NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Veterans Administration Medical Center
1600 Randalia
Fort Wayne, IN 46805

TELEPHONE NO.: AREA CODE (219) 426 5431

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

2. PERSON TO CONTACT REGARDING THIS APPLICATION

TELEPHONE NO.: AREA CODE (219) 426 5431

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 13-11983-01

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

DOROTHY WEINER, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

DOROTHY WEINER, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	3 millicuries
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2 curies
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	300 millicuries

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
Cobalt 57	Flood Source	5 mCi	Daily flood phanthom of Gamma Camera
Cobalt 57	Type E Vial	5 mCi	Dose Calibrator Reference Source

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
	Appendix F Procedures Followed; or
X	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM	R.S. LANDAVER, JR. & CO.	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD	R.S. LANDAVER, JR. & CO.	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY
Byproduct Material - General

(2) LICENSE FEE ENCLOSED $ Exempt

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
Raymond C Sullivan

(1) NAME (Type or Print)
Raymond C. Sullivan

(2) TITLE
Medical Center Director

c. DATE
24 July 1985

RECEIVED
AUG 7 1985
REGION III

NRC FORM 313M (9-81)

7. MEDICAL ISOTOPES COMMITTEE

1. Dorothy Weiner, M.D. - Radiologist
2. L. G. Palileo, M.D. - Pathologist
3. Representative from Medical Center's Management
4. Michael Dembickie, R.T., Technologist

Number: 7
July 24, 1985

8. TRAINING AND EXPERIENCE

A. Authorized User
   1. Dorothy Weiner, M.D.
   2. License Number 13-11983-91

B. Radiation Safety Officer
   1. Dorothy Weiner, M.D.

9. INSTRUMENTATION

A. Survey Meters

1. Victoreen, Model 498
2. Victoreen, Cutie Pie, Model 740F

B. Dose Calibrators

1. Squibb, Model CRC-16

C. Diagnostic Instruments

1. Searle Pho Gamma IV Camera
2. Searle Microdot Imager, Model 3132
3. Searle Data Store Playback System, Model 3122
4. Searle Historecorder, Model 10125
5. Raytheon Dual Probe Rectilinear Scanner, Series 600
6. Raytheon Digital Scaler, Assembly N-220
7. XDS Xenon Delivery System, Model 36-103
8. "NONEX" Xenon Gas Trap, Model 36-022
9. Mallinckrodt Ultravent Aerosol Shield
10. Searle Lem Camera
11. ADAC CAM II Computer

D. Other Pertinent Instrumentation

1. Atomic Products Area Alarm Monitor, Model H3100HA

10. CALIBRATIONS OF INSTRUMENTS

A. Survey Meters

1. Consultant: James E. Durlacher, CRP
   6741 Allisonville Road
   Indianapolis, Indiana 46220
   License # 13-02715-01

   Mr. Durlacher's services and procedures are on file with the Nuclear Regulatory Commission

B. Dose Calibrator

1. Daily check for constancy using the following sources: 14.6 uCu RA 226, 60 uCi CO 60, 266 uCi BA^{133}, 219 uCi CS^{137} and a 5.0 uCi new model # 2060984A-27 CO^{50} source with a $\pm$ 3.9% accuracy.
2. Quarterly and after repair for instrument linearity using an atomic products lineator model # 086-507 or according to Section 2 Appendix D.
3. Annually and after repair or adjustment for instrument according to Section 2 Appendix D.
4. After repair or adjustment for geometrical variation according to Section 2 Appendix D.

11. FACILITIES AND EQUIPMENT

A. Diagram attached.

B. Description: Hot Lab

1. Generator surrounded by lead shield which in turn is surrounded by lead bricks. Area also serves as storage for radioactive waste.
2. "L" shield where isotopes and kits are prepared.
3. Air conditioner unit; air enters here and through the door and leaves via the same channels. Unit can exhaust 400 ft 3/minute. Total volume of room is 1000 ft 3.
4. Dose calibrator.
5. Hot sink.
6. Lavatory sink

C. Imaging Room #1

7. Air conditioner unit; air enters here and through door and leaves via same channels. Unit can exhaust 400 ft 3/min. Total volume ft 2800 3/min.
8. Exhaust fan located in window. Installation suggested by NRC in 1978 for performing Xenon ventilation scans. Unit exhausts air into atmosphere at 400-500 ft 3/min.
9. Gamma Camera
10. Gamma Camera Control Panel Historecorder and Microdot Imager
11. Xenon Delivery System and Gas Trap

D. Imaging Room #2

12. Air conditioner unit; air enters here and through the door and leaves via same channel. Unit can exhaust 400 ft 3/min. Total volume of room is 2800 ft 3.
13. Rectilinear Scanner & Scaler

12. PERSONNEL TRAINING PROGRAM

All personnel who work directly with radioactive materials, or in the vicinity of radioactive materials shall be instructed as needed on areas where radioactive material is used or stored. They shall be informed of potential hazards associated with radioactive material and in precautions or procedures to minimize exposure in their respective duties. They shall be informed of pertinent NRC regulations and rules and regulations of the Medical Center's license. Personnel working directly with radioactive material will be informed of their obligation to report unsafe occurrences or malfunctions. All personnel working directly with radioactive materials will be informed annually or sooner if needed, of their radiation exposure reports. Personnel will be informed that all notices, regulations, and license conditions required by 10 CFR Part 19 will be located in the Nuclear Medicine Department desk filed under "NCR Rules and Regulations". All new personnel working directly with radioactive materials or in the vicinity of radioactive materials will be properly informed before assuming their new duites. Annual refresher training courses will be provided for personnel working in the vicinity of radioactive materials. Those working directly with radioactive materials will receive annual, or more if needed, refresher training courses in all areas, and whenever there is a change in duties, regulations, or terms of the license.

In addition, all technologists take part in bi-monthly meetings of the District Nuclear Medicine Society; monthly meetings of the District Radiology Society; In-Service Programs dealing with Nuclear Medicine and other fields; and at least one education meeting on the State or National Level per year.

13. PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

1. All orders for radioactive material must be placed by the Nuclear Medicine Senior Technologist or in his absence, the Supervisory Radiologic Technologist. Upon ordering, it must be determined that the materials and quantities ordered fall within the limits of the Medical Center's license.

2. During normal working hours, carriers are to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off duty hours, the Security Officer or the Medical Administration Clerk on duty must receive radioactive packages.

4. Any radioactive packages delivered between 4:30 p.m. and 8:00 a.m. or on Saturday or Sunday will be taken immediately to the Nuclear Medicine Department. The door will be unlocked, the package placed on top of the refrigerator located just inside the door and the door will be relocked. If the package is wet or appears damaged, the Radiation Safety Officer will be notified immediately. The carrier will be asked to remain at the hospital until it can be determined if he or the delivery vehicle is contaminated.

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS

1. Put on gloves to prevent possible contamination.

2. Visually inspect package for any sign of damage. If wet or crushed, stop procedure and notify Radiation Safety Officer.

3. Measure exposure rate at three feet from package and record. If more than 10 mR/hr., stop procedure and notify Radiation Safety Officer.

4. Measure surface exposure rate and record. If more than 200 mR/hr., stop procedure and notify Radiation Safety Officer.

5. Open outer package and remove packing slip.

6. Open inner package and verify that contents agree with those on packing slip (compare requisition, packing slip and bottle label).

7. Check to see that shipment does not exceed possession limits.

8. Check integrity of final source container for breakage of seals or vials, loss of liquid and discoloration of packing materials.

9. If integrity of final source container appears damaged, wipe external surface of source container and remove wipe to low background area. Assay wipe and record amount of removable activity (uCi/100 CM^2). Check wipes with thin end-window GM Survey Meter. Take precautions to prevent spread if contaminated.

10. Monitor packing material and package for contamination before discarding.

    (a) If contaminated, treat as radioactive waste.
    (b) If not contaminated, obliterate radioactive labels then discard in trash.

11. Records of results of package check will be maintained.

Number: 14
July 24, 1985

15. GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIALS

1. Appendix G Rules followed.

Number: 15
July 24, 1985

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

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. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

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

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

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

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

16. EMERGENCY PROCEDURES

1. Appendix H Procedures Followed

Number: 16
July 24, 1985

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

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

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

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

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 pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

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

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Dorothy Weiner,M.D.
OFFICE PHONE: 219-426-5431 Ext 338
HOME PHONE: 219-744-5611

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:
Michael Dembickie,R.T. 219-426-5431 Ext 368
Vincent Wirtner,R.T. 219-426-5431 Ext 368

* The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

17. AREA SURVEY PROCEDURES

1. All elution, preparation and injection areas will be surveyed daily with low range survey meter and decontaminated if necessary.

2. Waste storage areas and all other Lab areas will also be surveyed daily.

3. A weekly series of wipe tests will be performed to measure contamination levels. Wipes of elution, preparation and injection areas will be removed to Gamma Camera for measurement. Any measurement 1½ times over background shall be considered contaminated.

4. In case of contamination, the area shall be decontaminated and additional wipe test preformed until measurement is less than 1½ times background.

5. A permanent record will be kept of all survey results including negative results and will include:

   (a) Location and equipment used.

   (b) Date of survey.

   (c) Identification of person performing survey.

   (d) Measured exposure rate.

18. WASTE DISPOSAL

1. Appendix J Form Attached

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

X In the sanitary sewer system in accordance with § 20.303 of 10 CFR Part 20.

_____ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate)

X Returned to the manufacturer for disposal.

_____ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.**

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

3. Other solid waste will be (check as appropriate)

X Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. Not applicable.

Number: 19
July 24, 1985

20. THERAPEUTIC USE OF SEALED SOURCES

1. Not applicable.

Number: 20
July 24, 1985

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES

1. License #13-11983-01 was amended to include use of Xenon 133 gas. The information requested in Appendix M is being submitted in the form of the original amendment request. No changes in the procedure have occurred since the original amendment was approved.

Number: 21
July 24, 1985

VETERANS ADMINISTRATION
HOSPITAL
1600 RANDALIA DRIVE
FORT WAYNE, INDIANA 46805

IN REPLY
REFER TO: 114

July 17, 1978

United States
Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

Please amend our Radioactive Materials License for use of Xenon Gas. Details concerning our lab, to justify this request, are listed below:

1. Veterans Administration Hospital
   1600 Randalia Drive
   Fort Wayne, Indiana 46805

2. Current License Number: 13-11983-01

3. Radioactive Material - Xenon, Xe-133 Gas.

4. Type Study: Pulmonary Ventilation

5. Possession Limit - 300 mCi
   Estimate 100 mCi/week maximum, adjusted for 4 days pre-calibration, equals 170 mCi (100 mCi x 1.7 pre-calibrated factor). A maximum of 100 mCi trapped and decaying.
   Total extimate: 170 + 100 = 270 mCi.

6. Dosage:
   Average patient dose will be 10 mCi with higher doses used only when professional management of physician dictates.

7. Patient Load:
   Estimate a maximum of 10 patients/week, 520/year.

8. Source Radiopharmaceutical:
   New England Nuclear Corp. Atomlight Place, No. Billerica, Mass. 01862. Catalog number NRP-127 Xe-133 Gas, in unit dose vials. NDA approved, package insert on file in department.

Show veteran's full name, VA file number, and social security number on all correspondence.

~~7906060191~~ (72)

VETERANS ADMINISTRATION
HOSPITAL
1600 RANDALIA DRIVE
FORT WAYNE, INDIANA 46805

IN REPLY
REFER TO:

(2)

9. Imaging Equipment:
   Searle Pho-Gamma IV Camera.

10. Special Equipment:
   A. Delivery System - New England Nuclear Calidose Dispenser, Product Literature Obtained.
   B. Lung Function Unit - Nuclear Associates Inc., Catalog Number 36-103 (XDS System), Product Literature Obtained.
   C. Disposal System - Nuclear Associates "Nonex" Gas Trap, Product Number 36-023, Product Literature Obtained.

11. Dose Calibration:
   All doses will be checked, prior to patient use, in Nuclear Chicago Mediac Dose Calibrator.

12. Personnel Safety:
   All department personnel will wear whole body film badges and TLD finger badges.

13. Scale Drawing:
   Attached to this request.

14. Description of Storage Area (Hot Lab):
   Xe-133 gas will be stored in its 1/8 inch thick lead container within lead brick storage cave. A complete description of this room, storage cave, work area, radiation monitoring equipment, and safety procedures are the same as contained in our basic license submission. A separate room air conditioner continually changes air in Hot Lab. Unit can exhaust 400 ft^3/minute. The total volume of this room is 1000 ft^3 ((8x12$_1$ + 2x2) x10). Air can enter room through air conditioner and door. Air may leave via same channels. The maximum concentration of Xe-133 over 40 hours for 7 consecutive days, for this restricted area is calculated as follows:

A. Maximum Xe-133 per week is 300 mCi (Xe trap will be stored in this area when not in use).

B. Air flow volume will be 400 ft^3/minute.

C. Estimated escape fraction is 0.25 therefore:

$$C = \frac{A}{Q} \times f = \frac{300 \text{ mCi} \quad (1 \times 10^3)}{400 \text{ ft}^3\text{/minute} \ (6.797 \times 10^7)} \times 0.25 =$$

0.276×10^{-5} uCi/ML/40 hour week

This verifies that the MPC of 1×10^{-5} mCi/ML as stated in section 20.103 10CFR part 20 and schedule B, table 1 of part 20, will not be exceeded.

In the event of accidental release of Xe-133 in this area, we will place separate air conditioner on maximum exhaust, close door to hallway, evacuate personnel from area and leave area unoccupied for 50 minutes. Upon re-entry, room will be surveyed with low level survey meter to insure radiation levels have returned to normal. The 50 minute period will insure 20 changes of air as calculated below:

Air Flow Velocity	400 ft/minute
Total Air Volume	400 ft^3/minute
Volume of Room	1000 ft^3

Therefore:

$$\frac{RV}{AV/\text{minute}} = \text{Turn Over Time} = \frac{1000 \text{ ft}^3}{400 \text{ ft}^3} = 2.5 \text{ minute}$$

20 changes of air - (2.5x20) = 50 minute

Air removed from this area is released directly into an unrestricted area outside 2nd floor, away from any intake ducts.

VETERANS ADMINISTRATION
HOSPITAL
1600 RANDALIA DRIVE
FORT WAYNE, INDIANA 46805

IN REPLY
REFER TO:

• (4)

15. Description of Procedure:

The Xenon 133 gas will be used in the following manner: The dose will be measured in our dose calibrator. The patient will be instructed on the details of the procedure with special emphasis on the areas where his cooperation is needed. Just prior to the study, one or more practice runs will be done before the Xenon 133 gas is used. The unit dose vial will be loaded into the shielded Calidose Dispenser furnished by New England Nuclear. It will then be taken to the Imaging Area where the lung ventilation procedure will be done. The Dispenser will be connected to the Nuclear Associates Lung Function Unit. The Xenon 133 gas will be administered to the patient via this unit. Nose clamps will be used to prevent the patient from exhaling the Xenon 133 into the room. The lung ventilation procedure will be composed of the three standard phases of breath hold, equilibrium, and washout. These phases are automatically accomplished as the technician operates the remote control switch of the unit. Upon completion of the study, the used Xenon 133 will be drawn directly into the Nuclear Associates Xenon gas trap.

16. Description of Imaging Room:

All ventilation studies will be done in "Imaging Room" as shown on attached drawing, and fully described in our original license. Air may enter this room via separate air conditioner and door. Air may leave via same routes. Measured exhaust air flow velocity is 400 ft/minute. The maximum concentration of Xe-133 for this restricted area is calculated as follows:

A. Maximum Xe-133 per week = 100 mCi based upon patient use (10 mCi x 10 patients).

VETERANS ADMINISTRATION
HOSPITAL
1600 RANDALIA DRIVE
FORT WAYNE, INDIANA 46805

IN REPLY
REFER TO:

B. Escape Fraction = 0.25

C. Air Flow Volume = 800 ft^3
(400 ft/minute x 2 ft^2 AC outlet)

Therefore:

$$C = \frac{A}{V} \times f = \frac{100\ mCi\ \ (1 \times 10^3)}{800\ ft^3/minute\ (6.797 \times 10^7)} \times 0.25 =$$

0.046×10^{-5} mCi/ML/40 hour week.

This is within Regulatory Limits.

The maximum concentration of Xe-133 for unrestricted area (hallway and adjacent rooms) is calculated below:

A. Maximum Xe-133 released per year is based upon 300 mCi/week x escape fraction of 0.25 = 300 mCi x 0.25 x 52 weeks/year = 3900 mCi.

B. Total air flow volume from all areas is 2200 ft^3/minute (400 ft^3/minute in Hot Lab and 800 ft^3/minute in Imaging area plus 1000 ft^3/minute from existing heating duct return).

Therefore:

$$C = \frac{A}{V} = \frac{3900\ mCi\ \ (1 \times 10^3)}{2200\ ft^3/minute\ (1.484 \times 10^{10}\ ML/year} =$$

1.195×10^{-7} mCi/ML average/year.

This is below allowable 3×10^{-7} mCi/ML.

In event of accidental release of Xe-133 in this area, air conditioner will be set to maximum exhaust, doors to Hot Lab, rest room and hall will be closed and all personnel evacuated for a 64 minute period to insure 20 changes of air.

This is calculated below:

Total Air Flow Volume = 1200 ft^3/minute

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IN REPLY
REFER TO:

400 ft^3/minute in Hot Lab

800 ft^3/minute in Imaging Room

Total Volume of Rooms = 3800 ft^3

1000 ft^3 in Hot Lab

2800 ft^3 in Imaging Area

Therefore:

$$\frac{V}{\text{Air Flow/minute}} = \text{Turn Over Time} = \frac{3800}{1200} = 3.17 \text{ minute}$$

20 changes = 3.17 x 20 = 63.4 minute

17. Disposal Phase:

The disposal of the Xenon 133 gas will be done by trapping the Xenon 133 gas in a Nuclear Associates, Inc. "Nonex" Xenon Gas Trap Model #36-022. The potential leakage of Xenon 133 from this unit, as well as other sources of leakage, are included in the Escape Fraction figure. To insure that the trap is working efficiently, we will monitor the exhausted air from the trap using the following procedure: Immediately after the last Xenon 133 lung ventilation procedure each week, a 5 liter polyethylene bag will be placed over the exhaust port of the Xenon Trap, and the unit will be operated until the bag is full. The bag will be sealed and placed in front of the Gamma Camera and counted for one minute on the appropriate settings. The Counts Per Minute (CPM) will be recorded in a record book and compared with previous readings. A replacement cartridge will be installed whenever there is a significant increase in the weekly CPM. The saturated cartridge will be placed in the Hot Lab in a radiation waste barrel with other radioactive waste.

18. Equipment Operation and Monitoring for Leakage:

A.The Calidose Dispenser Delivery System will be checked prior

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IN REPLY
REFER TO:

(7)

to use to insure proper operation. The manufacturer's operating instructions will be followed.

B. The Lung Function Unit will be checked at the beginning of each week by filling it with oxygen and checking for leakage. Its operation will be checked during the practice runs prior to administration of the Xenon 133 gas. The manufacturer's operating instructions will be followed and the carbon dioxide absorber will be replenished as needed.

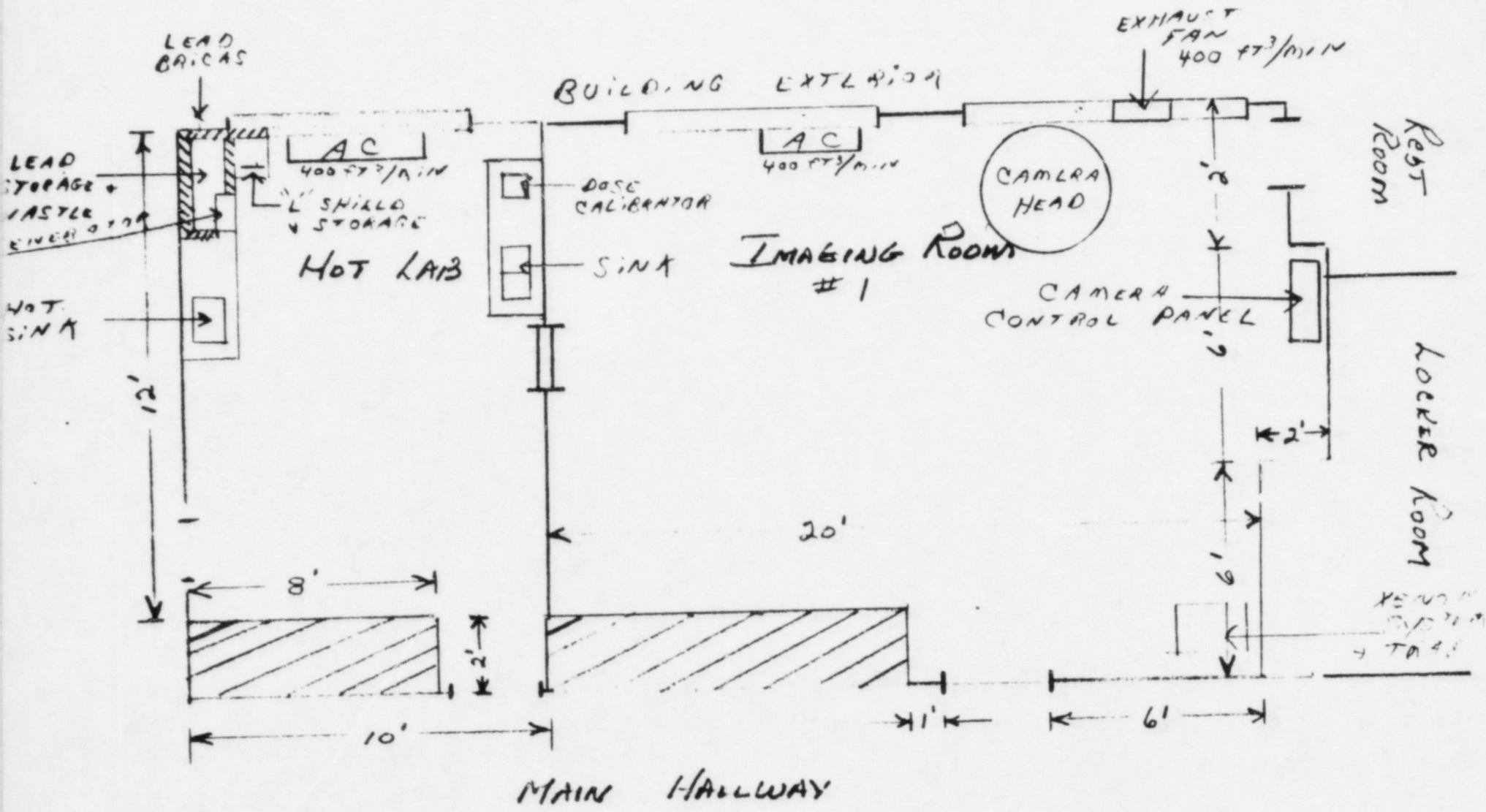
C. The Xenon Trap will be checked prior to each ventilation procedure to insure that it is securely connected to the Lung Function Unit. Xenon leakage from the exhaust port will be monitored as previously described. The manufacturer's operating instructions will be followed and the desiccant in the water trap will be checked daily and replenished as needed.

D. All exhaust vents and air conditioners will be checked twice a year to confirm their continued efficiency. In addition they will be checked whenever structural changes are made which could affect their efficiency. Records verifying these procedures will be maintained.

RICHARD GRIFFIN
Hospital Director

ENCLOSURES:
Scale Drawing

V.A. HOSPITAL - FT WAYNE, IN - NUCLEAR MEDICINE DEPT
2ND FLOOR - ROOM 2 N 332 - 1/4" = APPROX. 1'-
10' CEILINGS - 6" WALLS. - BRICK CONSTRUCTION
DENTAL AREA BELOW (ON 1ST FLOOR)



22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

1. Not applicable.

23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6b.

1. It has been determined that Bioassays will not be required since I-131 is used in microcurie rather than millicurie amounts.

2. Leak testing of sealed sources greater than 100 uCi with a half life greater than 30 days according to 10 CFR 35.14.

PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS

AS LOW AS REASONABLY ACHIEVABLE (ALARA)

V. A. MEDICAL CENTER
1600 Randallia Drive
Fort Wayne, IN 46805

I. MANAGEMENT COMMITTEE

A. We, the management of this V. A. Medical Center are committed to the program described in this paper for keeping individual and collective radiation exposure as low as reasonably achievable (ALARA). In accordance with this committment, 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 and a Radiation Safety Officer.

B. We will perform an annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc. and consultations with radiation protection staff or outside consultant.

C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost in our judgement is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sougnt, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be able 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 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.

II. RADIATION SAFETY COMMITTEE (RSC)

A. Review of proposed users and uses.

1. The Radiation Safety Committee will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of by-product material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The users should have systematized procedures to ensure ALARA, and have incorporated the use of special equipment such as syringe shields, gloves, etc. in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that the dose will be ALARA.

B. Delegation of authority.

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

2. The RSC will support the RSO in those instances when it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the committee will record the basis for its' action in the minutes of the Committee's 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 where the Investigational Levels in Table 1 are exceeded. The purpose of this review is to assess trends in occupational exposure as in index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

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

III. RADIATION SAFETY OFFICER (RSO)

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 procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

B. Educational responsibilities for an ALARA program.

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

2. The RSO will assure 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 formulation of 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 encourage the use of those procedures.

D. Reviewing instances of deviation from good ALARA practices.

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

IV. AUTHORIZED USERS

A. New procedures involving potential radiation exposures.

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of authorized user to those he supervises.

1. The authorized user will explain the ALARA concept and his committment to maintain exposure ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

A. The worker will be instructed in the ALARA concept and its' relationship to his working procedures and working conditions .

B. The worker will know that recourses are available if he feels that ALARA is not being promoted on the job.

VI. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURE

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

Table 1

		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.	1,875	5,625
3.	Skin of whole body.	750	2,250

The Radiation Safety Officer will review and record on Form NRC-5, current Occupational External Radiation Exposures, or an equivilent form, results of personnel monitoring not less than once in any calendar quarter as is required by 10 CFR 20, 20.401. The following actions will be taken at Investigational Levels as stated in Table 1:

A. Quarterly exposure of individuals to 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 exposure is less than Table 1 values for Investigational Level I.

B. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure 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, consider each exposure 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. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel

exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individuals Form NRC-5 or its' equivalent will be presented to the RSC at the first meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this Medical Center for review. The minutes containing details of the investigation will be made available to NRC inspectors for review at the time of the next inspection

D. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II. those actions listed in paragraph C will be followed.

VII. SIGNATURE OF CERTIFYING OFFICIAL

I hereby certify that this institution (or private practice), has implemented the ALARA Program set forth above.

James A. Woytassek

Signature

JAMES A. WOYTASSEK

Name (print or type)

Medical Center Director, VAMC, Fort Wayne, IN

Title

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