federation Proceedings (largest single scientific meeting in the world), this work created a sensation (analytically defined by Dr. Saroff by counting the number of attendees at its Poster Presentation, which was well over two standard deviations greater than any other in sight). It has had significant implications including pertinence to development of vaccines such as the potential malaria vaccines still under development and contributed to the basic understanding of the information content (defined as the logarithm of a probability distribution) of biological sequences.

Working with Dr. Jacob Robbins of the Clinical Endocrinology Branch at the National Institutes of Health, Dr. Pretorius did much to advance practical application of thyroid fine needle aspiration methods, having performed far more such procedures than any endocrinology fellow before or after his tenure. Dr. Pretorius also developed an extensive experience with thyroid cancer treatment and developed the second computer based clinical algorithm at the National Institutes of Health (the first was achieved by the National Heart Institute, several days earlier). This algorithm included a computer based dosimetric method for radioiodine. Dr. Pretorius began basic nuclear medicine studies pertinent to radioiodine therapy of thyroid cancer and with the use of a sensitive total body counter, published, among other things, the first reasonable baseline measures of neck retention of radioiodine in patients having undergone total thyroid ablation by surgical and chemical means. This baseline is not zero but is fundamental to the question of whether a thyroid cancer patient has

actually received optimal treatment for this multicentric type of cancer with its inevitable tendency to recurrence.

Dr. Pretorius'os initial professional experience was as an Endocrinologist in the United States Air Force, from 1981-1985. He obtained a broad clinical experience which included the first series of hyperthyroid patients to undergo thyroid aspiration biopsy. Prior to this work with Colonel Angelita Ramos Gabatin, M.D., it was generally thought that hyperthyroid patients would have too great a tendency to bleeding complications and should not undergo aspiration biopsy. The practical significance to the patients was diagnosis of two of twenty such patients with thyroid cancer which was then surgically proven. This work was significant since hyperthyroid patients are usually treated with quite low doses of radioiodine which are thought inappropriate for thyroid cancer treatment (which generally uses high doses).

While in the Air Force, Dr. Pretorius continued research on thyroid cancer, which did include use of lower, fractionated radioiodine (I-131) doses (10 and 20 mCi) for its treatment than anyone else has reported. Follow-up of the patients after 5 years disclosed that they were doing as well as patients treated with higher doses; however, the treatment was intensive and required appropriate hormonal and chemical (diet, diuretics, and subsequent but not coincident lithium) therapy.

Dr. Pretorius'es work with Dr. Orrison was one of the first clear demonstrations of the CT enhancement of pituitary tumors. This led to the current protocols for CT or MRI scanning of pituitary tumors shortly after injection of enhancing contrast.

Together with Dr. Mueller, in 1983, Dr. Pretorius was bold enough to suggest that one of their patients actually had a new clinical disease, Acquired Androgen Resistance. Though greeted with skepticism at the National Endocrine Society Meeting where it was first presented, this work was based on hormone receptor binding assays done in Dr. J. Wilson's laboratory in Dallas and it has stood the test of time. When Dr. Wilson presented Medical Grand Rounds two years ago at The University of Cincinnati, Dr. Pretorius was in the audience to hear another description of this first patient, who remains somewhat notorious to this day.

Upon discharge from the Air Force, Dr. Pretorius entered private practice with a prominent Endocrinologist entrepreneur in the Phoenix, Arizona area. The practice contracted with the local Samaritan Hospital (Desert Samaritan) to form the first economically successful MRI medical imaging center in the Phoenix area. Although Dr. Pretorius was not a partner in this venture (having joined the practice after the partnership formation), he did have first hand observation of its implementation. Within a few years all of the principals were either very wealthy or very disappointed. Dr. Pretorius left the practice to pursue further Nuclear Medicine training (the endocrinology practice also included a nuclear camera) since stricter rules required formal training rather than academic nuclear training Dr. Pretorius already had.

After completing a Nuclear Medicine Fellowship at the University of California San Diego, during which time he was married to the lovely Rosa Maria Robles, M.D., with whom he now has two sons, ages three and five years, Dr. Pretorius was offered an academic position at The University of Rochester in Nuclear Medicine and also a position in private practice of Nuclear Medicine at The Christ Hospital in Cincinnati. Although the academic position was attractive, the opportunity to pursue Positron Emission Tomography (PET) at The Christ Hospital in Cincinnati was more attractive.

As the Associate Director of Nuclear Medicine and PET, Dr. Pretorius was the primary faculty member with medical research interest. He was also responsible for

development of the clinical protocols for this facility. He developed a Modified Standard Uptake Value method for tumor analysis with FDG which has led to the highest reported accuracy, 97%, for breast cancer in a series of significant size, now numbering over 100 patients. Dr. Pretorius initiated the idea of a Nuclear Medicine Residency Program at The Christ Hospital and an American Association of Graduate Medical Education (AAGME) accredited program was founded. Throughout his career, Dr. Pretorius has been active in teaching, and remains on the Faculty of the University of Cincinnati as well as a consultant and faculty member for The Christ Hospital Nuclear Medicine Training Program.

While at The Christ Hospital, Dr. Pretorius was privileged to have a chance to work on a "cost ineffective" technique, clinical PET. As anyone working closely with PET is keenly aware, the cost effectiveness simply depends on the value attributed to human lives, which it impacts dramatically. There is no doubt that PET is the single most accurate noninvasive medical test for many of the major cancers and heart diseases. The realities of medical diagnostic imaging dictate that no significant number of patients or their insurers currently pay $2000 or more for a medical (such as PET) scan, thus, Dr. Pretorius is presently concerned with implementing positron imaging on more clinically applicable equipment such as modified SPECT cameras. These have already achieved 95% or greater agreement with PET results in several key clinical studies of both cardiac and cancer patients and have higher clinical throughput consistent with a competitive scan price.

Realizing that the source of positron isotopes (linear acelerator or cyclotron) remains an issue, Dr. Pretorius conceived the idea of a medical isotope distribution and imaging venture to control both aspects of this business. He has developed this concept with Dr. James L. Armitage, whom Dr. Pretorius actively recruited to the project because of Dr. Armitage's particular experience in medical imaging and leadership. At present, Dr. Pretorius and Dr. Armitage have produced committments for $904,000 for a corporation, Midwest Nuclear, Inc., with Dr. Armitage being the President of the corporation and Dr. Pretorius the Medical Director. Over 71% of the shares of this corporation are held by Dr. Pretorius or Dr. Armitage or their immediate family, who have and fully intend to retain control of its operations.