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.

301968

Licensee	
1. Warren Radiologists, Inc.	3. License Number 34-26762-01
2. Suite C 650 Youngstown Warren Road Niles, OH 44446	4. Expiration Date December 31, 2001
	5. Docket or Reference No. 030-34263

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-133 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-133 and generators).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at Suite C, 650 Youngstown Warren Road, Niles, Ohio.

11. Radiation Safety Officer: James D. Goettsch, D.O.

12. Licensed material shall be used by, or under the supervision of, James D. Goettsch, D.O.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
34-26762-01

Docket or Reference Number
030-34263

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 October 18, 1996; and

    B. Letter dated November 7, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 12/4/96

By James Mullauer
Nuclear Materials Licensing Branch, Region III

COPY

R4

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

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

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: WARREN RADIOLOGISTS INCORPORATED
   Received Date: 961021
   Docket No: 3034263
   Control No.: 301968
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: 1400
   Check No.: 15855

3. COMMENTS

Signed D. Hersey
Date 10-25-96

1996 OCT 25 AM 11:12

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

1. Fee Category and Amount: 7C #1400

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

3. OTHER

Signed SC
Date 10/25/96

OCT 31 1996

Log Oct 12 III
Remitter
Check No. 15855
Amount #1400
Fee Category 7C
Type of Fee APP
Date Check Rec'd 10/
Date Completed /25/96
By: SC

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)*

Warren Radiologists, Inc.
Suite C
650 Youngstown Warren Road
Niles, Ohio 44446

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

same as 2

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Dale E. Starchman, Ph.D.

TELEPHONE NUMBER
330-494-7353

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 7C AMOUNT ENCLOSED $1400.00

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

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

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

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
X	X [signature]	X 10-18-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			$		RECEIVED OCT 21 1996 REGION III
APPROVED BY			DATE		
pm: 10-18-96					30198

NRC FORM 313 (6-93)

PRINTED ON RECYCLED PAPER

Warren Radiologists, Inc.
Niles, Ohio

Byproduct Material		Amount	Purpose
5.a	Material in 10CFR 35.100	As needed	6.a Medical Use
5.b	Material in 10CFR 35.200 excluding generators	As needed	6.b Medical Use

September 1996

Radiation Safety Officer.
Authorized Users.

The radiation safety officer is designated as James D. Goettsch, D.O.

James D. Goettsch, D.O., is to be listed as an authorized user for uptake, dilution, and excretion studies (35.100) and for imaging and localization studies (35.200).

Dr. Goettsch was listed as an authorized user on NRC Byproduct Material License No. 34-12685-01 issued to Warren General Hospital, Warren, Ohio since February 1993.

Item No. 7
September 1996

8. Training for individuals working in or frequenting restricted areas.

8.1 We have developed a training program for your review that is appended as ATT 8.1

8.2 NA

9. Facilities and Equipment

9.1 Annotated drawing of the nuclear medicine area including the hot lab is enclosed as ATT 9.1. Also enclosed as part of ATT 9.1 is a list of instrumentation (survey meter, dose calibrator, and diagnostic systems) which are subject to revision as future needs change.

9.2 Survey instruments will be calibrated by commercial services which have established and implemented the model procedure for calibrating survey instruments that was published in Appendix B to Regulatory Guide 10.8, Revision 2 (or the equivalent as demonstrated by their having had their procedures approved by the NRC).

9.3 We have developed a dose calibrator calibration procedure for your review that is appended as ATT 9.3.

9.4 We have developed an external exposure monitoring program for your review that is appended as ATT 9.4.

9.5 NA

9.6 NA

10. Radiation Safety Program

10.1 We will issue the Radiation Safety Officer Delegation of Authority that is appended as ATT 10.1.

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

10.3 We have developed a leak test procedure for your review that is appended as ATT 10.3.

10.4 We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4.

10.5 We have developed spill procedures for your review that are appended as ATT 10.5.

10.6 We have developed a procedure for ordering and receiving radioactive materials for your review that is appended as ATT 10.6.

10.7 We have developed a package opening procedure for your review that is appended as ATT 10.7.

10.8 We have developed a procedure for a unit dosage record system for your review that is appended as Att 10.8.

10.9 We have developed a procedure for a multidose vial record system for your review that is appended as ATT 10.9.

10.10 NA

10.11 NA

10.12 We have developed area survey procedures for your review that are appended as ATT 10.12.

10.13.1 NA

10.13.2 We will collect spent aerosol in a shielded trap and for reusable traps, monitor the trap effluent with an air contamination monitor that will be checked regularly according to manufacturer's instructions. The trap effluent of single-use devices will not be monitored.

10.13.3 NA

10.13.4 NA

10.14 NA

10.15 NA

10.16 NA

11.1 We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

11.2 NA

Personnel Training Program
Nuclear Medicine Service

All personnel will be properly instructed before assuming duties with, or in the vicinity of radioactive materials or whenever there is a significant change in duties, regulations, or the terms of the license.

At a minimum, an annual in-service will be provided for nuclear medicine technologists as well as any other persons whose duties require working in or frequenting any portion of a restricted area.

Instructions of personnel as required by 10CFR19 will include:

A. All terms of the license pertinent to radiation safety.

B. Areas where radioactive material is used or stored.

C. Potential hazards associated with radioactive material.

D. Radiological safety procedures appropriate to their respective duties.

E. Pertinent N.R.C. regulations.

F. Conditions of the license.

G. Obligation to report unsafe conditions to the Radiation Safety Officer.

H. Appropriate response to emergency or unusual occurrence.

I. Right to be informed of their radiation exposure and bioassay results.

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

The following records will be maintained documenting the radiation safety training:

A. A description of the instruction

B. The date of instruction

C. Name of individual who gave the instruction

D. List of attendees

ATT 8.1
September 1996

TRAINING PROGRAM

Workers	Method	Frequency
1. Nuclear Medicine Supervisor	Lecture by Consulting Physicist	Annually[1]
2. Nuclear Medicine Technologist(s)	Instruction by Nuclear Medicine Supervisor	Annually[1]
3. Housekeeping Personnel	Instruction from Nuclear Medicine Technologists	Annually

[1]The Nuclear Medicine Supervisor will be responsible for orienting any technologist employee with respect to radiation safety practices in a one-on-one session. Consulting physicist reviews overall radiation safety program in detail with Supervisor twice a year and submits a written report. These reviews will be considered equivalent to an annual lecture. The Supervisor will be responsible for discussing any significant problem areas noted during the review with the technologist staff.

ATT 8.1
September 1996

Description of Nuclear Medicine Department
(See Diagram)

The department consists of the main imaging area next to the hot lab. A floor plan of the area is enclosed.

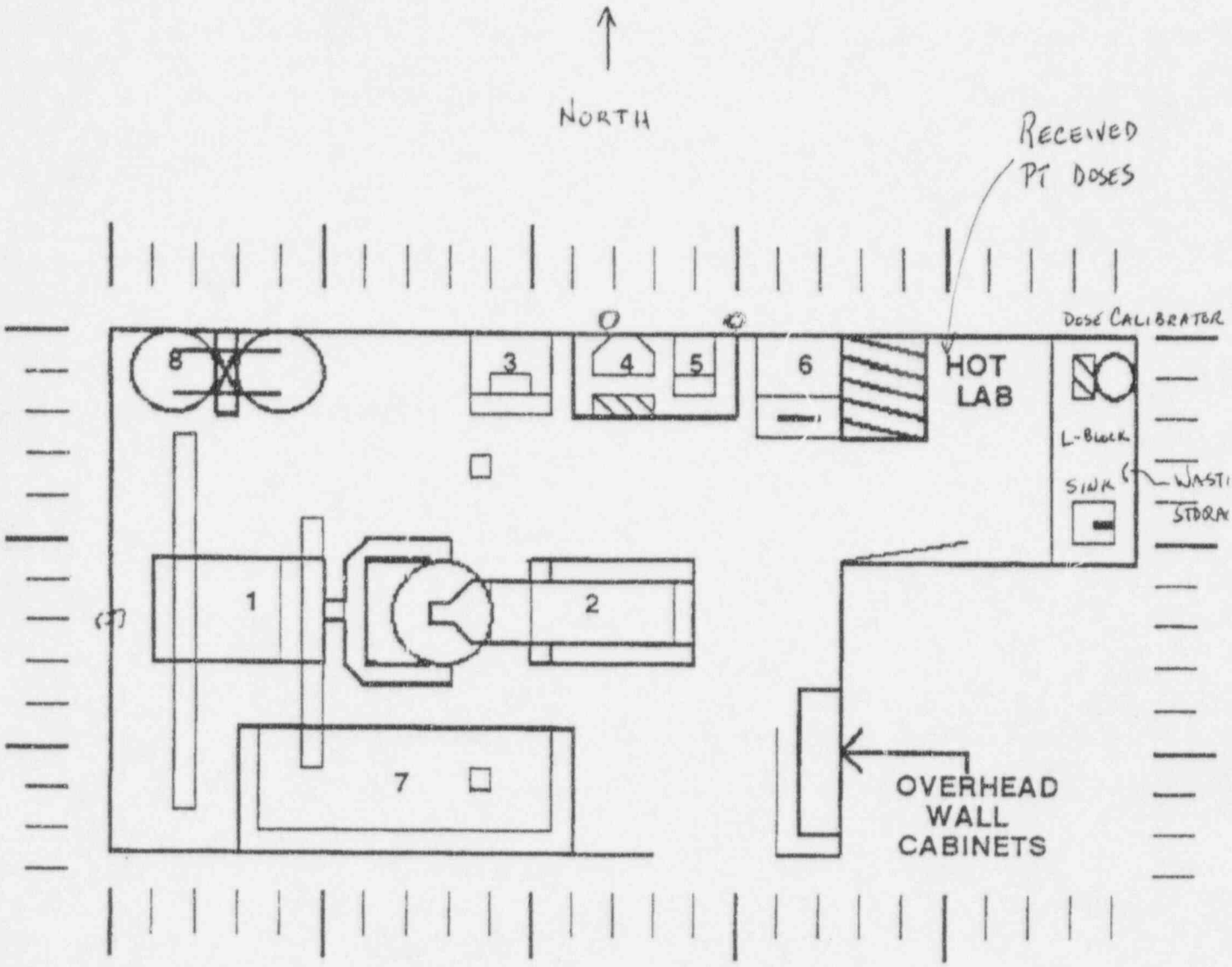
Pb Shield: A standard L block made of lead and leaded glass is available. Preparations are performed using this L block on the counter in the hot lab.

The hot lab area will be locked separately from the remainder of the nuclear medicine department. It will be locked when personnel are not present in the department.

Absorbent pads are used in areas where radioisotope storage and manipulation are performed with liquids.

All areas adjacent to the department are unrestricted areas. Surveys will be conducted to insure that these levels do not exceed the limits specified in 10CFR 20.

ATT 9.1
September 1996



1=CAMERA STAND
2=SPECT TABLE
3=DOT
4=NUCLEAR MAC COMPUTER
5=COLOR PRINTER
6=MICRODOT
7=WHOLE BODY TABLE
8=COLLIMATOR CART

1/4" = 1 Foot

SEPTEMBER 1996

Instrumentation

1. Survey Meter:

Type	Manufacturer	Model
GM	Ludlum	14C

2. Dose Calibrator — Capintec — CRC-15R

3. Instruments Used for Diagnostic Procedures:

Type	Manufacturer	Model
Gamma Camera	Siemens	7500
Well Counter	Picker	Spectroscaler 4R

Daily Dose Calibrator Constancy Checks

1. At the beginning of each day of use, perform the dose calibrator constancy check.

2. Place one relatively long lived source such as Cs-137, Co-60, Co-57, or Ra-226 in the dose calibrator. Assay this source using the setting appropriate to that source, then assay this reference source with the frequently used settings. Record the results. Compare each reading to previous values corrected for decay of the source.

The following information is to be recorded:

A. Model and Serial Number of dose calibrator.

B. Identity of radionuclide contained in the check source.

C. Date of check.

D. Activity measured.

E. Initials of the individual who performed the check.

3. If the measurements are not within ±5% of the predicted values, notify the RSO.

ATT 9.3
September 1996

Dose Calibrator Linearity Determination
(Quarterly)
DECAY METHOD

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity prepared for patient use.

1. Assay the Tc-99m vial in the dose calibrator to determine the net activity in milliCuries.

2. Repeat Step 1 at various time intervals over the next 3-4 days after the initial assay to achieve a final measured activity of 30 microcuries or less.

3. Calculate the predicted activity at time equals zero for each measured activity.

4. Compare the predicted activities.

5. The measured activities should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate that the instrument may require repair or adjustment.

6. Notify the RSO if the linearity error exceeds 5 percent so that an evaluation of the status of the dose calibrator can be made.

7. The following information is to be recorded:
   A. Model and serial number of dose calibrator
   B. Calculated activities
   C. Measured activities
   D. Date of the check
   E. Signature of the individual performing the test

8. If the linearity error exceeds 10 percent, a mathematical correction will be applied to correct activity readings for dosages above 10 microcuries.

Dose Calibrator Linearity Determination
(Quarterly)
(continued)

SHIELD METHOD

Lead sleeves of various thicknesses to test linearity may be substituted for steps 1 through 3 above. The sleeve set will be calibrated in accordance with the manufacturer's instructions.

Dose Calibrator Geometry Independence

We will establish and implement the model procedure for testing the geometric independence of the dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2. (Copy not attached to this application, but available in the facility).

Dose Calibrator Accuracy Determination
(Annually)

Check the accuracy of the dose calibrator for two radionuclides e.g Cs-137 and Co-57. The activities of these reference standards have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

1. Assay each of the reference standards in the dose calibrator at the appropriate setting, and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement in the log.

2. The activity for each source should agree with the certified activity of the reference source within ±5 percent after decay corrections.

3. Keep a log of these accuracy checks.

4. The following information is to be recorded:

   A. Model and serial number of dose calibrator.

   B. Model and serial number of each source used.

   C. Radionuclide for each source.

   D. Decay corrected calibrated activity for each source.

   E. Measured activity for each source.

   F. Date of test.

   G. Signature of the individual performing the test.

5. Accuracy checks that do not agree within ±5 percent indicate that the instrument may require repair or adjustment. Notify the RSO if the accuracy error exceeds 5 percent.

6. If the accuracy error exceeds 10 percent, the dose calibrator will be repaired or replaced.

ATT 9.3
September 1995

Personnel External Exposure Monitoring Program

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

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor as deemed appropriate by the RSO. Individuals who are likely to exceed 10 percent of the maximum permissible dose will be monitored. The monitoring devices will be processed by a contract service on a monthly basis.

3. All individuals who, on a regular basis, handle radioactive material that emits ionizing photons will be issued a film or TLD finger monitor as deemed appropriate by the RSO. Individuals who are likely to exceed 10 percent of the maximum permissible dose will be monitored. These monitors will be processed by a contract service on a monthly basis.

4. Other individuals who are exposed to radiation on an occasional basis such as 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.

ATT 9.4
September 1996

Memo To: All Employees

From: Chief Executive Officer

Subject: Delegation of Authority

James D. Goettsch, D.O. has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

ATT 10.1
September 1996

Leak Testing

Leak tests will be performed at 6-month intervals. The leak testing will be sufficiently sensitive to detect 0.005 microcurie of activity.

Leak tests will be performed by the consultant physicist Dale E. Starchman, Ph.D. Dr. Starchman is certified by the American Board of Radiology and by the American Board of Health Physics. In the event that Dr. Starchman is unavailable for a specific scheduled leak test, it will be performed by W. R. Hedrick, Ph.D., D. L. Hykes, Ph.D., L. R. Milavickas, Ph.D. or by P. Shaheen, M.S. all of whom are physicists certified by the American Board of Radiology.

The test sample will be taken from those surfaces on which one might expect contamination if there were to be leakage. The test sample will be counted in a radiation detection instrument with a sensitivity to detect 0.005 microcuries.

A Cs-137 reference source will be used to calibrate the system.

The following sample calculation demonstrates that this counting system is sufficiently sensitive to detect 0.005 microcuries.

Activity in test sample (uCi)

$$= \frac{\text{Net count rate sample}}{\text{Net count rate reference}} \times \text{Activity Reference Source (uCi)}$$

Background count rate = 1000 CPM

Reference source activity = 0.5 uCi

Reference source count rate = 100,000 CPM

Net reference count rate = 100,000 CPM - 1000 CPM = 99,000 CPM

Test sample count rate = 2000 CPM

Net sample count rate = 2000 CPM - 1000 CPM = 1000 CPM

$$A\ (uCi) = \frac{1000}{99{,}000} \times 0.5$$

A (uCi) = 0.005 uCi

Procedures for Leak Testing Sealed Sources

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

2. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used.

3. Use a 2" X 2" NaI well counter to count the samples.

4. Assay a Cs-137 check source to estimate the detection efficiency of the counting system.

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

6. Record the wipe sample counts per minute or total counts and counting time. Then calculate and record the estimated activity in microcuries on the wipe samples.

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

8. If the wipe sample activity is 0.005 microcurie or greater, notify the RSO. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State license, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e)(2) of 10 CFR Part 35.)

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

ATT 10.2
September 1996

Rules for Safe Use of Radiopharmaceuticals

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

2. Wear disposable gloves while handling radioactive materials. Gloves will be worn during injections of radiopharmaceuticals whenever possible. However, in certain cases it may be necessary to perform the injection without gloves.

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

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

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

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

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

8. Wear a finger exposure monitor as prescribed by the Radiation Safety Officer.

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

10. Never pipette by mouth.

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

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

13. Confine radioactive solutions in shielded containers that are clearly labeled. Radiopharmaceuticals multidose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A log book should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

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

Spill Procedures

Minor Spills of Liquids and Solids:

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

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

3. Clean up the spill using disposable gloves and absorbent paper. Carefully fold the absorbent paper with the clean side out and place in the plastic bag for transfer to a radioactive waste container. Also put contaminated gloves and any other contaminated disposable material in the bag.

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

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

6. The Radioactive Spill Report and Radioactive Spill contamination Survey will be completed by the individuals who cleaned up the spill.

ATT 10.5
September 1996

Spill Procedures

Major Spills of Liquids and Solids:

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

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

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

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

5. Notify the RSO immediately.

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

7. The RSO will supervise the cleanup of the spill. The Radioactive Spill Report and the Radioactive Spill Contamination Survey will be completed by individuals who cleaned up the spill.

ATT 10.5
September 1996

Relative Hazards of Common Radionuclides

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

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

Procedures for Ordering and Accepting Delivery of Radioactive Material

1. All radioactive material for the Nuclear Medicine Service will be ordered by or under the direction of the Chief Nuclear Medicine Technologist or the acting chief. These individuals will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. Ordering of routinely used materials in the Nuclear Medicine Service.

   a. Written records that identify the isotope, compound, activity levels, and supplier, etc. will be maintained.

   b. The written records will be referenced when opening or storing a radioactive shipment.

3. Written records will be maintained for all ordering and receipt procedures.

4. During normal working hours, carriers will be instructed to deliver radioactive package directly to the Nuclear Medicine Service.

5. During off-duty hours, delivery of radioactive packages is prohibited.

ATT 10.6
September 1996

Opening Packages Containing Radioactive Material
Nuclear Medicine

Put on gloves to prevent hand contamination.

Visually inspect the package for any sign of damage (e.g. wetness, crushed). If damage is noted, notify the Radiation Safety Officer.

All incoming packages will be surveyed at the surface and at three feet from the surface to assure that the exposure levels do not exceed the acceptable exposure rates. The transport index noted on packages with Yellow II or Yellow III labels is the approximate exposure rate in mR per hour at three feet from the package surface; the surface exposure rate for such packages should not exceed 200 mR/hr (Yellow III) or 50 mR/hr (Yellow II). The exposure rate from packages with White I labels should be less than 0.5 mR/hr at the package surface. If the above levels are exceeded, notify the Radiation Safety Officer.

Wipe the external surface and count the wipe sample in the NaI well counter. If the level of removable contamination exceeds 6600 dpm per 300 cm^2, notify the Radiation Safety Officer. The NRC Regional Office must be notified if removable contamination exceeds 0.01 microcuries (22,000 dpm) per 100 cm^2.

Monitor the packing material and package for contamination before releasing from area. If contaminated, treat as radioactive waste. If the material is to be discarded in regular trash, obliterate radiation labels.

Record the results of checking each package in the log book.

Verify that the contents agree with the packing slip. Check the user request to ensure that the material received is the material that was ordered.

RECORDS OF UNIT DOSAGE USE

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

1. Radionuclide;
2. Generic name or its abbreviation or trade name;
3. Date of receipt;
4. Supplier;
5. Lot number or control number, if assigned;
6. Activity in milliCuries or microCuries as recorded on the unit dosage or packing slip and its associated time;
7. Date of administration or disposal;
8. If administered,
    a. Prescribed dosage (unless already recorded in clinical procedure manual)
    b. Measured activity in milliCuries or microCuries and date and time of measurement
    c. Patient's name;
9. If discarded, the date and method of disposal; and
10. Initials of the individual who made the record.

RECORDS OF MULTIDOSE VIAL USE

For each multidose vial that is received from a supplier or that is prepared, make a record of the:

1. Radionuclide;

2. Generic name or its abbreviation or trade name;

3. Date of receipt or preparation;

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

5. Supplier or kit manufacturer;

6. If administered,

    a) Prescribed dose (unless already recorded in clinical procedure manual),

    b) Date and time dosage was drawn and measured,

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

    d) Measured activity in milliCuries or microCuries,

    e) Patient name;

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

8. Initials of the individual who made the record.

ATT 10.9
September 1996

Area Survey Procedures
Nuclear Medicine

1. All preparation and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.

2. Scanning area will be surveyed weekly.

3. The weekly surveys will consist of:

a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr. If the radiation level exceeds 0.06 mR/hr in the scanning areas or 2 mR/hr in the hot lab, then the individual performing the survey shall notify the RSO immediately.

b. A series of wipe tests to measure contamination levels. A NaI well counter or gamma camera will be utilized to perform these measurements. Area will be cleaned and re-monitored if the reading exceeds action levels. If after cleaning the removable contamination still exceeds action level, then the individual performing the survey shall notify the RSO immediately. The action levels in dpm/100 cm^2 for surface contamination by radionuclides are shown:

	P-32, Co-58 Fe-59, Co-60, Se-75 I-125, I-131, Yb-169, Au-198	Cr-51 Tc-99m Hg-197
1. Unrestricted areas personnel clothing	200	2000
2. Restricted areas protective clothing used only in restricted areas, skin	2000	20000

ATT 10.12
September 1996

4. A record will be kept of all survey results, including negative results for at least three years. The record will include:

a. Plan of the area surveyed.

b. Date of survey.

c. Trigger levels for each area.

d. Initials of persons conducting the survey.

e. Identification of equipment used to make the survey.

f. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

g. Detected contamination levels, keyed to locations on drawing.

h. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

APPENDIX G

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

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

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

ALARA PROGRAM

Warren Radiologists, Inc.
(Licensee's Name)

September 1996
(Date)

1. Management Commitment

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

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

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

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

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

2. Radiation Safety Committee

a. Review of Proposed Users and Uses

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

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

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

b. Delegation of Authority

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

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

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

c. Review of ALARA Program

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

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

---

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

Table 1

Investigational Levels

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

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

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

3. Radiation Safety Officer

a. Annual and Quarterly Review

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

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

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

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

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

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

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

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

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

b. Authorized User's Responsibility to Supervised Individuals

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

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

5. Individuals Who Receive Occupational Radiation Doses

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

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

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

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

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

a. Personnel dose less than Investigational Level I.

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

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

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

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

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

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

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

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

7. Signature of Certifying Official*

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

X James D. Goettsch, MD
Signature

X James D. Goettsch
Name (print or type)

X Vice President, Warren Radiologists, Inc
Title

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

DEC 0 4 1996

James D. Goettsch, D.O.
Radiation Safety Officer
Warren Radiologists, Inc.
Suite C
650 Youngstown Warren Road
Niles, OH 44446

Dear Dr. Goettsch:

Enclosed is your NRC Material License Number 34-26762-01 in accordance with your request.

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

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

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

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

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

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

301968

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
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No. 34-26762-01
Docket No. 030-34263

Enclosures: New License Package

DOCUMENT NAME: M:\03034263.CL6
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OFFICE	DNMS/RIII									
NAME	JRMullauer:brt									
DATE	12/2/ /96									

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WARREN
RADIOLOGISTS
INCORPORATED

Robert J. Rodgers, D.O. · James D. Goettsch, D.O.
650 Youngstown Warren Rd. · Suite C · P.O. Box 28 · Niles, Ohio 44446
(330) 544-3636 Fax (330) 544-9449 800-246-2976

November 7, 1996

License Management Section
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville rd.
Lisle, Illinois 60532 4351

Re: Control Number 301968
Attn: James R Mullauer, M.H.S.

Dear Mr. Mullauer:

This is in response to your request for additional information dated October 29, 1996 regarding the application for NRC Byproduct Material License for Warren Radiologists, Inc. in Niles, Ohio.

The item-by-item responses and a revised facility diagram are attached.

Sincerely,
James D. Goettsch, DO
James D. Goettsch, D.O.

Warren Radiologists, Inc.
Suite C
650 Youngstown Warren Road
Niles, Ohio 44446

1. Facility Diagram

   A revised facility diagram which identifies areas across the walls from use is enclosed. Radiopharmaceuticals are supplied in unit doses. Each unit dose is provided within a shielded container. Used syringes are returned to supplier so that waste maintained on site is minimal. Biohazard material maintained on site is stored in shielded containers.

2. Dose Calibrator Calibration

   a. Constancy

      1) If a radium-226 source is used for constancy, the activity will be greater than 10 microcuries. If other sources are used, the activity will be greater than 50 microcuries.

      2) If the constancy results differ from the expected value by ±5%, the RSO will be notified. The operation of the dose calibrator including zero, background, and diagnostic test will be checked and the constancy check repeated. If the error exceeds 10% the dose calibrator shall be repaired or replaced.

   b. Linearity

      1) The linearity test will be performed at installation, quarterly, and following repair.

      2) The linearity test will be ascertained over the entire range of activities employed.

   c. Accuracy

      1) The accuracy test will be performed at installation, annually, and following repair.

      2) Sources used for dose calibrator accuracy will have activities greater than 50 microcuries.

d. The dose calibrator will be inspected quarterly to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to manufacturer's instructions.

e. The Radiation Safety Officer will review, approve, and sign all records of linearity, accuracy, and geometrical variation tests.

WARREN
RADIOLOGISTS
INCORPORATED

Robert J. Rodgers, D.O. · James D. Goettsch, D.O.
650 Youngstown Warren Rd. · Suite C · P.O. Box 28 · Niles, Ohio 44446
(330) 544-3636 Fax (330) 544-9449 800-246-2976

NOVEMBER 7, 1996

License Management Section
U. S. Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, Illinois 60532 4351

Re: Control Number 301968
Attn: James R Mullauer, M. H. S.

Dear Mr. Mullauer:

This is in response to your request for additonal information dated October 29, 1996 regarding the application for NRC Byproduct Material License for Warren Radiologists, Inc. in Niles, Ohio.

The item-by item responses and a revised facility diagram are attached.

Sincerely,

James D. Goettsch, D.O.

James D. Goettsch, D. O.

PM 11/19/96

Warren Radiologists, Inc.
Suite C
650 Youngstown Warren Road
Niles, Ohio 44446

1. Facility Diagram

A revised facility diagram which identifies areas across the walls from use is enclosed. Radiopharmaceuticals are supplied in unit doses. Each unit dose is provided within a shielded container. Used syringes are returned to supplier so that waste maintained on site is minimal. Biohazard material maintained on site is stored in shielded containers.

2. Dose Calibrator Calibration

a. Constancy

1) If a radium-226 source is used for constancy, the activity will be greater than 10 microcuries. If other sources are used, the activity will be greater than 50 microcuries.

2) If the constancy results differ from the expected value by ±5%, the RSO will be notified. The operation of the dose calibrator including zero, background, and diagnostic test will be checked and the constancy check repeated. If the error exceeds 10% the dose calibrator shall be repaired or replaced.

b. Linearity

1) The linearity test will be performed at installation, quarterly, and following repair.

2) The linearity test will be ascertained over the entire range of activities employed.

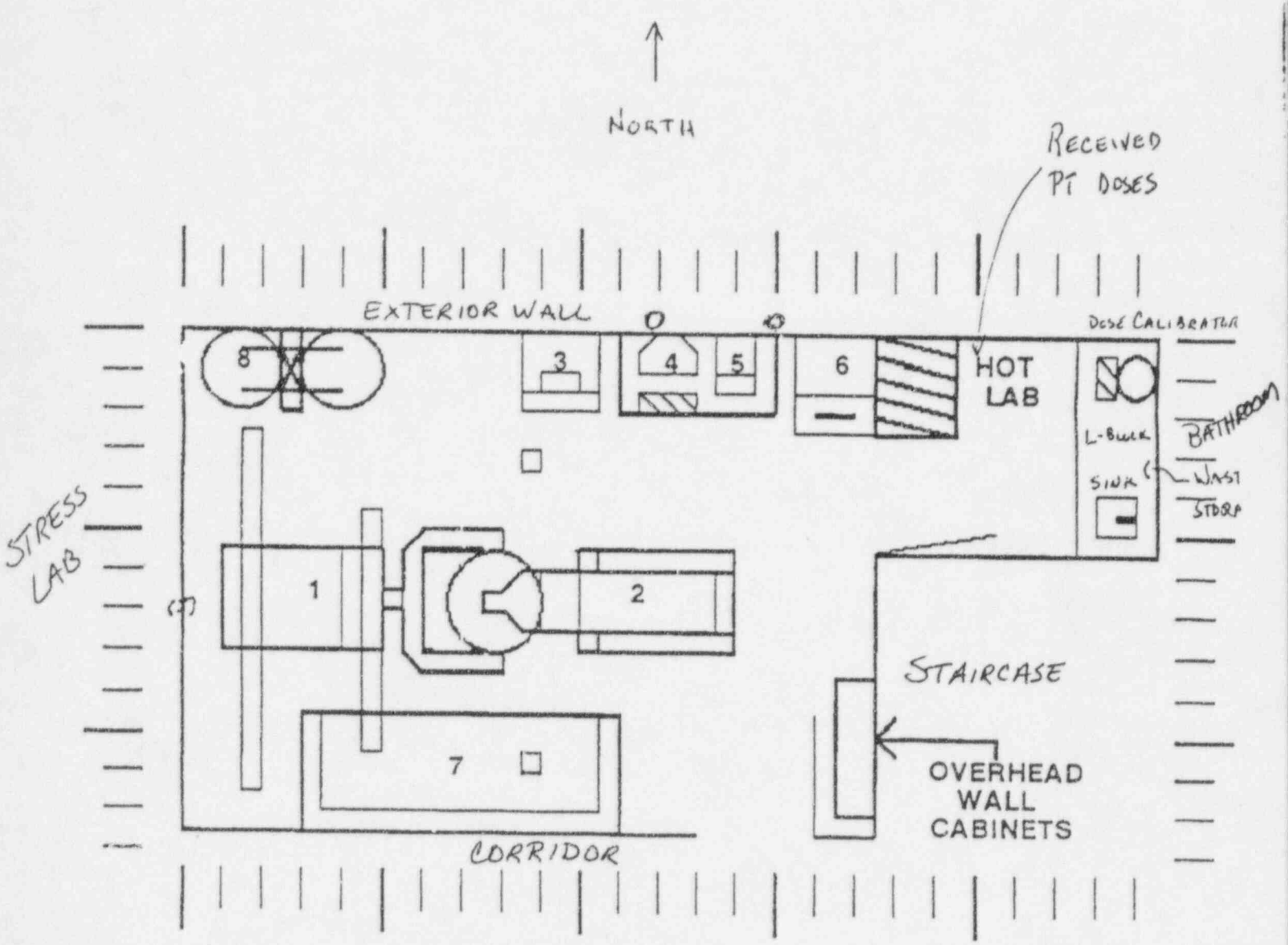
c. Accuracy

1) The accuracy test will be performed at installation, annually, and following repair.

2) Sources used for dose calibrator accuracy will have activities greater than 50 microcuries.

d. The dose calibrator will be inspected quarterly to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to manufacturer's instructions.

e. The Radiation Safety Officer will review, approve, and sign all records of linearity, accuracy, and geometrical variation tests.



1=CAMERA STAND
2=SPECT TABLE
3=DOT
4=NUCLEAR MAC COMPUTER
5=COLOR PRINTER
6=MICRODOT
7=WHOLE BODY TABLE
8=COLLIMATOR CART

1/4" = 1 Foot

SEPTEMBER 1996

OCT 2 9 1996

James D. Goettsch, D.O.
Radiation Safety Officer
Warren Radiologists, Inc.
Suite C
650 Youngstown Warren Road
Niles, Ohio 44446

Dear Dr. Goettsch:

We have reviewed your application dated October 18, 1996, requesting a new NRC license and find that we need the following additional information to complete our review. Please respond to the following items in the same order as presented in this letter.

1. Facility Diagram

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

2. Dose Calibrator Calibration

   a. Constancy

      (1) Item 9.3 of your application states that you will place one relatively long lived source in the dose calibrator to check constancy. Please confirm that if a Radium-226 source is used, the activity will be greater than 10 microcuries and if other sources are used, the activity will be greater than 50 microcuries.

      (2) Item 9.3 also states that if constancy results are greater than +/- 5% of the predicted values, notify the RSO. Please describe what action will be taken by the RSO if these values are exceeded.

   b. Linearity

      (1) Item 9.3 implies that a linearity test will be performed quarterly. Please confirm that a linearity test will be performed at installation, every 3 months and following repair.

      (2) Item 9.3 states that linearity test should be ascertained over the entire range of activities employed. Please confirm that linearity test will be ascertained over the entire range of activities employed.

301968

c. Accuracy

(1) Item 9.3 implies that dose calibrator accuracy tests will be performed annually. Please confirm that accuracy tests will be performed at installation, following repair and every 12 months.

(2) Please confirm that the sources used for dose calibrator accuracy tests will have activities greater that 50 microcuries.

d. Please confirm that the dose calibrator will be inspected at least quarterly to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturers instruction.

e. Please confirm that the Radiation Safety Officer will review, approve and sign all records of linearity, accuracy and geometrical variation tests.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days and refer to Control Number 301968.

Upon failure to file an answer within the specified time, we will consider that your have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

If you have any questions or require clarification on any of the information stated above you may contact us at (708) 829-9873.

Sincerely,

Original Signed By
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No. 34-26762-01
Docket No. 030-34263

DOCUMENT NAME: M:\03034263.DF6

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NAME	JMULLAUER:jaw									
DATE	10/ /96									

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

October 22, 1996

James D. Goettsch
Radiation Safety Officer
Warren Radiologists Incorporated
650 Youngstown Warren Road, Suite C
Niles, OH 44446

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Application Dated 10/18/96)

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. 301968
License No. 34-26762-01