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.

302019

Licensee	
1. Doctors Diagnostic Center	3. License Number 21-26766-01
2. 2405 East 14 Mile Sterling Heights, MI 48034	4. Expiration Date January 31, 2002
	5. Docket or Reference No. 030-34275

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 (excluding xenon and generators)	B. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding xenon and generators).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2405 East 14 Mile, Sterling Heights, Michigan.

11. Radiation Safety Officer: Marcel Zughaib, M.D.

070035

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 21-26766-01
Docket or Reference Number: 030-34275

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
Marcel Zughaib, M.D.	10 CFR 35.200 (excluding xenon and generators), limited to cardiovascular clinical procedures.
Maria Crumes, M.D.	10 CFR 35.100 and 35.200 (excluding xenon and generators).

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

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

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

    A. Application dated September 11, 1996, and

    B. Letter dated December 23, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 31 January 1997

By William P. Ruebold
Nuclear Materials Licensing Branch, Region III

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:

57

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: DOCTORS DIAGNOSTIC CENTER
   Received Date: 961104
   Docket No: 3034275
   Control No.: 302019
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: 1400
   Check No.: 3800

3. COMMENTS

Signed D. Hersey
Date 11-5-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_1/)

1. Fee Category and Amount: 7C $1400

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

3. OTHER

Signed SC
Date 11/14/96

NOV 1 8 1996

Log NOV 6 III
Remitter
Check No. 3800
Amount $1400
Fee Category 7C
Type of Fee App
Date Check Rec'd 11/12/96
Date Completed 11/14/96
By: SC

1996 NOV 12 AM 10:01

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

U. S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIAL LICENSE

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

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

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

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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)*
   Doctors Diagnostic Center
   2405 East 14 Mile
   Sterling Heights, MI 48034

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED
   same as no.2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION
   Neil A. Keller
   Medical Physics Consultants
   TELEPHONE NUMBER
   313-662-3197

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5.	RADIOACTIVE MATERIAL. a. Element and mass number; b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.	6.	PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7.	INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8.	TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9.	FACILITIES AND EQUIPMENT.	10.	RADIATION SAFETY PROGRAM.
11.	WASTE MANAGEMENT.	12.	LICENSEE FEES *(See 10 CFR 170 and Section 170.31)* FEE CATEGORY 7 C AMOUNT ENCLOSED $ 1,400

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

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Patricia Joseph / Director	Joseph	9.11.96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		RECEIVED NOV 04 1996 REGION III
APPROVED BY			DATE		
PMJ 10-30-96					302019

NRC FORM 313 (6-93) PRINTED ON RECYCLED PAPER

DOCTORS DIAGNOSTIC CENTER
2405.E. FOURTEEN MILE ROAD
STERLING HEIGHTS, MI 48034

U.S. Nuclear Regulatory Commission
Region III
Materials and Licensing Section
801 Warrenville Road
Lisle, Illinois 60532-4351

RE: NRC License Application
Doctors Diagnostic Center

Enclosed is a new license application for Doctors Diagnostic Center. Please note the following:

1. This facility will be used for routine diagnostic nuclear medicine scanning.

2. The three (3) physicians listed are authorized users currently on NRC licenses. See the application for referencing the license numbers.

3. We have eliminated the use of xenon, Mo99-Tc-99m generators, and radiopharmaceutical therapies and doses of NaI-125 and NaI-131 over 30 uCi from our application. We request exemption from the Quality Management Program, 10 CFR Part 35.32, at this time.

If you have any questions concerning this application, please contact us or our consulting physicist, Neil Keller, at 313-662-3197.

Sincerely,

NRC FORM 374 (6-89) U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 2 PAGES

MATERIALS LICENSE

Amendment No. 03

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 representation, 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.

399711

Licensee	
1. Consultants in Cardiology, P.C. 2. 29255 Northwestern Hwy. Suite 201 Southfield, MI 48034	In accordance with letter dated December 21, 1995 3. License Number 21-26635-01 is amended in its entirety to read as follows: 4. Expiration Date March 31, 2000 5. Docket or Reference No. 030-33785

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.200	A. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols) limited to cardiovascular clinical procedures	A. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols), limited to cardiovascular clinical procedures.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 29255 Northwestern Hwy., Suite 201, Southfield, Michigan.

11. Radiation Safety Officer: Marcel Zughaib, M.D.

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

Authorized Users	Material and Use
A. Joan Crawford, D.O.	10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols), limited to cardiovascular clinical procedures.

NRC Form 374A (9-88) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGES 2 OF 2 PAGES

License number: 21-26635-01

Docket or Reference number: 030-33785

Amendment No. 03

Authorized Users	Material and Use
B. Harold Z. Friedman, M.D.	10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols), limited to cardiovascular clinical procedures.
C. Marcel E. Zughaib, M.D.	10 CFR 35.200 (excluding generators, xenon, and radioactive aerosols), limited to cardiovascular clinical procedures.

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

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

    2. The U. S. Nuclear Regulatory Commission, Region 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. The licensee is not required to have a Radiation Safety Committee described in 10 CFR 35.22. The Radiation Safety Officer may make radiation safety program changes permitted by 10 CFR 35.31 with the advice and consent of the licensee's management.

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

    A. Application dated February 1, 1995; and

    B. Letters dated April 18, 1995 and June 21, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 11/4/96

By James Mullikin
Nuclear Materials Licensing Branch, Region III

COPY

DOCTORS DIAGNOSTIC CENTER

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Item 11 WASTE MANAGEMENT
11.1 Waste Disposal

RADIOACTIVE MATERIAL AND USE

Item 5	**Item 6**	
Byproduct Material	**Amount**	**Purpose**
Material in 35.100	As needed	Uptake, dilution, and excretion
Material in 35.200	As needed	Image and localization studies, excluding generators, Xenon-133, and Nal125 and Nal-131 over 30 uCi

RADIATION SAFETY PROGRAM RESPONSIBILITY
Item 7.1 Authorized Users for Medical Use

Authorized User	**Materials**
Marcel E. Zughaib, M.D.	35.200 (excluding generators, xenon, and radioactive aerosols)

Dr. Zughaib is currently listed on Consultants in Cardiology, P.C., Southfield, Michigan License No. 21-26635-01

Herbert Weisenthal, D.O. 35.100, 35.200 (excluding generators, xenon, and Nal-125 and Nal-131 over 30 uCu

Dr. Weisenthal is currently listed on Universal Imaging, Inc., Taylor, Michigan License No. 21-26532-01 for the above materials.

Maria Crumes, M.D. 35.100, 35.200 (excluding generators, xenon, and Nal-125 and Nal-131 over 30 uCu

Dr. Crumes is currently listed on Universal Imaging, Inc. Taylor, Michigan License No. 21-26532-01 for the above materials.

Radiation Safety Officer
Item 7.3
Marcel E. Zughaib, M.D.

PERSONNEL TRAINING PROGRAM

Item 8.1

Personnel

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction.

Training Frequency

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

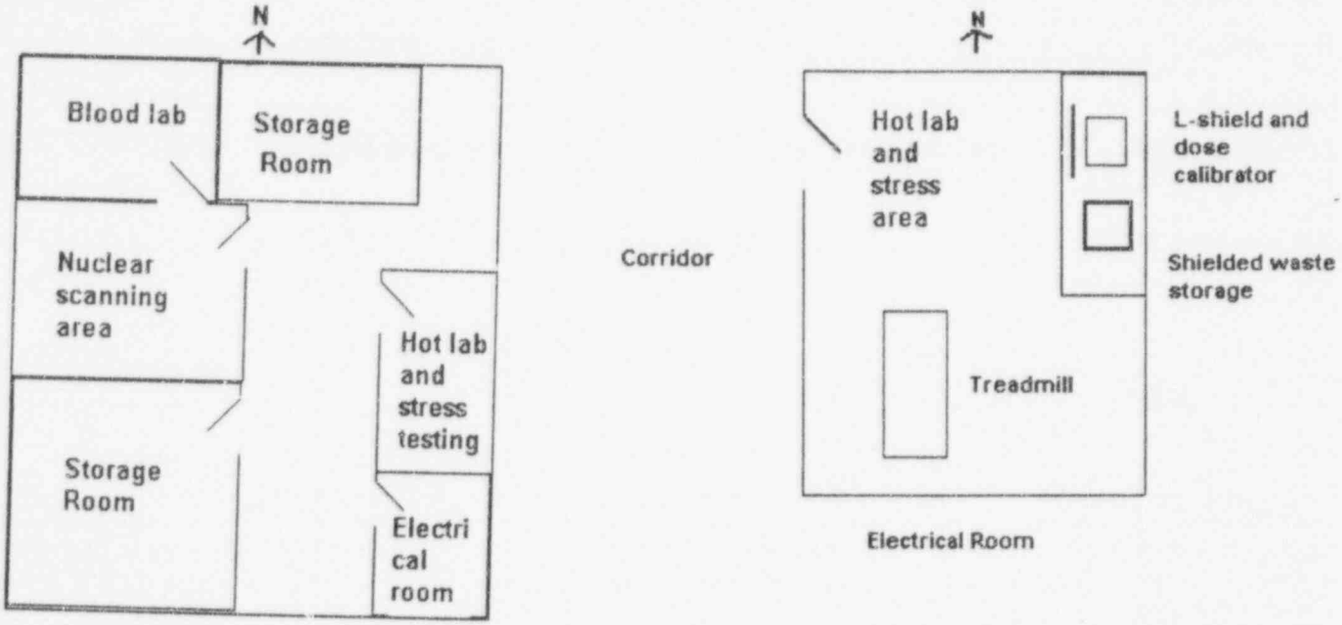
Instruction Topics

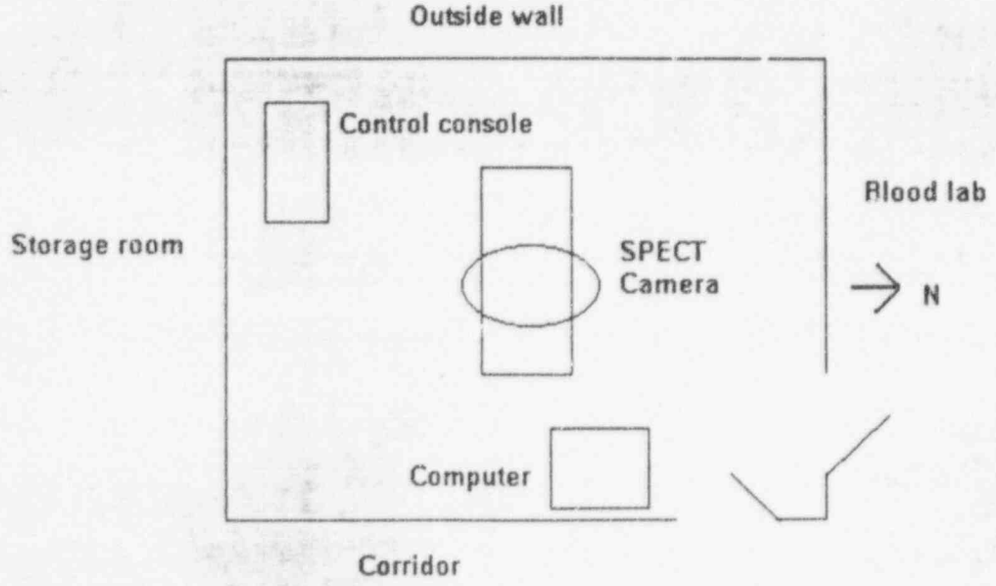
1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10 CFR 19.

Documentation of the list of topics covered, the date of the instruction, and the names of those attending will be kept on hand for review.

FACILITY DIAGRAM
Item 9.1

Nuclear Medicine Department
Doctors Diagnostic Center
2405 E. 14 Mile Road
Sterling Heights, MI 48034





EQUIPMENT LIST

Item 9.1

Gamma Scintillation Cameras:
Siemens Orbiter SPECT camera

Dose Calibrator:
Capintec CRC-5

Survey Meters:
Bicron Model 2000 Low scale 0 to 0.2 mR/hr
High scale 0 to 2 R/hr

Other:
Syringe shields
Lead (Pb) bricks for shielding
L-shield

CALIBRATION OF SURVEY METERS

Item 9.2

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

1. The manufacturer or:
2. Medical Physics Consultants: (NRC License No. 21-20153-01)
3. Any authorized user licensed to perform survey meter calibrations as a service.

CALIBRATION OF DOSE CALIBRATOR

Item 9.3

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

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

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

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

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

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

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

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

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

PERSONNEL MONITORING PROGRAM
Item 9.4

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

2. All individuals who are occupationally exposed to radiation on a regular basis and may receive greater than one tenth the quarterly permissible limits will be issued a film or TLD whole body monitor.

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

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

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

6. All film and TLD badges will be changed on a monthly basis. The present supplier for personnel dosimetry services is Landauer, Inc., Glenwood, Illinois and is NVLAP accredited.

BIOASSAY PROGRAM

Bioassays shall be performed on any individual who helped prepare or administer a dosage of I-131 for a patient that has been hospitalized pursuant to 10 CFR Part 35.75.

RADIATION SAFETY OFFICER

Item 10.1

The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from the radiation safety practices approved by facility management and/or the Radiation Safety Committee, if applicable.

2. Establish, implement, and collect in a centralized location policies and procedures as follows:
    a. Authorization for the purchase of radioactive material.
    b. Receipt and opening of packages containing radioactive material.
    c. Storage of radioactive material.
    d. Inventory control of radioactive material.
    e. Safe use of radioactive material.
    f. Emergency procedures in the event of loss, theft, etc.
    g. Periodic radiation surveys
    h. Checks of radiation survey and other radiation safety instruments.
    i. Disposal of radioactive material.
    j. Personnel training of those who work in or frequent areas of radioactive material use or storage.

3. Maintain a record systems to include at least the following:
    a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.
    b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

4. Review and sign the following radiation safety program records, if applicable:
    a. Sealed Source Inventories
    b. Sealed Source Leak Tests
    c. Misadministration Documentation
    d. Changes in the radiation safety program
    e. Radiation surveys of sealed source storage

5. Inform facility management at least annually of the status of the licensed material program.

6. Establish personnel exposure investigational levels as a part of the ALARA program and philosophy.

7. Approve or disapprove minor changes

RESPONSIBILITIES

The Radiation Safety Officer shall:

1. Ensure that ionizing radiation will be used safely, to include the review as necessary of training programs, equipment, facility design, supplies and procedures.

2. Ensure that ionizing radiation is used in compliance with all state and federal regulations and all licenses and registrations granted for usage.

3. Ensure that the usage of ionizing radiation is consistent with the As Low As Reasonably Achievable (ALARA) philosophy and program.

4. Establish investigational levels for individual occupational radiation exposures, consistent with the ALARA philosophy and program.

5. Assume the day to day responsibility of management of the radiation safety program, reportable to the committee as noted below.

DUTIES

The RSO shall:

1. Be familiar with all pertinent regulations, all license applications, all licenses (their conditions and amendments).

2. Review the training and experience of the proposed authorized users to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and all licenses issued to the facility.

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the facility.

4. Review recommendations on ways to maintain individual and collective doses ALARA.

5. Prescribe special conditions that will be required during a proposed method of use of ionizing radiation such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review on the basis of safety, and approve with the advice and consent of the management, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted within the regulations.

7. Review quarterly a summary of the occupational radiation dose records, consistent with the ALARA program.

8. Review quarterly all incidents or unusual occurrences, such as misadministrations of ionizing radiation, spills, etc. which involved ionizing radiation.

9. Identify radiation safety problems, as well as initiate, recommend, provide and verify corrective actions.

10. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used are appropriately instructed as required in 10 CFR 19.12.

11. Review at least annually the radiation safety program to insure compliance with all regulations, conditions of licensure and the ALARA program to include records, inspection results and adequacy of the management control system.

12. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

MAINTAINING OCCUPATIONAL RADIATION EXPOSURES ALARA
Item 10.2

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

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

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

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practical level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Radiation Safety Officer
   a. Review of Proposed Users and Uses
      (1) The RSO will thoroughly review the qualifications of each application with respect to the types and quantities of materials and methods of use for which application has been made to ensure that the applicant will be able to take appropriate measurements to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposures ALARA.
(3) The RSO will review the efforts of the applicant to maintain exposures ALARA.
(4) The RSO will ensure that the users justify their procedures and that individual collective doses will be ALARA.

b. Delegation of Authority
(1) The RSO will have the authority of enforcement of the ALARA concept.
(2) The management will support the RSO when it is necessary for the RSO to assert authority. If management has overruled the RSO, it will record the basis for its actions in the minutes of the quarterly meeting.

c. Review of ALARA Program
(1)The RSO will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
(2) The RSO will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table I are exceeded. The principal purpose of this review is to access trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table I: Investigational Levels

	Level I (mrems per quarter)	Level II (mrems per quarter)
1. Total Effective Dose Equivalent: (dose estimated from film badge)	125	375
2. Skin or any extremity	1,250	3,750
3. Eye dose equivalent	375	1,125

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

d. Education Responsibilities for the ALARA Program
   (1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.
   (2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, and the RSO are committed to implementing the ALARA concept.

e. Cooperative Efforts for Development of ALARA Procedures
   Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to followed.

   (1)The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
   (2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

f. Reviewing instances of Deviation from Good ALARA Practices

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

3. Authorized Users
   a. New Methods of Use Involving Potential Radiation Doses
      (1) The authorized user will consult with the RSO during the planning stage before using radioactive materials for new uses.
      (2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA.

   b. Authorized User's Responsibility to Supervised Individuals
      (1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
      (2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

4. Individuals Who Receive Occupational Radiation Doses
   a. Workers will be instructed in the ALARA concept and its relationship to work procedures and work conditions.
   b. Workers will be instructed in resources available if they feel that ALARA is not being promoted on the job.

5. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Doses

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

   The RSO will review and record on a form (e.g., dosimeter processor's report) results of personnel monitoring to show compliance with occupational dose limits of 10 CFR Part 20.1201. This may be done quarterly. The following actions will be taken at the investigational levels as stated in Table 1:

   a. Personnel dose less than investigational Level I.

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

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

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

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

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

d. Re-establishment of investigational Levels to levels above those listed in Table I. In cases where a worker or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented by the RSO.

6. Signature of Certifying Official

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

_____

Marcel E. Zughaib, M.D.
Radiation Safety Officer

_____

Management, Doctors Diagnostic Center

PROCEDURE FOR LEAK TESTING SEALED SOURCES
Item 10.3

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

1. Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or

2. Anyone licensed by the NRC to perform leak testing as a service.

LABORATORY SAFETY RULES
Item 10.4

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

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

3. Before leaving the area, monitor your hands and clothing for contamination in a low background area.

4. Use remote handling tools whenever possible to prevent direct handling of containers of radioactive materials. **Use syringe shields when administering radioactive doses.**

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

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

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear extremity personnel monitoring devices during the preparation, assay, and injection of radiopharmaceuticals. Additionally these devices should be worn when holding patients during procedures.

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

10. Never pipette by mouth.

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

12. With a radiation detection survey meter, survey the generator storage (if applicable), kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area.

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

14. Always keep radioactive materials in shielded locations or containers. Sealed flood sources will be kept in shielded containers when not in use.

15. Avoid splashing or forming an aerosol during dose preparation.

16. Assay each patient dose, except prescriptions of less than 10 uCi, in the dose calibrator prior to administration.

17. Always check the patient's name, ID., the prescribed radiopharmaceutical and dosage prior to administration.

18. When practical, use a cart to move large sources of radioactivity, such as flood sources, etc. As stated above, flood sources will be shielded when not in use.

EMERGENCY PROCEDURES
Item 10.5

Minor Spills

1. **NOTIFY**: Notify persons nearby that a spill has occurred.
2. **PREVENT THE SPREAD**: Cover the spill with absorbent paper.
3. **CLEAN UP**: Use disposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.
4. **SURVEY**: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.
5. **REPORT**: Report the incident to the RSO. The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

Major Spills

1. **CLEAR THE AREA**: Notify all persons not involved in the spill to vacate the room.
2. **PREVENT THE SPREAD**: Cover the spill with absorbent paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. **SHIELD THE SOURCE:** This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. **CLOSE THE ROOM:** Leave the room and lock the door(s) to prevent entry.
5. **NOTIFY:** Notify the RSO immediately.
6. **PERSONNEL DECONTAMINATION:** Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.
7. **REPORT:** The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the Report and Survey are completed properly.

PACKAGE ORDER AND RECEIPT PROCEDURES
Item 10.6

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

2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
   (1) Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.
   (2) The above records will be checked to confirm that material received was ordered through proper channels.

3. For deliveries during normal working hours, packages are received in the hot lab.

4. If off duty deliveries are a necessity, carriers approved by security and the hospital will be allowed to proceed to the Nuclear Medicine Hot Lab. The carrier will then place the package within the Nuclear Medicine Hot Lab and re-lock all doors opened to gain access.

5. All packages containing radioactive material will be stored in a secured area to prevent unauthorized access to these items.

SAMPLE MEMORANDUM

TO: Security/Emergency Room Personnel

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Materials

When off duty deliveries are necessary, the carrier should proceed to the Emergency Room. Delivery personnel approved by Security will be allowed to proceed to the Nuclear Medicine Department. Approved delivery personnel (Syncor, Mallincrodt, etc.) will have a key to unlock the Hot Lab and place the package in a designated drop-off area. The door to the department will then be locked after delivery.
If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the Hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call our Hospital Radiation Safety Officer, Kaneez B. Shaikh, M.D.

	Name	**Home Phone**
Radiation Safety Officer:	Marcel E. Zughaib, M.D.	_____
Chief Nuclear Medicine Tech:	_____	_____
Nuc. Med. Physician On Call:	_____	_____

PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL
Item 10.7

1. Put on gloves to prevent hand contamination.

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

3. Measure and record the exposure rate from the package at 1 meter and at the package surface. If the rate is greater than 10 mR/hr, stop and notify the RSO.

4. Measure and record the exposure rate on the surface of the package in the same orientation as the data taken in step 3 above. If greater than 200 mR/hr, stop the procedure and notify the RSO.

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

6. Wipe the external surface of the final source container in compliance with 10 CFR 20.1906. Assay the wipe sample with a well counter, uptake probe, or other instrument sensitive enough to detect 200 dpm. Trigger levels for most packages are 2200 dpm/100 cm^2 according to 10 CFR Part 71.87. If there is any contamination, notify the RSO.

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

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

9. Record the receipt and all readings taken.

BYPRODUCT MATERIAL USAGE RECORDS
Item 10.8
UNIT DOSE RECORDS - WILL CONTAIN:

1. Technical Data
   a. Radionuclide
   b. Chemical form or abbreviation
   c. Date of receipt
   d. Activity as recorded on the packing slip
   e. Supplier
   f. Lot or control number

Please note that the above information is included on the unit dose slip that is supplied for each individual dose received from a professional radiopharmacy.

2. Administrative Data
   a. Time and date of administration
   b. Measured activity
   c. Patient name and ID number
   d. Method of disposal
   e. Initials of person recording the information
   f. Date of disposal or return to supplier

NOTE: Please note that unit doses are decayed in storage in a shielded biohazard container and logged as waste on the waste disposal record as Tc-99m waste, Tl-201 waste, etc. Each unit dose syringe is not logged seperately, but doses of the approximate same half-life are decayed in storage together in bulk and logged as such, e.g., Tc99m waste, Tl-201 waste, etc.

Item 10.9

MULTIDOSE VIAL RECORDS - WILL CONTAIN:

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

2. Administrative Data
   a. Data and time dosage was drawn
   b. Prescribed dosage
   c. Calculated inverse concentration (cc/mCi) at drawing time
   d. Calculated volume needed for prescribed dose
   e. Measured activity
   f. Patient name and ID number
   g. Method of disposal and date
   h. Initials of person recording information

Please note that the prescribed dose is on the prescribed dose list. The prescribed dose is a specified range approved by an authorized user. Also note that the method of disposal for these doses is the same as that described in the note under Item 10.8, i.e., the doses are decayed in storage by half-life.

MOLYBDENUM CONCENTRATION RECORDS

Item 10.10

This facility will only use unit doses or Tc-99m dispensed from an NRC or Agreement state licensed radiopharmacy. The measured Tc-99m activity in millicuries and the ratio of the total Mo-99 microcuries per millicurie of Tc-99m are documented by the unit dose pharmacy. The ratio must be less than specified in 10 CFR 35.204 (a)

AREA SURVEY PROCEDURES

Item 10.12

1. Areas of radiopharmaceutical preparation administration will be surveyed daily for ambient radiation exposure rates.

2. Areas of radiopharmaceutical storage and radiopharmaceutical waste storage will be surveyed weekly for ambient radiation exposure rates.

3. Areas of radiopharmaceutical preparation, administration or storage **(including waste storage),** will be wipe tested weekly for removable contamination. **Wipe tests will be recorded in disintegrations per minute (dpm).**

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

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 200 dpm.

6. The trigger level for exposure rate surveys will be established by the Radiation Safety Officer in compliance with 10 CFR 35.70(d).

7. The trigger level for removable contamination surveys will be the detection of Regulatory Guide 10.8

   e.g. Action Level: Tc-99m 2,000 dpm/100 sq. cm
   I-131 200 dpm/100 sq. cm.

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

9. A record shall be kept of all survey results. These records will be retained for a period of three (3) years. The record will include:
    a. Location, date, and type of equipment used.
    b. Initials of the person conducting the survey.
    c. Drawing of the area surveyed.
    d. Trigger levels keyed to the location on the drawing.
    e. Results keyed to the location on the drawing.
    f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

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

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:
    A = Calculated source activity of sample isotope in dpm
    B = Measured source counts of sample isotope in cpm
    C = Measured background counts in cpm
    D = B - C (Net Counts in cpm)

Efficiency Factor = Calculated Activity in dpm (A) divided by Net Counts in cpm (D)

Wipe Sample in dpm = Net Counts of Wipe Sample x Efficiency Factor

12. The RSO will be notified of all positive wipe test and ambient survey results.

AIR CONCENTRATION CONTROL
Item 10.13
WORKER DOSE FROM AEROSOLS
We will collect spent aerosols in a single use shielded trap and therefore no effluent monitoring is needed.

PUBLIC DOSE FROM AIRBORNE EFFLUENT
We will not directly vent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.

WASTE DISPOSAL

Item 11.1

LIQUIDS

1. Disposal to the sanitary sewer system may be made in accordance with 10 CFR 20.2003. A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.
2. Permissible concentrations in effluents will be kept within the limits enumerated in Table 3, of Appendix B of 10 CFR 20.
3. Additionally, licensed commercial radioactive waste services such as ADCO may be used.

DECAY IN STORAGE

1. Only material with a physical half-life of less than 65 days will be decayed in storage at the facility.
2. Each container will be tagged to include:
    a. The date sealed or set into storage
    b. The longest-lived isotope in the container
    c. The initials of the person setting the waste for decay.
3. Material will be decayed for at least 10 half-lives.
4. Prior to disposal as in-house waste, each container will be monitored as follows:
    a. Low-range GM survey meter will be checked for proper operation.
    b. Waste will be monitored in a low level area.
    c. Any shielding around the container will be removed.
    d. All surfaces of each individual container will be monitored.
    e. Only those containers which cannot be distinguished from background levels will be disposed of after all radioactive labels have been defaced.
    f. The date on which the container was placed in storage will be recorded.
    g. The date of disposal will be recorded.
    h. The type of material will be recorded.

UNIT DOSE WASTE

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy. Materials that cannot be returned to the unit dose pharmacy will be decayed in storage as specified above.

FEB 03 1997

Patricia Joseph, Director
Doctors Diagnostic Center
2405 East 14 Mile
Sterling Heights, MI 48034

Dear Mr. Joseph:

Enclosed is your NRC Material License Number 21-26766-01 in accordance with your request.

This also acknowledges receipt of your application dated September 11, 1996, requesting an exemption from the requirements of 10 CFR 35.32, "Quality Management Program" (QMP). We cannot give you an exemption from the requirements of 10 CFR 35.32, QMP, however, we agree that a QMP need not be implemented at this time. Should you wish to institute procedures in accordance with the provisions of Section 35.32(a)(1), in the future, it will be necessary to submit a QMP to our office for review and approval prior to its implementation.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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

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

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

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

   b. You have notified the U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Nuclear Materials Licensing Branch, in writing, that activities authorized by the license will be initiated.

302019

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).

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
William P. Reichhold
Nuclear Materials Licensing Branch

License No. 21-26766-01
Docket No. 030-34275

Enclosure: New License Package

DOCUMENT NAME: M:\03034275.CL7
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	WPReichhold:brt							
DATE	01/31/97							

OFFICIAL RECORD COPY

December 23, 1996

ATTN: Bill Reichhold
Materials and Licensing
U.S. Nuclear Regulatory Commission
Materials and Licensing Section
801 Warrenville Road
Lisle, IL 60532-4352

RE: Control No. 302019
License Application
Doctors Diagnostic Center
Sterling Heights, Michigan

Dear Mr. Reichhold:

The following letter is a response to your questions from December 4 regarding our license application.

Authorized Users

Please approve Dr. Zughaib for cardiovascular clinical procedures as listed on Consultants in Cardiology, P.C. License 21-26635-01. Please add Maria Crumes, M.D. as an authorized user for materials in 10 CFR Part 35.100 and 35.200. Dr. Crumes is currently listed on Universal Imaging, Inc. NRC License No. 21-26532-01.

Radiation Safety Officer (RSO)

1. Dr. Zughaib will be available as RSO by phone or in person if necessary at this facility.

2. Dr. Zughaib or his designee will be at Doctors Diagnostic Center approximately 1 to 2 days week performing his duties as RSO.

3. Dr. Zughaib can respond immediate by phone and within one half hour in person to an emergency involving radioactive materials when he is not present at this facility.

Pm: 1-15-97

4. Dr. Zughaib will be able to adequately perform the duties of the Radiation Safety Officer at both facilities. He will be in contact with management and the nuclear medicine technologists of both facilities as necessary to perform the duties as described in 10 CFR Part 35.21. Record reviews will be done at least quarterly as described in 10 CFR Part 35.21. Both of the facilities are clinics doing routine nuclear medicine procedures. Radionuclide therapies are will not be done at Doctors Diagnostic Center.

Training

The method of radiation safety training will be done mostly in person and through written correspondence. These inservices will be documented. Quizzes will be given occasionally as part of these reviews. In addition, video tapes may be viewed.

Facility

1. Enclosed is a scaled diagram of the nuclear medicine area.

2. Specific room numbers are not known at this time.

3. The radiopharmaceutical storage area is indicated on the diagram.

4. The door to the hot lab area will be lockable. Keys will be made available to management, nuclear medicine technologists, and professional radiopharmaceutical delivery people.

Dose Calibrator

1. Linearity will be performed using the "lead-sleeve" method or using timed decay. The check will be done from the range of highest patient dose down to 30 microcuries.

2. The actual activity of the calibration sources used for accuracy will be within plus or minus 5% of the activity stated on the sources.

Radiation Safety Committee

Doctors Diagnostic Center is not a medical institution. It is a clinic.

RSO Duties

Quarterly review of the radiation survey records will be part of the RSO duties.

ALARA Program

Enclosed is a signed copy of the ALARA program. This document is signed by Dr. Zughaib and management of Doctors Diagnostic Center.

Laboratory Safety Rules

Assayed doses will not be administered to a patient if they differ by more than 10% from the prescribed dose.

Receipt and Ordering

The original memo for receipt of packages containing radioactive material indicated two Radiation Safety Officers. This was incorrect. There is only one Radiation Safety Officer, Dr. Zughaib, as indicated on the enclosed corrected memo.

Package Opening Procedures

Monitoring (wipe tests and surveys) the external surface of packages containing radioactive materials will be done according to 10 CFR Part 20.1906.

Records of Byproduct Material Use

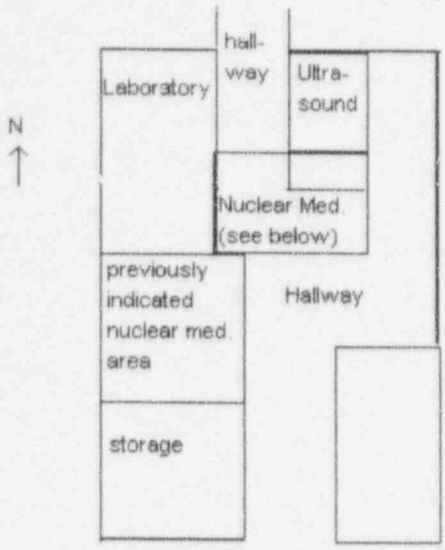
Unit doses: The prescribed dose will be listed on a prescribed dose list. Doses will be ordered and administered only within the range of these prescribed doses.

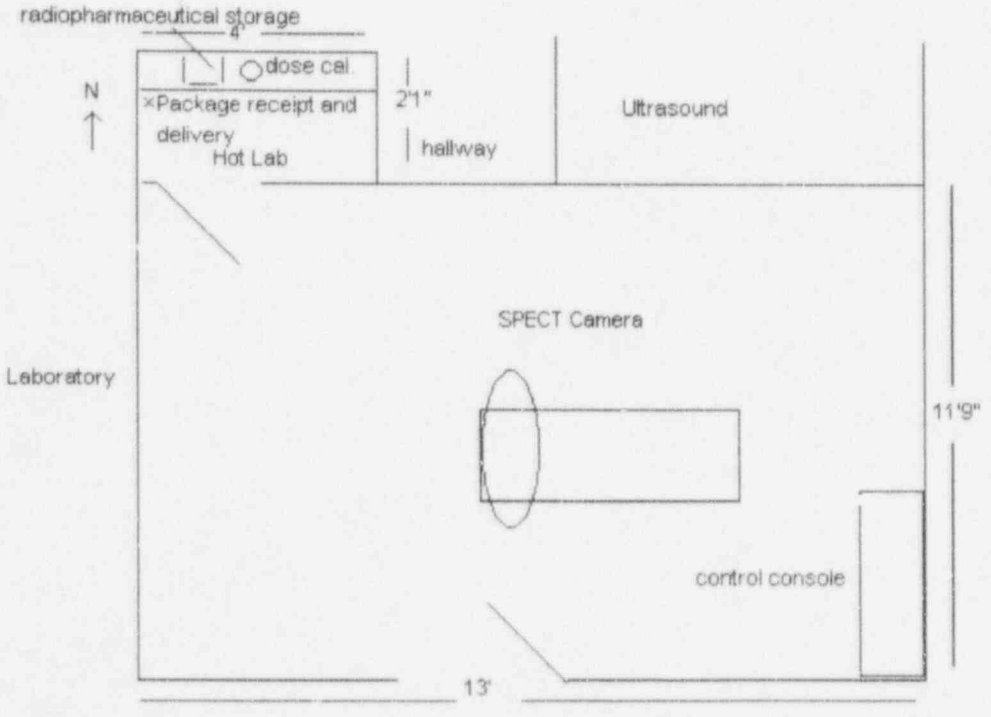
Multidoses: The date of preparation will be recorded for each vial if a multidose vial is used.

Area Surveys: Radiopharmaceutical preparation and administration is in the hot lab and scanning areas as indicated on the diagram. Area surveys will be done in both of these areas.

Bioassay Program: We will not be using iodine-131 over 30 uCi and will not perform radionuclide therapies. For this reason a bioassay program is not necessary. We request exemption from 10 CFR Part 35.32 - Quality Management Program.

Doctors Diagnostic Center
2405 E. 14 Mile Road
Sterling Heights, MI 48034
Lower Level





SAMPLE MEMORANDUM

TO: Management/Clinic Personnel

FROM: Radiation Safety Officer

SUBJECT: R ɔceipt of Packages Containing Radioactive Materials

When off duty deliveries are necessary, the carrier should proceed to the Hot Lab. Delivery personnel approved by management will be allowed to proceed to the Nuclear Medicine Department. Approved delivery personnel (Syncor, Mallincrodt, etc.) will have a key to unlock the Hot Lab and place the package in a designated drop-off area. The door to the department will then be locked.

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

If you have any questions concerning this memorandum, please call our Radiation Safety Officer, Marcel E. Zughaib, M.D.

	Name	Home Phone
Radiation Safety Officer:	Marcel E. Zughaib, M.D.	_____
Chief Nuclear Medicine Tech:	_____	_____
Nuclear. Med. Physician On Call:	_____	_____

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

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

d. Re-establishment of investigational Levels to levels above those listed in Table I. In cases where a worker or group of workers' doses need to exceed an investigational level, a new, higher investigational level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigational levels will be documented by the RSO.

6. Signature of Certifying Official

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

X _____

Marcel E. Zughaib, M.D.
Radiation Safety Officer

_____

Management, Doctors Diagnostic Center

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

November 6, 1996

Marcel E. Zughaib, M.D.
Radiation Safety Officer
Doctors Diagnostic Center
2405 East 14 Mile
Sterling Heights, MI 48034

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter & Application Dated 09/11/96)

Dear Licensee:

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

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

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

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

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

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

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

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

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

Nuclear Materials Support Branch

Mail Control No. 302019
License No. 21-26766-01