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

Goshen General Hospital
200 High Park Avenue
Goshen, Indiana 46526

TELEPHONE NO.: AREA CODE (219) 533-2141

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Frank T. Bloe, Consultant
Nuclear Medicine Associates
TELEPHONE NO. AREA CODE (216) 641-5799

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 13-18845-01

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

Refer to Item #8

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.)*

Shaun D. Gunderson, M.D. with consultation from Nuclear Medicine Assoc.
Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	200
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	200
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	400

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

8506040080 850515
REG3 LIC30
13-18845-01 PDR

Applicant Log: Dec. 15-III
Check No. 029069
Amount/Fee Category 7C-$580
Type of Fee REN
Date Check Rec'd 12-26-84
Received By aac

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

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

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer Jr. & Sons	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer Jr. & Sons	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE
(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X [signature]

(1) NAME *(Type or Print)*

X FRANK N. YAGER

(2) TITLE

X Administrator

c. DATE

X 12-10-84

NRC FORM 313A (6-81)

CONTROL NO. 77950

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.

RADIATION SAFETY COMMITTEE

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer
2. the hospital administrator or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;
3. an authorized user for each type of use permitted by the license; and
4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

APPENDIX B

RADIATION SAFETY COMMITTEE

Responsibility:

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties:

The committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of all individuals who use radioactive materials (including physicians, technologists, physicists, and pharmacists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by 19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

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

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspections, written safety procedures, and the adequacy of the institution's management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

Meeting Frequency:

The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

NAME OF AUTHORIZED USER	AUTHORIZATION
Shaun D. Gunderson, M.D.	Groups I, II, III Xenon-133, I-131 for treatment of hyper-thyroidism and cardiac dysfunction
David M. Barnes, M.D.	All
Jeanne Grossnickle, M.D.	Groups I, II, III, Xenon-133

For training and experience of these physicians, please refer to NRC license #13-18845-01

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Prepared: 11/30/84
Lic. #13-18845-01

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Dosimeter

      Manufacturer's model number: 3700

      Number of instruments available: 1

      Minimum range: 0.0 mR/hr to 0.5 mR/hr

      Maximum range: 0.0 mR/hr to 50 mR/hr

   b. Manufacturer's name: Eberline

      Manufacturer's model number: E-520 with HP 270 probe

      Number of instruments available: 1

      Minimum range: 0.0 mR/hr to 0.2 mR/hr

      Maximum range: 0.0 mR/hr to 2000 mR/hr

2. Dose Calibrator(s)

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-30

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Picker	Dynacamera Series 5
Uptake Probe & Scaler	Picker	Spectroscaler V R

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

CALIBRATION OF INSTRUMENTS

A. Survey meters will be checked for operability each day of use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within ± 20% of the reading displayed after calibration, the instrment will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy. They will consist of:

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3 - 5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1 - 0.5 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1 - 0.3 mCi	100 uCi or more	Within ± 5%

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standard sources.

3. The calibration procedure will be as follows:

a. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5 of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo-Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within ± 5%. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less that 200 mCi will be drawn and used. The reduced amount will

then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 5%. If test result error exceeds ± 5%, arrangements will be

made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck Kit from Calcorp, Inc. The manufacturer's instructions for use dated 3/2/82 will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed ± 2%.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be

shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within ± 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse analyzer will be calibrated using Tc-99m and a uniform flood check will be performed each day of use.

2. Uptake probes will be calibrated each day of use with a long lived reference standard such as Cs-137 or Ba-133.

FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete, refrigerator) so as to not exceed 2mR/hr at the surface of the barrier.

Mo-99/Tc-99m generator when used will be stored and eluted in the designated area. It will be shielded with lead bricks such that levels from all avenues of approach do not exceed 2.0mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patient's well-being may be compromised. Under these circumstances, the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM		PURPOSE
1.	Warning tape, chalk & signs	posting of area
2.	Plastic bags, small	shoe covers, wet containers
3.	Disposable gloves	hand protection
4.	Masking tape	fasten shoe covers, etc.
5.	Forceps, tongs	safe handling
6.	Large plastic bags	for contaminated material
7.	Sponges, 4 x 4	sopping up
8.	Paper towels	blotting & drying
9.	Radiac wash or detergent	detergent
10.	Scouring powder	friction
11.	Tags	identification
12.	Scissors	cut absorbent paper, etc.
13.	Whatman #1 filter paper	taking swipes following decontamination
14.	Chux	cover area following decontamination
15.	G-M survey meter	monitoring

Facilities and Equipment

Diagram

Air Supply

Air Exhaust

___ Scanner
1 Uptake/Well
2 Camera
3 Lockable Door
4 Receipt Area
5 Generator
6 Kit Preparation
7 Isotope Storage
8 Dose Preparation
9 Waste Storage
10 Dose Calibrator
11 Refrigerator

Adjacent Areas

A Exterior
B Hall
C Office/Clerical
___
___
___
___
___

Sink

Lead Castle

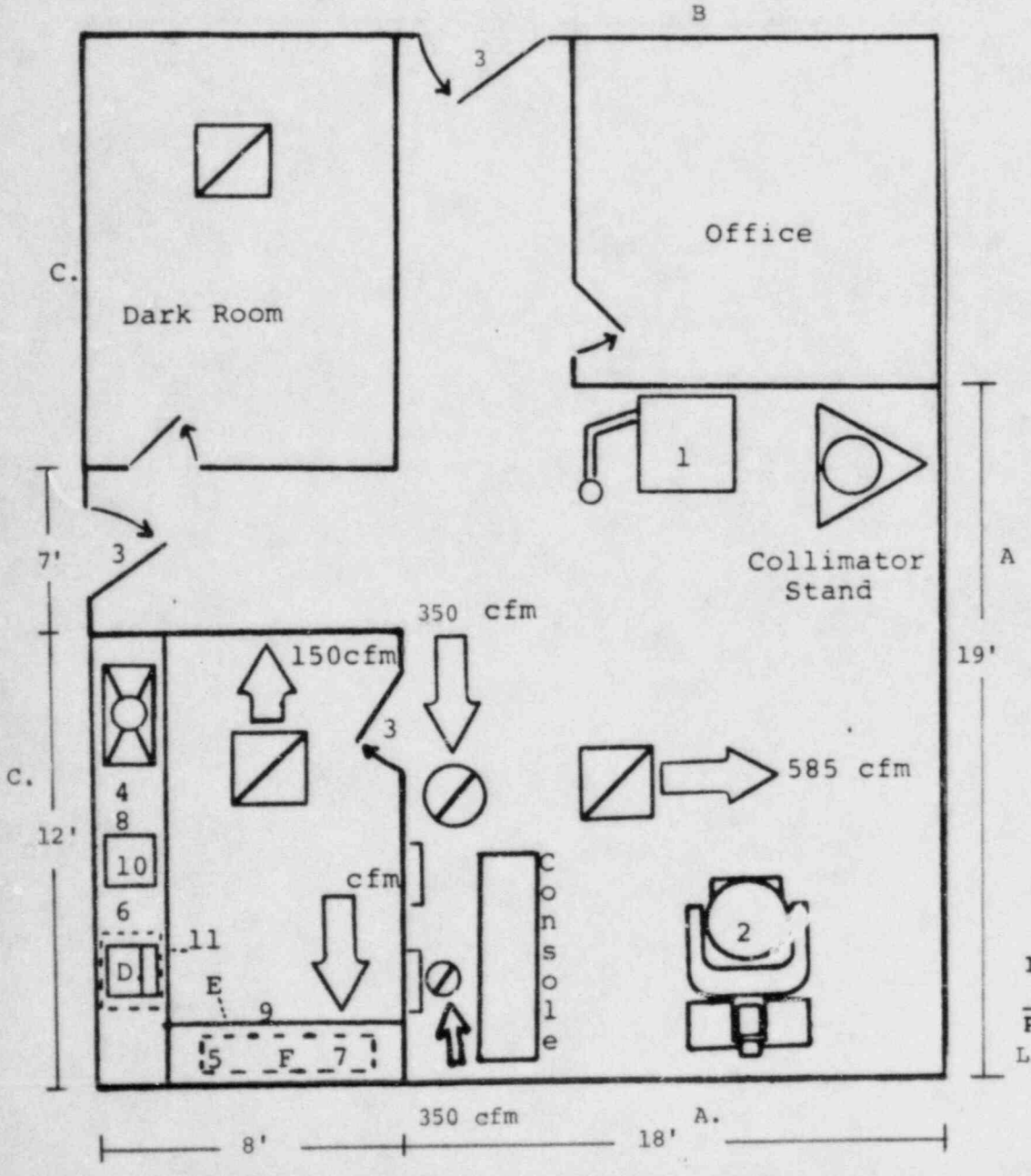
Lead Shielding

D Pb lined refrigerator
___L x ___W x ___H x 1/8"T

D Pb L-shield
___L x 12"W x 16"H x 1/2"T

E Mfg. generator shield
___L x ___W x 12"H x 3/4"T

E Pb castle
18"L x 12"W x 12"H x 2"T



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Lic. #13-18845-01

PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

1. The nuclear medicine department will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.

2. Every effort will be made to hire nuclear medicine technology registered or registry eligible personnel to work with radioactive material. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:

   a. Indicate areas where radioactive materials are used or stored.
   b. Potential hazards associated with radioactive materials.
   c. Radiological safety procedures appropriate to their respective duties.
   d. Pertinent NRC regulations.
   e. The rules and regulations of the license.
   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.
   j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license correspondence), as required by 10 CFR, Part 19.

   If evaluation of the radiation handling techniques of a new technologist is found to be inadequate, arrangements will be made to send the employee for a 40 hour formal course from our consulting physicists, Nuclear Medicine Associates, Cleveland, Ohio. This course combines didactic and clinical training which will include points "b" through "i" listed above, as well as quality control and patient procedures.

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1 of 2 pages
Prepared: 11/30/84
Lic. #13-18845-01

3. Our consulting physicists, mentioned in this addendum, will visit our facility quarterly to review all procedures, equipment and records. Personnel will receive refresher training relative to duties, regulations, or terms of the license during these visits or by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.

4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, as in the case of certain patients who need special care, personnel so involved will be present under the direction of the nuclear medicine technologist, who will ensure that the exposure of these persons is held to the minimum required for the performance of the nuclear medicine procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their orientation process and annually thereafter in the form of verbal instructions and/or interdepartment memos.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist or his/her designee will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license, and that possession limits are not exceeded. The receipt area identified in the Item #11 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to Nuclear Medicine. If this is not practical, responsible personnel (indicated in the memorandum below) will sign for packages containing radioactive materials and immediately take them to this location. Alternatively, trained nuclear medicine personnel will sign for and transport packages to the appropriate department.

3. During off-duty hours, supervisory personnel will arrange to have delivery of radioactive packages in accordance with the procedures outlined in the following directive:

TO: Managerial Personnel of: (e.g.) Security, Nursing, Receiving, Radiology, Nuclear Medicine

FROM: Radiology Department

SUBJECT: Delivery of packages containing radioactive materials

If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will have the carrier escorted to nuclear medicine by personnel who have been assigned this duty. Alternatively, hospital personnel will deliver the package to the receipt area. Under these conditions, people transporting the packages will receive special training for this purpose. Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials. The packages will be secured against unauthorized removal. When delivered packages are wet or appear to be damaged, the RSO is to be immediately contacted.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

*Radiation Safety Officer:

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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 after receipt 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 uCi/100 cm2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 1m.

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 sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 1m from package surface and record. If > 10 mR/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If > 200 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.

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

(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.

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ADDENDUM ITEM #14

The procedure for safely opening packages containing radioactive materials as outlined in Appendix F, Licensing Guide 10.8 will be subscribed to with the following exceptions. The procedures shall not be applicable to prepackaged in vitro kits received without evidence of shipping damage except that radiation labels will be obliterated. Evaluation of final source container wipe smears will be performed with a survey meter listed in Item #9 of license application.

APPENDIX G

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL IN THE NUCLEAR MEDICINE DEPARTMENT

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.

ADDENDUM ITEM #15

General rules for the safe use of radioactive materials, as outlined in Appendix G of the Licensing Guide will be subscribed to at this institution. Additionally, in accordance with 10 CFR 20.501, authorization is requested to dispose of the following records subsequent to NRC inspection of these records.

1. Dose calibrator accuracy, constancy and linearity checks.
2. Survey meter calibration records.
3. Instrument calibration and quality assurance records. (e.g., camera, well, uptake probe, etc.)
4. Records of training for occupational and nonoccupational personnel.
5. Radiation Safety Committee minutes.

Provided that:

1. The record was examined during a routine NRC inspection.
2. The record is in excess of two years from the date of generation.
3. Disposal of the record does not conflict with the requirements of other state and federal agencies.

APPENDIX H
EMERGENCY PROCEDURES

Minor Spills

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

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

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

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

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

Major Spills

1. **CLEAR THE AREA:** Notify all persons not involved in the spill to vacate room.

2. **PREVENT THE SPREAD:** Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

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

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

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

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

RADIATION SAFETY OFFICER:
OFFICE PHONE: **HOME PHONE:**

ALTERNATIVE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

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SURVEY PROCEDURE

A. Routine elution, preparation and designated injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a low level G-M survey meter.

The procedure will be as follows:

a. Perform wipe tests.
b. Place smear(s) in a "baggy" or disposable glove.
c. Adjust response time to the longest time constant, if applicable.
d. Select most sensitive range.
e. Turn beta shield on probe to open position.
f. Wait until reading stabilizes.
g. Read and record background.
h. Place smear in contact with open position of probe.
i. Wait until the reading stabilizes.
j. Read and record wipe results.

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

E. A permanent record will be k[illegible] the weekly or monthly survey results, including negative [illegible]esults. The record will include:

1. Location, date and type of equipment used.

2. Name of person conducting the survey.

3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

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

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

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

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of:

_X_ A. In the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.

_X_ B. 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.

2. Mo-99/Tc-99m generators will be:

_X_ A. Returned to manufacturer for disposal.

_X_ B. 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.

3. Other solid waste will be:

_X_ A. 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.

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APPENDIX K

RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with paragraphs 20.203 or 20.204 of 10 CFR Part.20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions:

    a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.

    b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with ccoperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with I-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. 1511. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

l. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Exposure Rates in mR/hr

Date	3 feet from bed	10 feet from bed

(Comply with all checked items)

_____1. Visiting time permitted. _____
_____2. Visitors must remain _____ from patient.
_____3. Patient may not leave room.
_____4. Visitors under 18 are not permitted.
_____5. Pregnant visitors are not permitted.
_____6. Film or TLD badges must be worn.
_____7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
_____8. Tag the following objects and fill out the tag:

_____door _____bed _____chart _____wrist

_____9. Disposable gloves must be worn while attending patient.
_____10. Patient must use disposable utensils.
_____11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
_____12. Smoking is not permitted.
_____13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
_____14. Other instructions.

In case of an emergency contact:

RSO _____
Name On-duty/Off-duty Telephone numbers

ADDENDUM ITEM #19

The procedures and precautions for radiopharmaceutical therapy as described in Appendix K of Regulatory Guide 10.8 will be implemented but with the following exceptions:

For I-131 Therapy

1. The urine will not normally be collected when patients are treated with I-131.

2. Only patients containing > 30 mCi must be hospitalized. If a patient is hospitalized with < 30 mCi, radiation safety procedures shall be applied until such time as the residual activity in the patient is < 8 mCi. (Reference: NCRP #37).

3. Liquid sources will be opened in a vented hood if available. Gloves, tongs, and lead shielding will be utilized by personnel handling I-131 sources.

4. Liquid I-131 sources received in closed remote displacement containers designed for direct oral administration to a patient will be treated with the same radiation safety precautions as are employed in the use of capsules containing this radionuclide. Devices equivalent to the Oral Radioisotope Administration Set #32-27 available from Paramedical Inc., Watertown, Massachusetts, will be used for this purpose.

5. The criteria and procedures for a personnel bioassay program will be as described in Regulatory Guide 8.20, September, 1979.

For P-32 Therapies

1. Nursing instructions as defined in Appendix K shall not apply to P-32 except in the colloidal form in which case the nurse will be advised to observe the wound and report any drainage to the Radiation Safety Officer. The RSO will be responsible for the supervision of changing the dressings.

CONTROL NO. 77950

Item #21

Procedures and Precautions for Use with Radioactive Gases

I. Quantities:

A. An average of 10 exams per week may be done.

B. Average activity per exam is 10 mCi.

C. Possession limit of 400 mCi is authorized.

II. Use and Storage:

A. Xenon-133 will be stored in the fumehood located in the hot lab. It will be stored in its original shipping container until used. Accessory lead shielding will be used (i.e., 1/8" - 1/4" lead vials or sheet) whenever survey measurements at the face of the hood are 2.0 mR/hr or more.

B. The exhaust system for the entire department is handled by a two-speed fan mounted at rooftop and greater than 10 meters away from any potential re-entry port to the hospital. Even though a higher exhaust rate is available, it will not be used in concentration calculations that follow.

The exhaust blower is operated continuously at low speed. There is total exhaust ventilation rate of 865 cfm for both the camera room and the hot lab. The camera room exhaust rate is 700 cfm and supply air is provided at 585 cfm. The hot lab exhaust rate is 165 cfm and supply air is provided at 150 cfm. Thus, both rooms are under negative pressure at all times. There are also two transfer grills (12" x 12") from the camera room through the wall common to the hot lab to supply make-up air from the camera room into the hot lab. These two transfer grills are located six inches above the floor and eight feet above the floor.

Room sizes are as follows: Camera Room = 19' x 18' x 9'. Ante Room = 7' x 8' x 9'. Hot Lab = 12' x 8' x 9'.

III. Procedure for Routine Use:

A. The camera room door will be opened to a six inch gap at the door jamb if patient's condition permits.

The patient will be fitted with the rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient condition permits.

The Xenon will be administered and three to four views obtained. During the washout phase, the Xenon will be collected in the gas trap until practically no Xenon remains in the patient as evidenced by the camera persistence scope.

Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon. Visitors will be excluded from the camera room during Xenon use unless their presence is required for patient care or desired for educational or observational purposes.

B. An activated charcoal gas trap will be used for patient studies. A RadX Ventil-Con delivery system with gas trap or equivalent is used. This system will be used in accordance with manufacturer's instructions.

Face masks that cover both mouth and nose or nose clamps for use with the mouthpiece delivery systems will be employed to reduce leakage of the Xenon into the camera room.

C. On a semi-annual basis, the exhaust flow rates from the camera rooms and the hot lab will be checked to assure that a change in exhaust rate has not occurred and a check of the air supply will be made to assure negative pressure in the rooms.

IV. Emergency Procedures:

In the event there is an accidental patient associated loss of Xenon into the camera room, the exhaust system will clear the room to levels less than 1×10^{-5} uCi/ml in less than 12 minutes.

Activity per loss (A) = 10 mCi = 1×10^{4} uCi

Room Volume (V) = 19' x 18' x 9' + 12' x 8' x 9' + 7' x 8' x 9'

= 4446 $ft.^{3}$

= 1.2×10^{8} ml

Clearance rate $(\lambda) = \frac{865 \text{ cfm}}{4446 \text{ ft.}^3}$

= .19 $min.^{-1}$

Initial concentration $(C_o) = \frac{1 \times 10^{4} \text{ uCi}}{1.2 \times 10^{8} \text{ ml}}$

= 8.3×10^{-5} uCi/ml

Evacuation time (t) = 12 minutes

Final concentration $(C) = C_o e^{-\lambda t}$

= $(8.3 \times 10^{-5}) e^{-.19 \times 12}$

= 8.5×10^{-6} uCi/ml

This value is less than 1×10^{-5} uCi/ml.

All unnecessary personnel will evacuate the room. The camera room door will be guarded against inadvertant entry during this time period. A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered.

V. Air Concentration of Xenon-133 in Restricted Areas:

A. It is estimated that 100 mCi will be used per week (A).

B. 15% of the Xenon will be lost into the camera room due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon. An additional 5% loss during storage will make up a total assumed loss of 20%. (f)

C. A minimum room exhaust rate of 865 cfm will be used in this calculation.

$V = 865 \text{ cfm} \times 6.797 \times 10^{7} \text{ ml/40 hr wk/cfm}$

$V = 5.8 \times 10^{10} \text{ ml/wk}$

D. The average concentration (C) will be:

$$C = \frac{A \times f}{V}$$

$$= \frac{100 \text{ mCi} \times 1 \times 10^{3} \text{ uCi/mCi} \times .20}{5.8 \times 10^{10} \text{ ml}}$$

$$= 3.4 \times 10^{-7} \text{ uCi/ml}$$

This value is less than required for restricted areas (1×10^{-5} uCi/ml).

VI. Methods of Xenon-133 Disposal:

A. All Xenon unused will be disposed of by decay in storage in the hood. Containers and apparatus will be surveyed unshielded with the low level survey meter held on contact with source containing device. If levels are the same as background, the containers will be disposed after defacing the labels.

All escaped Xenon will be vented through the exhaust system.

1. It is assumed that 1.04 Curies of Xenon will be vented to the atmosphere per year. This includes activity liberated as both accidental losses and leakage.

2. An air flow rate of 865 cfm will be used in the calculation: