

L+L = 20862
28739
030-21276
02201

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE - MEDICAL	Approved by OMB 3150-0041 Expires 9-30-83
---	---	---

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 Nuclear Diagnostics of Fairfield 1305 Post Road Fairfield, CT 06430 TELEPHONE NO.: AREA CODE (203) 255 - 9973	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 John A. Creatura, M.D. TELEPHONE NO.: AREA CODE (203) 384 - 3228	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input checked="" type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) Jay Meizlish, M.D. Charles Heller, M.D. John A. Creatura, 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.) John A. Creatura, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE					
RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED	MAXIMUM POSSESSION LIMITS	ADDITIONAL ITEMS:	MARK ITEMS DESIRED	MAXIMUM POSSESSION LIMITS
	"X"	(In millicuries)		"X"	(In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000 each standard	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI					

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
Co-57	New England Nuclear NES-206 vial E 20ml epoxy 27ml plastic vial	5 mCi	dose calibrator reference source License Fee Information on Next Page
Co-57	New England Nuclear NES-391	5 mCi	LFOV gamma camera flood source

8510300219 850920
REG1 LIC30
06-20682-01 PDR

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. 1 Date: October, 1980

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)	
<input type="checkbox"/>	Names and Specialties Attached; and	<input checked="" type="checkbox"/>	Appendix G Rules Followed; or
<input type="checkbox"/>	Duties as in Appendix B; or _____ (Check One)	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE Info Attached		<input checked="" type="checkbox"/>	Appendix H Procedures Followed; or
<input checked="" type="checkbox"/>	Supplements A & B Attached for Each Individual User; and (Dr. Meizlish only)	<input type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES (Check One)	
9. INSTRUMENTATION (Check One)		<input type="checkbox"/>	Appendix I Procedures Followed; or
<input checked="" type="checkbox"/>	Appendix C Form Attached; or	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
<input type="checkbox"/>	List by Name and Model Number	18. WASTE DISPOSAL (Check One)	
10. CALIBRATION OF INSTRUMENTS		<input checked="" type="checkbox"/>	Appendix J Form Attached; or
<input type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or _____ (Check One)	<input type="checkbox"/>	Equivalent Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One)	<input type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	Equivalent Procedures Attached	<input checked="" type="checkbox"/>	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
<input checked="" type="checkbox"/>	Description and Diagram Attached	<input type="checkbox"/>	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM		<input type="checkbox"/>	Appendix L Procedures Followed; or _____ (Check One)
<input checked="" type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133)	
<input checked="" type="checkbox"/>	Detailed Information Attached	<input type="checkbox"/>	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One)		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
<input type="checkbox"/>	Appendix F Procedures Followed; or	<input type="checkbox"/>	Detailed Information Attached
<input checked="" type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
<input type="checkbox"/>		<input type="checkbox"/>	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)		SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	<input checked="" type="checkbox"/> FILM	R. S. Landauer & Co.	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input checked="" type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	R. S. Landauer & Co.	Monthly
	<input type="checkbox"/> OTHER (Specify)		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

d. OTHER (Specify)

RECEIVED BY LFMB

Date: 6/19/85

Log: Same 14-I

By: Jacques

Orig. To: [blank]

Action Compl: 6/20/85

Bridgeport Radiology

14054

8580-7C

Applications

6/19/85

Jacques

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

Bridgeport Hospital

MAILING ADDRESS

267 Grant St., P.O. Box 5000

CITY

Bridgeport

STATE

CT

ZIP CODE

06610

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.
See License 06-01060-01

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)

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

John A. Creatura, M.D.

(1) NAME (Type of Print)

John A. Creatura, M.D.

(2) TITLE

Radiation Safety Officer

(1) LICENSE FEE CATEGORY:

7C

c. DATE

5/15/85

(2) LICENSE FEE ENCLOSED: \$ 580.00

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

RECEIVED
85 JUN 19 10:16
U.S. N.R.C.
FEE MGMT. BRANCH

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Jay L. Meizlish, M.D.	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE Connecticut
---	---

3. CERTIFICATION		
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Nuclear Medicine	Board Certified	9/84
Internal Medicine	Board Certified	9/80
Cardiovascular Disease	Board Certified	9/83

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES			
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION	Nuclear Medicine Residency/Fellowship Yale University School of Medicine Department of Radiology 333 Cedar Street New Haven, CT 06510		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY	1982 - 1984		
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		As per Nuclear Medicine Fellowship; see #4		

Training and Experience

John A. Creatura and Charles Heller are both currently authorized for the given uses under Materials License No. 06-01060-01 of Bridgeport Hospital, Bridgeport, Connecticut.

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: Ludlum Measurements, Inc.
Manufacturer's model number: #3 geiger counter, #44-7 probe with thin end window
Number of instruments available: 2
Minimum range: 0 mR/hr to 0.2 mR/hr
Maximum range: 0 mR/hr to 200 mR/hr
- b. Manufacturer's name: Nuclear Associates
Manufacturer's model number: 05740 Cutie Pie exposure rate meter
Number of instruments available: 1
Minimum range: 0 mR/hr to 25 mR/hr
Maximum range: 0 mR/hr to 25000 mR/hr

2. Dose calibrator

Manufacturer's name: Capintec, Inc.
Manufacturer's model number: CRC-7
Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Elscint	Apex LFOV

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Calibration of Survey Instruments

- 1) Survey instruments will be calibrated at least annually and following repair.
- 2) Calibration will be performed at two points on each range up to 1R/hr.

These points will cover both halves of the scale, and be separated by 35 - 50% of full scale. A survey instrument will be considered properly calibrated when the instrument readings at these points are within $\pm 10\%$ of the calculated or known values for each point checked. Readings within $\pm 20\%$ are considered acceptable if a calibration chart or graph is prepared and attached to the instrument. Ranges above 1R/hr will at least be checked for operation and approximately correct response to radiation.

- 3) Survey instruments will be calibrated either

- a) by the manufacturer

- b) by Nuclear Instrument Company

65 Grove Street, P.O. Box 178

Rockland, MA 02370

NRC License # 20-16972-01

- c) by Bridgeport Hospital

Radiation Safety Office

267 Grant Street

Bridgeport, CT 06602

Calibrations performed at Bridgeport Hospital will be done as specified in Bridgeport Hospital's NRC License # 06-01060-01, under the supervision of authorized personnel of the radiation safety office.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

 X First elution from new Mo-99/Tc-99m generator (only when using generators)

or

 X Other* (specify) ~50 mCi Tc-99m (the most active source vial received from our supplier)

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57 (NES-206)	3-5	<u> 5 </u>	<u> 5% (99% confidence) </u>
Ba-133	0.1-0.5	<u> </u>	<u> </u>
Cs-137 (NES-356)	0.1-0.2	<u> 0.2 </u>	<u> 5% (99% confidence) </u>
Ra-226	1-2	<u> </u>	<u> </u>
<u> </u>		<u> </u>	<u> </u>

C. X The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

or

 Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μ Ci of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.

* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ± 5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ± 5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

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 to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time* (hr)	Correction Factor
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be $15.625 \text{ mCi} \times 15.853 = 247.7 \text{ mCi}$ and $15.625 \text{ mCi} \times 0.126 = 1.97 \text{ mCi}$, respectively.

- On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).
- The activities plotted should be within ± 5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ± 5 percent indicate the need for repair or adjustment of the instrument.
- If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ± 2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

- Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.
- Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay

as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

- Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

- Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.
- The true activity of a sample is calculated as follows:

$$\text{True Activity} = \text{Measured Activity} \times \text{Correction Factor}$$

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

- Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.
- It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2} = 6.02$ hours has been used in calculating these correction factors.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

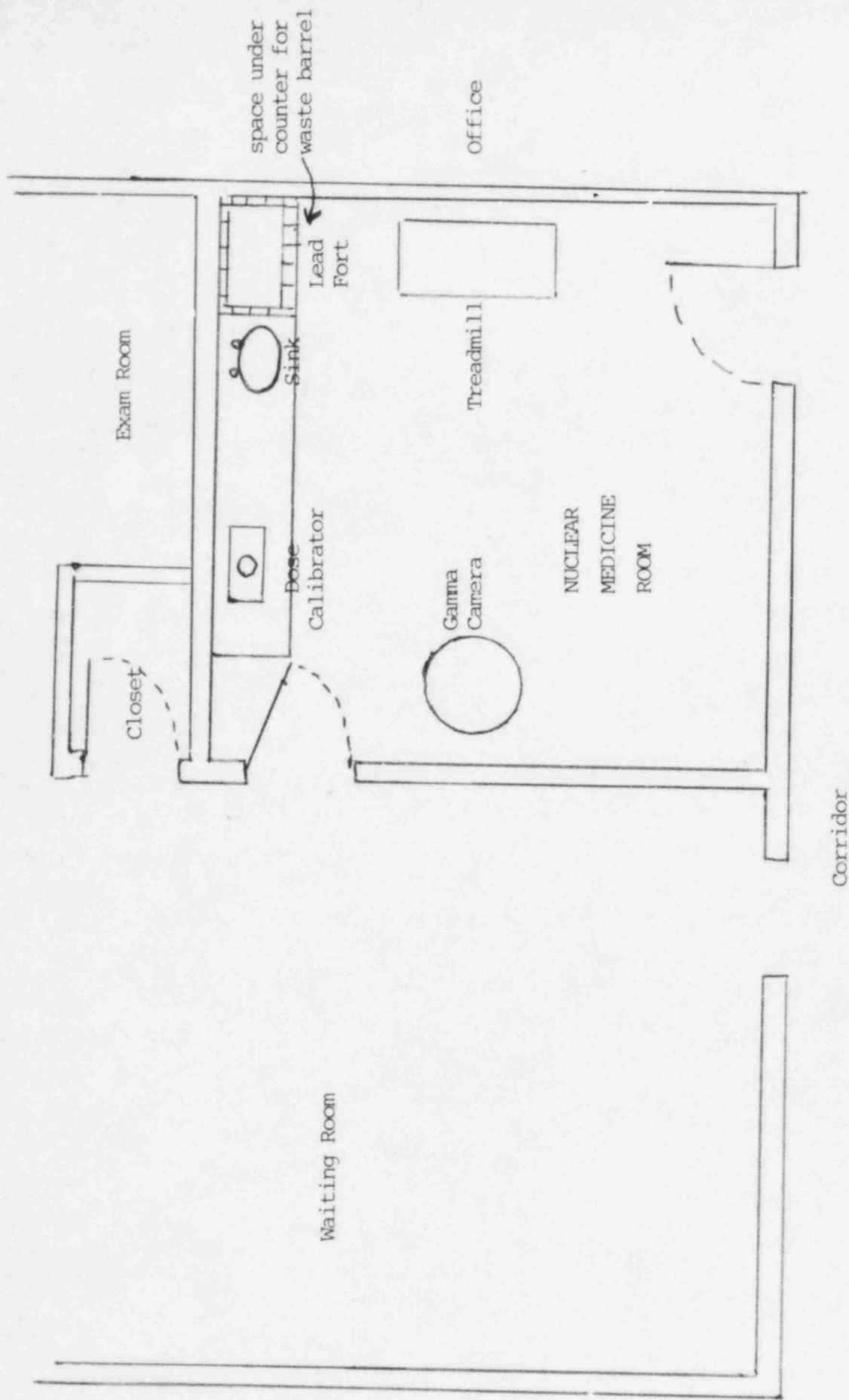
1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.
2. Repeat step 1 for a total of 3 determinations, and average results.
3. The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.
5. Keep a log of these calibration checks.
6. Calibration checks that do not agree within ± 5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.
7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

Facilities and Equipment

The nuclear medicine room shown on the accompanying sheet will be used for the receipt, storage (including waste), and preparation of radioactive material, as well as for patient imaging.

Radiopharmaceuticals, generators (when needed) and calibration sources will be stored in the lead fort, with sufficient shielding (mainly 2-inch thick lead bricks) to limit radiation levels in all accessible areas to less than 2mR/hr. Preparation of radiopharmaceuticals will be performed on the counter top, with similar shielding. The counter top will be covered with disposable pads during preparations, and both auxiliary shielding (lead bricks) and protection utensils (forceps, tweezers) will be available. Radioactive waste being held for decay will be stored in containers beneath the counter top, and shielded with sufficient lead or other metal to maintain radiation levels in all accessible locations at less than 2mR/hr. The room shall be so shielded that radiation levels in surrounding unrestricted areas are less than 0.2mR/hr.



Lead fort construction:
lead bricks, 2" thick

Scale: 1/4" = 1'

Item 11

5/15/85

Personnel Training Program

Personnel will be properly instructed:

- a) before assuming duties with, or in the vicinity of, radioactive materials;
- b) during refresher courses, to be held at least annually;
- c) whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction will normally be supervised by either the RSO or the medical physics consultant.

Instruction will include:

- a) pertinent NRC regulations;
- b) rules and regulations of the licensee;
- c) all terms of the license pertinent to radiation safety;
- d) potential hazards associated with radioactive material;
- e) radiologic safety procedures appropriate to each worker's respective duties;
- f) areas where radioactive material is used or stored;
- g) obligation to report unsafe conditions to the RSO;
- h) appropriate response to emergencies or unsafe conditions;
- i) right of personnel 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 10 CFR Part 19.

Ancillary personnel (clerical, nursing, housekeeping, etc.) whose duties require them to work in the vicinity of radioactive material will be identified by the supervisory nuclear medicine technologist, who oversees activities in the area. These individuals will be instructed both initially and annually thereafter on a refresher basis regarding radiation hazards and appropriate precautions.

Procedures for Ordering and Receiving Radioactive Material

The supervisory nuclear medicine technologist will place all orders for radioactive materials, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded. A system for ordering and receiving radioactive material will be established and maintained. This system will include a written record that identifies the isotope, compound, activity and supplier of radioactive material ordered and received. Incoming packages will be inspected no later than 3 hours following receipt during normal working hours. No orders will be placed for receipt of radioactive material when the office is closed (normally, at night and over the weekend).

Instructions for Opening Packages Containing Radioactive Material

- 1) Log with appropriate identification in the package monitoring log book the receipt of any package containing radioactive material.
- 2) Without touching the package, visually inspect it for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer (RSO).
- 3) Put on disposable plastic gloves (even if package appears intact).
- 4) Measure and record the maximum exposure rate 3 feet from the external surface of the package (use the GM survey meter, set to the 0 - 20mR/hr range). If the package reading is greater than 10mR/hr, stop the procedure, immediately place the package in the lead storage area, and notify the RSO.
- 5) Measure exposure rate at the surface of all (six) sides of the package (use the GM survey meter, set to the 0 - 200mR/hr range). Do not actually touch the box with the bare probe, since this will contaminate the probe if the box surface is itself contaminated. Record maximum reading. If greater than 200mR/hr, stop the procedure, immediately place the package in the lead storage area, and notify the RSO.
- 6) Carefully open the outer package (following manufacturer's instructions, if supplied) and remove packing slip. Visually inspect the packing material for any sign of damage (e.g., wetness, stains, other unusual markings). If damage is noted, stop the procedure and notify the RSO.
- 7) Carefully open the inner package (normally a leaded container) to verify and visually check the integrity of the final source container (normally a glass vial or syringe). Compare requisition, packing slip and bottle label. If intact, the inner container and its contents should be stored in the designated area (normally the lead storage cave).
- 8) Take wipes of the external surfaces of the final source container, and remove to a low background area. Monitor wipes with a sufficiently sensitive instrument (use the GM survey meter, set to the most sensitive range, with the thin end window open). Record both background and wipe readings. If any wipe exceeds background, notify the RSO.
- 9) Monitor all disposable packing material with a sufficiently sensitive instrument (use the GM survey meter, set to the most sensitive scale). If any radiation above background is detected, treat the material as radioactive waste. Otherwise, obliterate all radioactive labels and dispose in the normal trash.

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.

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.
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.

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.

RADIATION SAFETY OFFICER John Creatura, MD

OFFICE PHONE: (203) 384-3228

HOME PHONE (203) 333-5197

**ALTERNATE NAMES AND TELEPHONE NUMBERS
DESIGNATED BY RADIATION SAFETY OFFICER:**

James E. Bond, Physics Consultant

Office Phone: (203) 384-3228

Home Phone: (203) 287-9784

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

Area Survey Procedures

- 1) All elution, preparation and injection areas will be surveyed daily with a GM survey meter sufficiently sensitive to detect 0.1mR/hr, and decontaminated if necessary. Acceptable levels of radiation are less than 0.2mR/hr in noncontrolled areas and less than 2mR/hr in controlled areas.
- 2) Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.
- 3) Waste storage and all other laboratory areas will be surveyed weekly.
- 4) The weekly and monthly surveys will consist of:
 - a) A measurement of radiation levels with a GM survey meter sufficiently sensitive to detect 0.1mR/hr.
 - b) A series of wipe tests to measure contamination levels. Alcohol wipes will be taken in all areas currently being used for elution, preparation and injection. Each wipe shall cover an area of at least 100 cm². Each wipe will be surveyed with a thin-end window GM survey meter sufficiently sensitive to detect 0.01mR/hr (\approx natural background). The measurement will be done in a low-background location. An area will be cleaned and resurveyed if measured exposure exceeds natural background.
- 5) A record will be kept of all survey results, including negative ones.

The record will include:

 - a) The date and name of the individual conducting the survey.
 - b) Measured exposure rates, keyed to locations on a drawing.
 - c) Detected contamination levels, keyed to locations on a drawing.
 - d) Corrective action taken, together with reduced exposure rates or contamination levels following the corrective action, and any appropriate comments.

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)

☒ 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)

☒ Returned to the manufacturer for disposal.

OR ☒ 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.**

* 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.

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

☐ Other (specify): _____

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

☒ 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. _____

Treatment of Hyperthyroidism With I-131

Patients being treated for hyperthyroidism using I-131 will be administered I-131 in capsule form only, to minimize the risk of iodine uptake by medical personnel. The capsules will be administered to the patient only in the presence of an authorized physician. Treatments will be given on an outpatient basis, due to the comparatively small quantity of radionuclide used in this type of procedure.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Nuclear Diagnostics of Fairfield

(Licensee's Name)

5/15/85

(Date)

1. Management Commitment

- a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) 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)¹ and a Radiation Safety Officer (RSO).
- b. We will perform a formal 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 the radiation protection staff or outside consultants.
- 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 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 where reasonable. Where 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 (RSC)²

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 uses for which he has applied 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. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
- (3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

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 in those instances where it is necessary for the RSO to assert his/her 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.

¹Private practice physician licenses do not include an RSC.

²The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

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 Investigational Levels in Table 0-1 below 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).³
- (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.

3. 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 Section 6 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. 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 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 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 require changes in the program to maintain exposures ALARA.

4. 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 Persons Under His/Her Supervision

- (1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.
- (2) The authorized user will ensure that persons under his/her supervision who are

³The 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 further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

- a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions
- b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure 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 O-1 below. These levels apply to the exposure of individual workers.

Table O-1

	<i>Investigational Levels (mrems per calendar quarter)</i>	
	<i>Level I</i>	<i>Level II</i>
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 nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer 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 O-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 O-1 values for the 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 and will report the results of the 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 such 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, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC 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 institution 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. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational 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 RSC 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 6.c above will be followed.

7. Signature of Certifying Official⁴

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

⁴ The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

Signature

John A. Creatura, M.D.

Name (print or type)

Radiation Safety Officer

Title

Institution (or Private Practice) Name and Address:

Nuclear Diagnostics of Fairfield

1305 Post Road

Fairfield, CT 06430