

APPLICATION FOR MATERIALS LICENSE - MEDICAL

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 Stanley H. Levy, M.D. 10601 W. Seven Mile Road Detroit, Michigan 48221 TELEPHONE NO.: AREA CODE (313) 861-7353	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 Ray A. Carlson TELEPHONE NO.: AREA CODE (313) 494-7364	3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input type="checkbox"/> AMENDMENT TO LICENSE NO. _____ c. <input checked="" type="checkbox"/> RENEWAL OF LICENSE NO. 21-07059-01
4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) Stanley H. Levy, M.D. Henry A. Shevitz, 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.) Henry A. Shevitz, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X		IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
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		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.	X	300
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
Amount: 9.622 g Net: 9.515 g Gross: 9.515 g Date Check Rec'd: 2/15/85 Received By: [Signature]			RECEIVED FEB 15 1985 REGION III

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: Oct, 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	<input type="checkbox"/>	Equivalent Rules Attached
<input type="checkbox"/>	(Check One)		
<input type="checkbox"/>	Equivalent Duties Attached	16. EMERGENCY PROCEDURES (Check One)	
8. TRAINING AND EXPERIENCE		<input checked="" type="checkbox"/>	Appendix H Procedures Followed; or
<input type="checkbox"/>	Supplements A & B Attached for Each Individual User; and	<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 checked="" type="checkbox"/>	Appendix I Procedures Followed; or Note Modification
<input checked="" type="checkbox"/>	Appendix C Form Attached; or	<input 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 checked="" type="checkbox"/>	Appendix D Procedures Followed for Survey Instruments; or	<input type="checkbox"/>	Equivalent Information Attached
<input type="checkbox"/>	(Check One)	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One)	
<input checked="" type="checkbox"/>	Appendix D Procedures Followed for Dose Calibrator; or Note Modification	<input checked="" type="checkbox"/>	Appendix K Procedures Followed; or
<input type="checkbox"/>	(Check One)	<input 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
<input checked="" type="checkbox"/>	Description of Training Attached	<input type="checkbox"/>	(Check One)
<input type="checkbox"/>		<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 checked="" 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 checked="" type="checkbox"/>	Appendix F Procedures Followed; or Note Modification	<input type="checkbox"/>	Detailed Information Attached
<input type="checkbox"/>	Equivalent Procedures Attached	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
		<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	Siemens Gammasonic	Monthly
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		
b. FINGER	<input type="checkbox"/> FILM		
	<input checked="" type="checkbox"/> TLD	Siemens Gammasonic	Monthly
	<input type="checkbox"/> OTHER (Specify)		
c. WRIST	<input type="checkbox"/> FILM		
	<input type="checkbox"/> TLD		
	<input type="checkbox"/> OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL		
NAME OF HOSPITAL		b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.
MAILING ADDRESS		
CITY	STATE ZIP CODE	
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)		b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
		(1) NAME (Type or Print)
		STANLEY H. LEVY, M.D.
(1) LICENSE FEE CATEGORY: Renewal		(2) TITLE
		DOCTOR OF MEDICINE
(2) LICENSE FEE ENCLOSED: \$ 580.00		c. DATE
		2-12-85

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.

APPENDIX C
INSTRUMENTATION

1. Survey meters

- a. Manufacturer's name: Bicron
Manufacturer's model number: Surveyor
Number of instruments available: 1
Minimum range: 0 mR/hr to 0.5 mR/hr
Maximum range: 0 mR/hr to 50 mR/hr
- b. Manufacturer's name: _____
Manufacturer's model number: _____
Number of instruments available: _____
Minimum range: _____ mR/hr to _____ mR/hr
Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

Manufacturer's name: Capintec
Manufacturer's model number: CRC-6
Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	PHO/Gamma V

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

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

☒ First elution from new Mo-99/Tc-99m generator

☒ Other* (specify) ^{or} If generators are not in use, a source of Tc-99m with activity equivalent to the maximum activity assayed to clinical situations will be used.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One millicurie or more	within $\pm 5\%$
Ba-133	0.1-0.5	100 microcuries or more	within $\pm 5\%$
Cs-137	0.1-0.2	100 microcuries or more	within $\pm 5\%$
Ra-226	1-2	N/A	N/A
N/A		N/A	N/A

- C. ☒ 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.

As an alternative to our present procedure, the dose calibrator can be checked for activity linearity with the use of a device called Calicheck from Calcorp, Inc. The manufacturer's instructions for use as revised on March 2, 1982, will be followed. Test results will be recorded and retained for inspection. Corrective action as stated in our license application will be followed if unacceptable linearity is demonstrated.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

- ☒ 1. Survey instruments will be calibrated at least annually and following repair.
- ☒ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

a. By the manufacturer

b. At the licensee's facility

- (1) Calibration source

Radionuclide

Manufacturer's name

Model no.

Activity in millicuries

or

Exposure rate at a specified distance

Accuracy

Traceability to primary standard

- (2) The calibration procedures in Section I of Appendix D will be used

or

- (3) The step-by-step procedures, including radiation safety procedures, are attached.

☒

- c. By a consultant or outside firm

- (1) Name Medical Physics Consultants

- (2) Location Suite B 3200 West Liberty, Ann Arbor, MI 48104

- (3) Procedures and sources

☒

have been approved by NRC and are on file in License No. 21-16327-01

have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

the attached "Certificate of Instrument Calibration."

the consultant's reporting form as attached.

are described in the attachment, and the consultant's report will contain the information on

the attached "Certificate of Instrument Calibration."

the consultant's reporting form as attached.

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 semi-log coordinate paper, plot the net measured activity and the calculated activity versus time.
- 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 exposure⁹)

- 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:

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

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

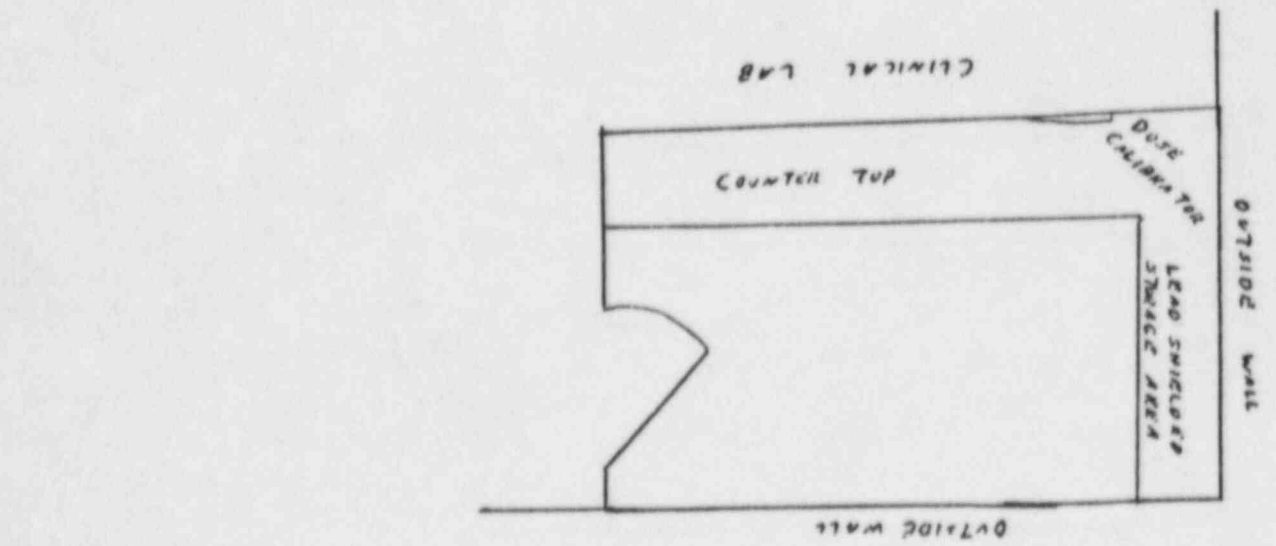
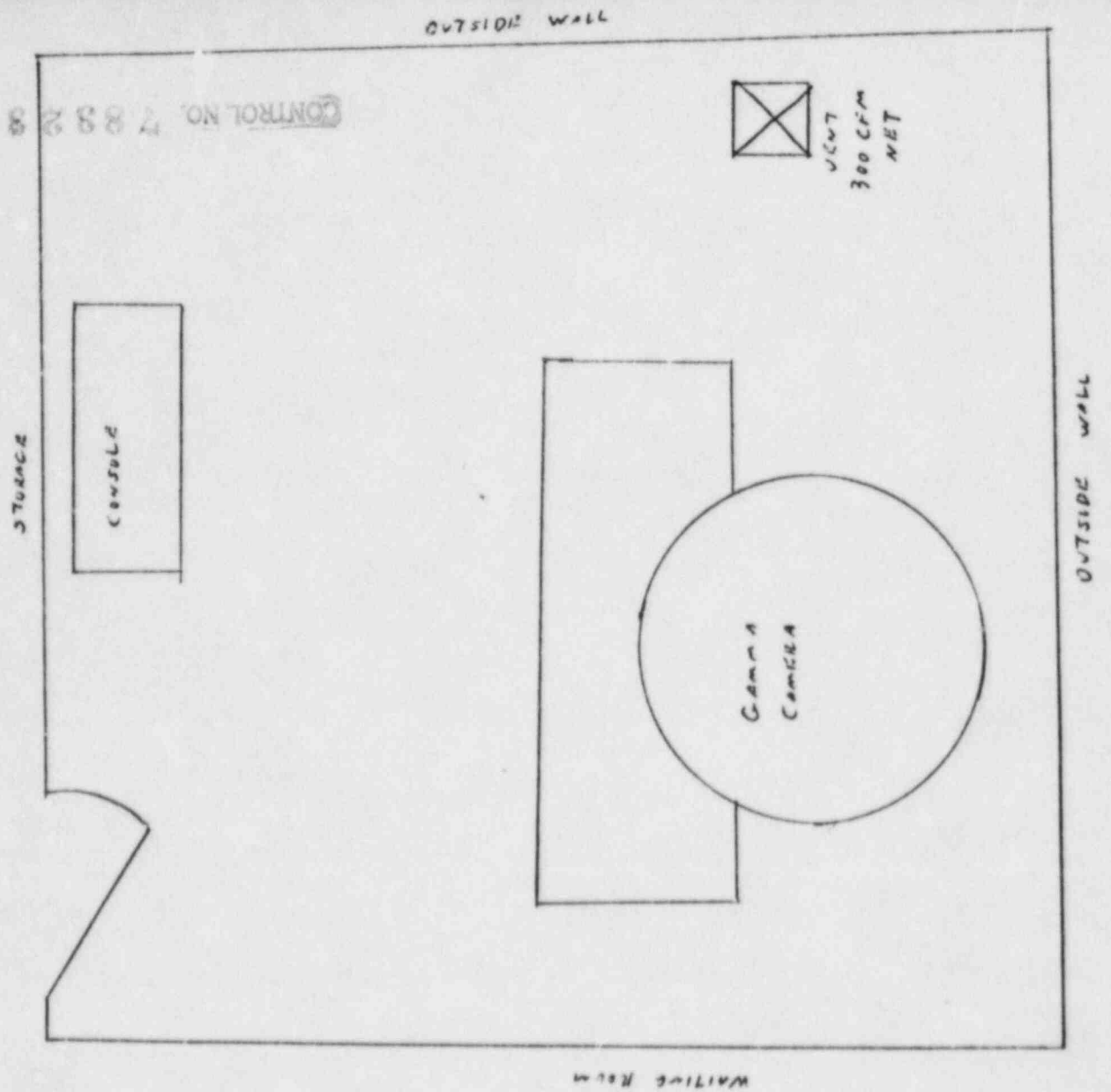
Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* 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.



Item 12 Personnel Training Program

The training program will be of sufficient scope to ensure that all personnel, including clerical, nursing, housekeeping, and security personnel, receive proper instruction in the items specified in Section 19.12 of 10 CFR Part 19, including:

- a. Areas where radioactive material is used or stored.
- b. Potential hazards associated with radioactive material.
- c. Radiological safety procedures appropriate to their respective duties.
- d. Pertinent NRC regulations.
- e. The rules and regulations of the licensee.
- f. The pertinent terms of the license.
- g. Their obligation to report unsafe conditions.
- h. Appropriate response to emergencies or unsafe conditions.
- i. Their right to be informed of their radiation exposure and bioassay results.

Personnel will be properly instructed:

- a. Before assuming their duties with or in the vicinity of radioactive materials.
- b. During annual refresher training.
- c. Whenever there is a significant change in duties, regulations, or the terms of the license.

REGULATIONS FOR THE USE OF RADIONUCLIDES

ORDERING:

All radionuclides orders will be placed through the Nuclear Medicine Department. Only those radionuclides present on the authorized list will be ordered, and in quantities not exceeding those specified on this list. A current record of all standing radionuclides orders will be maintained by the Department.

RECEIPT:

The receipt of radionuclides will be recorded by the Nuclear Medicine Department. Any radionuclides received but not ordered, or any errors in activity or form, will be reported immediately to the Radiation Safety Officer. All incoming packages shall be monitored for leakage, contamination, or damage before opening. If leakage or contamination is found, the NRC will be notified immediately along with the Michigan Health Department and the manufacturer.

CONTROL:

Each radionuclide will be checked to assure accuracy of the:

- (a) Activity.
- (b) Volume.
- (c) Specific activity.
- (d) Calibration.

All radionuclides will only be accepted during normal working hours.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds $0.01 \mu\text{Ci}/100 \text{ cm}^2$ or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).
2. For all packages, the following additional procedures for opening packages will be carried out:
 - a. Put on gloves to prevent hand contamination.
 - b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
 - c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If $>10 \text{ mR/hr}$, stop procedure and notify Radiation Safety Officer.
 - d. Measure surface exposure rate and record. If $>200 \text{ mR/hr}$, stop procedure and notify Radiation Safety Officer.
 - e. Open the package with the following precautionary steps:
 - (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.
 - (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.
 - (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).
 - (4) Check also that shipment does not exceed possession limits.
 - f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.
 - g. Monitor the packing material and packages for contamination before discarding.
 - (1) If contaminated, treat as radioactive waste.
 - (2) If not contaminated, obliterate radiation labels before discarding in regular trash.
3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

* In the case of special orders (e.g., therapy doses), also compare with physician's written request.

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.

-OR-

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

☒ Other (specify): See #3

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 radiobutopic 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. N/A

* At present, all (used and unused) syringes, needles, and other radioactive waste will be returned to the unit dose supplier for ultimate disposal at their facility.

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.*
 2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.
 3. Waste storage areas 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 survey meter sufficiently sensitive to detect 0.1 mR/hr.
 - b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.
 5. A permanent record will be kept of all survey results, including negative results. The record will include:
 - a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.
 - b. Name of person conducting the survey.
 - c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.
 - d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).
 - e. Detected contamination levels, keyed to locations on drawing.
 - f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
 6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2 .
- * For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

Allow the use of end-window GM type survey meter for assaying wipe tests. The wipe will be assayed by holding them up to, but not touching the end of the probe. The action level will be: any reading above background will be considered to be contaminated, which then needs to be cleaned up and rewiped.

Gamma sensitivity: 2500 cpm/mR/hr
Window thickness: 1.4 to 2 mg/cm^2
Efficiency: 30% for Tc-99m
Minimum range: 0 to 0.5 mR/hr
Maximum range: 0 to 50 mR/hr

In support of our request for the use of Xe-133 gas the following information is submitted.

A. Quantities to be used:

1. Estimated number of patients per year is 520, with a dose of 10 mCi per patient.
2. The possession limit request is 200 mCi.

B. Use and Storage areas:

1. The Xe-133 will be both stored and used in the Department of Nuclear Medicine. The Xe-133 will be stored in the shipping container behind a lead shielded storage area.
2. The ventilation in the area where the Xe-133 will be stored and used is 300 CFM. The exhaust vents are located in the ceiling and vent directly to the roof.

C. Procedures for routine use.

1. Position patient and set up.
 - (a) Single breath - the patient inhales the Xe-133 gas and holds breath during scintigraphy.
 - (b) Rebreathing - a rebreathing study is performed through the system until equilibrium is achieved.
 - (c) Washout - the Xe-133 is exhaled from the patient and collected in the Xe-133 trap.
2. The Xe-133 gas will be supplied by New England Nuclear or Diagnostic Isotopes, and will be dispensed and collected by the Pulmonex Xenon System model no. 130-500 from Atomic Products Corp.
3. Nose clamps or face masks will be used in order to reduce possible contamination of the air.

D. Emergency Procedures in case of accidental release of Xe-133

1. All personnel and patients will leave the room and close the door.
2. Notify the Radiation Safety Offices.
3. Do not enter the room for a minimum of 10 minutes.

E. Air Concentration of Xe-133 in restricted areas.

1. Maximum amount of activity to be used per week is (A).
2. Estimate of Xe-133 lost during use and storage (f).
3. Volume of air available per week for dilution of the Xe-133 (v) =

$$A = \frac{10 \text{ mCi}}{\text{patient}} \times \frac{10 \text{ patients}}{\text{week}} \times 1 \times 10^3 \frac{\text{uCi}}{\text{mCi}} = 1 \times 10^5 \frac{\text{uCi}}{\text{week}}$$

F = assume 25%

$$\begin{aligned} V &= A \times f \\ &= 1 \times 10^5 \text{ uCi/week} \times 0.25 \\ &= 2.5 \times 10^4 \text{ uCi/week} \\ &= 2.5 \times 10^9 \frac{\text{ml}}{\text{week}} \end{aligned}$$

The required ventilation rate is

$$\frac{2.5 \times 10^9 \text{ ml/week}}{40 \text{ hrs/week}} \times \frac{1}{1.7 \times 10^6} = \frac{\text{cfm}}{\text{ml/hr}} = 36.7 \text{ cfm}$$

The actual ventilation in the area is 300 CFM which is greater than the required ventilation for a restricted area.

F. Method of Disposal

1. The Xe-133 will be collected in the model 130-500 Pulmonex Xenon system from Atomic Products Corp.

- (a) Maximum amount of Xe-133 to be released per year (A)
- (b) Air Flow per year (V)

$$A = 1 \times 10^5 \frac{\text{uCi}}{\text{week}} \times 52 \frac{\text{week}}{\text{year}} = 5.2 \times 10^6 \frac{\text{uCi}}{\text{year}}$$

Assume 75% of all Xe-133 is trapped in the system. Therefore

$$A = 5.2 \times 10^6 \frac{\text{uCi}}{\text{year}} \times 0.25$$

$$= 1.3 \times 10^6 \frac{\text{uCi}}{\text{year}}$$

$$V = 300 \frac{\text{ft.}^3}{\text{min.}} \times 1.49 \times 10^{10} \frac{\text{ml}}{\text{ft.}^3/\text{min}}$$

$$= 4.47 \times 10^{12} \text{ ml/year}$$

$$C = \frac{1.3 \times 10^6 \text{ uCi/year}}{4.47 \times 10^{12} \text{ ml/year}}$$

$$= 2.9 \times 10^{-7} \text{ uCi/ml}$$

2. The trap system will be surveyed monthly to ensure that the trap is working efficiently. The survey will be conducted using a Nuclear Associates Model 36-751 "Xen Alert" Xe-133 room air/trap

2. (Continued)

monitor. A replacement cartridge will be installed when the trap's exhaust reaches 1.0 MPC. The "Xen Alert" room air/trap monitor will be calibrated according to the manufacturers instructions annually.

The ventilation system will be checked to determine that it is operating according to the specifications by the use of a velometer at least semiannually.

The exhaust vent will be located at the side of the building at the level of the third floor and at least twenty feet from any air intake or windows that open.

The charcoal cartridges from the Xenon trap will be sealed in a plastic bag and stored until it is decayed and may be disposed off.

There are no air-in-take vents into the room. The 300 CFM exhaust rate will create a negative pressure in the room. Based upon this the ten minutes waiting time before re-entry into the room is reason able. In addition a low level GM survey meter or the "Xen Alert" will be used to determine that the room is safe to re-enter.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Stanley H. Levy, M.D.

(Licensee's Name)

January 31, 1985

(Date)

I. 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.

¹ Private practice physician licenses do not include an RSC.

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.

² The 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.

³The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRF 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.

- (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

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

*Investigational Levels
(m.rems per calendar quarter)*

	<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.

⁴The 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.

Stanley H. Levey MD
Signature

STANLEY H. LEVEY, MD
Name (print or type)

DOCTOR OF MEDICINE
Title

Institution (or Private Practice) Name and Address:
Stanley H. Levey, M.D.

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