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

Bartholomew County Hospital
2400 East 17th Street
Columbus, Indiana 47201

TELEPHONE NO.: AREA CODE (812) 379 4441

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

Steve A. Spinosi, 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. 13-01631-05

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

See 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.)*

Gary L. Folkman with consultation from Nuclear Medicine Associates, 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	X	3.0
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	4000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1000

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	X	500

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

RECEIVED BY FDMS
Date 4/1/83
Log
By
Orig. To
Action Compl.

Ex. 170.11(a)(9)
FEE EXEMPT

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
	Supplements A & B Attached for Each Individual User; and
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
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; with Addendum
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; with 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; with Addendum
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	Detailed Information Attached; and for I-125 Seeds
	Appendix L Procedures Followed; or *(Check One)*
X	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: Fee Exempt

(2) LICENSE FEE ENCLOSED: $ 0

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X Robert S. Borczon

(1) NAME *(Type or Print)*

X Robert S. Borczon

(2) TITLE

X Executive Director

c. DATE

X 3-19-1985

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MAR 21 1985
REGION III

NRC FORM 313M (9-81)

CONTROL NO. 7 8570

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.

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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.

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NAME OF AUTHORIZED USER	AUTHORIZATION
Donald Charles Moore, M.D. ✓	All
Robert G. Reed, M.D. ✓	Diagnosis
F.B. Andrews, M.D. ✓	All,except Au-198
Shaffer B. Berkshire Jr., M.D. ✓	I,II,III,IV,Xenon-133
Richard Pitman, M.D. ✓	I,II,III,Xenon-133 I-131 for hyperthyroidism and cardiac dysfunction
Newell Pugh, M.D. ✓	VI
David Ross, M.D. ✓	VI
Peter Garrett, M.D. ✓	VI

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APPENDIX C

INSTRUMENTATION

1. **Survey meters**

   a. **Manufacturer's name:** Eberline

   Manufacturer's model number: E-520

   Number of instruments available: 1

   Minimum range: 0 **mR/hr to** 0.2 **mR/hr**

   Maximum range: 0 **mR/hr to** 2000 **mR/hr**

   b. **Manufacturer's name:** Victoreen

   Manufacturer's model number: 740-F

   Number of instruments available: 1

   Minimum range: 0 **mR/hr to** 25 **mR/hr**

   Maximum range: 0 **mR/hr to** 25 **R/hr**

2. **Dose Calibrator(s)**

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-4

   Number of instruments available: 1

3. **Instruments used for diagnostic procedures**

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Searle	HP
Gamma Camera	Picker	4/15
Uptake Probe	Picker	Spectroscaler 4R
Well Counter	Picker	Spectroscaler 4R

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

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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. Well counters will be calibrated each day of use with a long lived reference standard such as Cs-137, Ba-133, Co-57, or simulated I-125.

3. 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
12 Generator
6 Kit Prepafation
5 Isotope Storage
6 Dose Preparation
9 Waste Storage
10 Dose Calibrator
11 Refrigerator

Sink
Lead Castle

Adjacent Areas

A. Corridor
B. Teletherapy

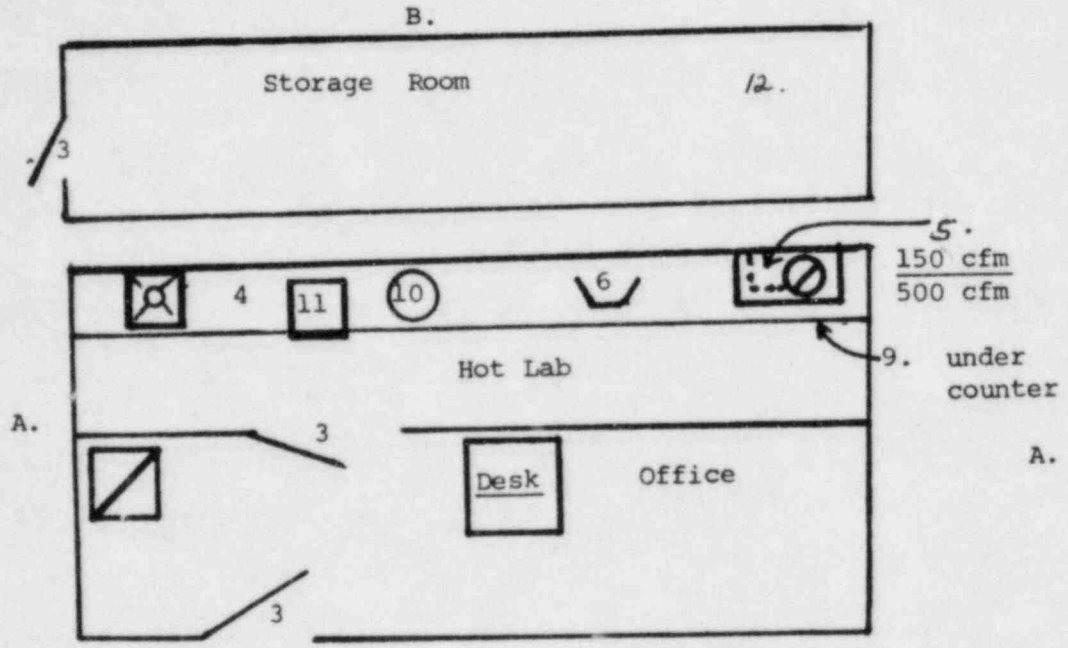
Lead Shielding

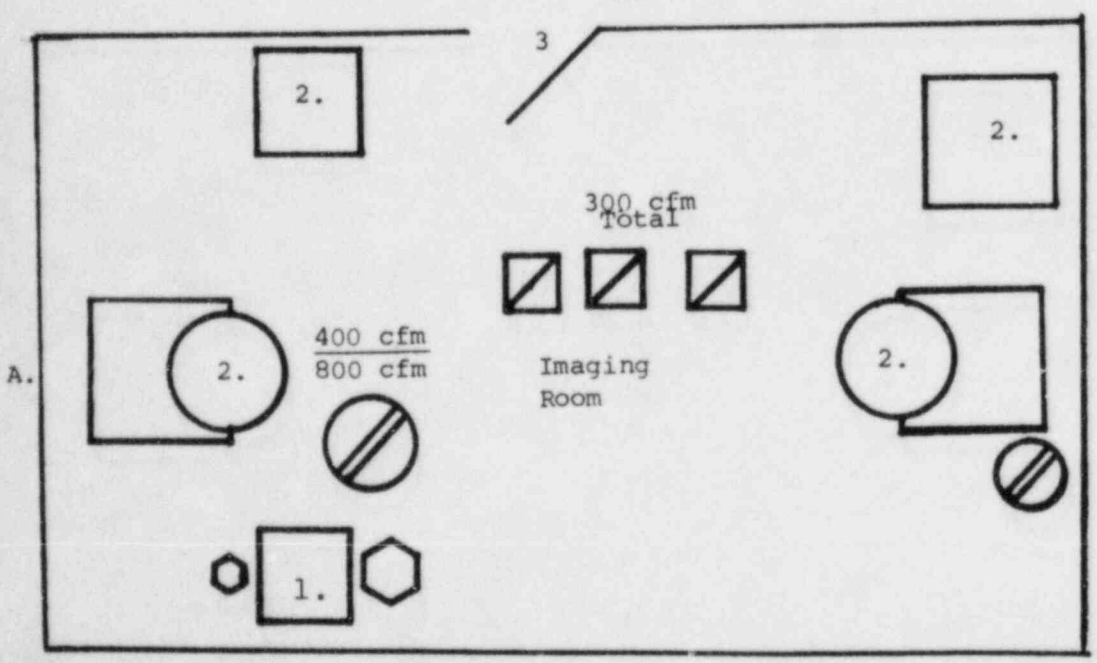
5 Lead Castle
18" L x 18" W x 12" H x 2" T

6 L-Shield
12" L x 12" W x 12" H x ½" T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T





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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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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.

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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, Maintenance, E.R.,Pathology E.R., Pathology

FROM: (e.g.) RSO

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:

Gary Folkman
Phone Number: Through Hospital Operator

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APPENDIX P

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.

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.

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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.

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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 PROCEDURES

A. All 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 monitored monthly, via wipe test.

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. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm.

E. A permanent record will be kept of the weekly or monthly survey results, including negative results. 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.

F. Area will be cleaned if the contamination level exceeds 200 dpm/100cm2, except in the case of some Tc-99m spill where less radiation exposure would be received by personnel if the area is secured and contamination is allowed to decay.

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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.

X C. Other (specify): Return to radiopharmacy.

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.

___ C. Disposed of by commercial waste disposal service.

X D. Other (specify): Return to radiopharmacy.

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.

___ B. Disposed of by commercial waste disposal service.

X C. Other (specify): Return to radiopharmacy.

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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 cooperative 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._____. 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

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ADDENDUM ITEM #19

The procedures and precautions for radiopharmaceutical therapy as described in Appendix K of Regulatory Guide 10.8 will be implemented 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.

ITEM #20

THERAPEUTIC USE OF SEALED SOURCES

Special procedures for patients treated with byproduct material listed in Group VI, Schedule A, Section 35.100 of 10 CFR, Part 35 are as follows:

a. Areas where sealed sources will be stored will be found in map accompanying this application.

b. See "Safety Precautions in Clinical Applications". (Item #20, Form E).

c. The form, Nursing Instructions for Patients Treated with Radioactive Sources, (Item #20, Form A), will be completed immediately after sources are implanted and placed in the patient's chart. Nurses will be instructed via Item #20, Form F.

d. Nurses caring for brachytherapy patients will be assigned personnel monitoring devices. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient and to personnel handling sealed sources.

e. Sources will be transported from the storage site to place of use via the original shipping container or an equivalent lead container which is at least 1" thick.

f. At the initiation of treatment, an inventory will be performed on all therapy sources to insure total accountability. At the conclusion of treatment, another inventory will be performed to insure that all sources have been returned. (Refer to Item #20, Form B). In addition, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all personnel monitoring devices assigned to nurses will be collected. Item #20, Form C will be used as a check-off procedure.

g. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's bedside, three feet away and at the entrance to the room. The Radiation Safety Officer or his designate

will then determine how long a person may remain at these positions and will post these times in the patient's chart. Refer to Item #20, Form D. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR, Part 20. (i.e., 2 mrems in any one hour or 100 mrems in any seven consecutive days).

h. Patients treated with sealed sources will be assigned to a private room.

i. For I-125 seeds, the Radiation Safety Program to be implemented will be that as outlined in the attached Guidelines listed as page 10 of this item.

ITEM #20, FORM A

NURSING INSTRUCTIONS
FOR PATIENTS TREATED WITH RADIOACTIVE SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity:

Date and Time of Administration: _____

Date and Time Sources are to be removed: _____ Isotope: ____

_____

Exposure Rates in mR/hr

Bedside 3 feet from bed 10 feet from bed

_____ _____

_____

_____

(Complete checked items)

_____1. Wear personnel monitoring device.
_____2. Wear rubber gloves.
_____3. Place laundry in linen bag and save.
_____4. Housekeeping may not enter the room.
_____5. Patient may not have visitors.
_____6. No pregnant visitors.
_____7. No visitors under 18 years of age.
_____8. A dismissal survey must be performed <u>before</u> patient is discharged.
_____9. Patient must have a private room.
_____10. Other instructions.

RSO

_____

Name On-duty/Off-duty telephone numbers

ITEM #20, FORM B

RECEIPT/SHIPMENT RECORD
RADIATION SOURCE THERAPY APPLICATIONS

Patient _____ ID# _____ RM _____

PRE-TREATMENT INVENTORY

Subtotal

_____ sources of _____ mg _____

_____ sources of _____ mg _____

_____ sources of _____ mg _____

_____ sources of _____ mg _____

Applicator(s) _____ Total _____ mg.

POST TREATMENT INVENTORY

_____ sources of _____ mg _____

_____ sources of _____ mg _____

_____ sources of _____ mg _____

_____ sources of _____ mg _____

Applicator(s) _____ Total _____ mg.

COMMENTS:

Certified by: _____ Date: _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

CONTROL NO. 0357

ITEM #20, FORM C

RADIATION THERAPY SOURCE USAGE RECORD

Patient _____ ID# _____ RM _____

Ordering Physician _____

Applicator(s) used _____ Sources _____
mR/hr at 1 meter from applicator (not after loading) _____mR/hr
Date and time of insertion _____ a.m./p.m. _____

	Yes	See comments
Lead aprons not worn during insertion?	( )	( )
X-ray techs informed prior to obtaining localizing films?	( )	( )
Recovery room nurses instructed to use time/distance?	( )	( )
Patient assigned private room?	( )	( )
Exposure monitors issued to nursing personnel?	( )	( )
Safety instruction given to nurse?	( )	( )
Safety procedures placed in patient's chart?	( )	( )
Caution sign placed on patient's chart?	( )	( )
Caution signs placed on patient's room door?	( )	( )
Nursing care rotated?	( )	( )
Known pregnant nurses not attending patient?	( )	( )
Pregnant visitors prohibited?	( )	( )
Visitors under 18 prohibited?	( )	( )
Safety survey performed and recorded?	( )	( )
Limits of nursing care time posted?	( )	( )
Removal notice posted in patient's chart prior to removal of all posted signs?	( )	( )
All signs removed?	( )	( )
Room surveyed and background radiation levels present?	( )	( )

Date/Time of Removal _____ a.m./p.m. _____
Applicator _____ Sources _____

COMMENTS:

CERTIFIED BY: _____ Date _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

ITEM #20, FORM D

RADIATION HAZARD EVALUATION FORM
(to be filled out by Radiation Safety Officer for his use)

Name _____ Date and _____

Time of Death _____

Radioisotope _____

Amount Administered _____

Route of Administration _____

Amount Present _____

Distribution with body _____

_____

_____

_____

Indicate Distances _____

Suggest ring badges if exposure

0.25 R/hr @ 25 cm

See NCRP #37 p. 27

Limit hand exposure to 1.5 Rems.

Date of Survey _____

Instrument Used _____

Signed: _____
Radiation Safety Officer

Date: _____

ITEM #20, FORM E
SAFETY PRECAUTIONS IN CLINICAL APPLICATIONS

I. Transfer and Preparation of Sources

a. Forms will be used to record pre and post-use inventory. (Item #20, Form B)
b. Sources will be dispensed with suitable protective devices and techniques, to include long forceps and TLD finger badges.

II. Application of Sources to the Patient

a. Distance, time, and when possible, shielding, will be used to reduce radiation exposure to personnel attending the patient.
b. Appropriate signs will be used to indicate levels of radiation exposure.
c. Consideration will be given to the proximity of patients in adjoining rooms.
d. A patient being treated with brachytherapy sources will wear suitable identification.
e. Patient will not be allowed to leave his room unless accompanied by a hospital attendant.
f. Persons who have short-lived sources which are not removable from their bodies will be allowed to leave the hospital provided precautions necessary to prevent other persons from receiving more than the permissible dose of radiation are observed.

III. Removal of Sources from Patient

a. Sources will be removed with same safety precautions as those used in their application.
b. No linens, dressings, clothing or equipment will be removed from room until all sources are accounted for.
c. Assurance of complete removal of all sources will be obtained using a G-M survey meter held in the treatment area of the patient.
d. Should the patient die before brachytherapy is complete, the sources will be removed at once.

IV. Return of Sources to Storage

a. Following cleaning, sources will be returned immediately to their storage place.
b. Post-use inventory forms will be completed to insure complete return of all sources to storage.
c. Inventory of all sealed sources will be performed on a quarterly basis and recorded.

ITEM #20, FORM F

1. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patient. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

2. Nurses should spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear a personnel monitoring device.

3. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Nuclear Medicine Department. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

4. Pregnant nurses should not be assigned to the personal care of these patients.

5. Never touch needles, capsules or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact the Nuclear Medicine Department at once.

6. Bed bath given by the nurse should be omitted while the sources are in place.

7. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.

8. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the radiologist or member of the Nuclear Medicine Department.

   Special orders will be written for oral hygiene for patients with oral implants.

9. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, utensils or bedding unless specifically ordered.

10. These patients must stay in bed unless orders to the contrary are written.

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

12. Visitors should sit at least three feet from the patient and should remain no longer than the times specified on the form posted on the patient's door and in his chart.

13. No nurse, visitor or attendent who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

14. Emergency Procedures:

    a. If an implanted source becomes loose or separated from the patient, or

    b. If the patient dies, or

    c. If the patient requires emergency surgery, immediately call _____

    Phone # _____ _____
    (Days) (Nights)

15. At the conclusion of treatment, call the Radiation Safety Officer and request that the patient and room be surveyed to be sure all radioactive sources have been removed.

ITEM #20

GUIDELINES

RADIATION SAFETY PRECAUTIONS FOR THERAPEUTIC USE OF I-125 SEEDS

GENERAL

1. Personnel who prepare, insert or retrieve I-125 seeds must wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.

2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.

3. In transporting seeds from storage - preparation areas to the place of use, adequate shielding must be employed to insure compliance with 10 CFR 20.105(b).

INSTRUCTIONS TO NURSES (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.

2. Handle dislodged seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.

3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer.

4. All bed linen must be checked with a radiation survey meter before being removed from the patient's room to insure that no dislodged sources are inadvertently removed.

5. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instrumetns, or utensils unless specifically ordered.

6. Emergency Procedures

a) If a seed becomes loose or dislodged from the patient, or

b) If the patient dies, or

c) If the patient requires emergency surgery, immediately

call _____

Telephone # _____ _____
(Days) (Nights)

7. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

Procedures and Precautions For Use
Of Radioactive Gases (eg; xenon)
Bartholomew County Hospital

I. Quantities to be Used:

Patient Information:

A. 4 studies per week
B. 20 mCi per patient

Possession limit: 500 mCi

II. Use and Storage Area:

A. Xenon-133 will be used in the imaging room as indicated in the diagram per Item #11.

B. Air is exhausted from the camera room via a dedicated exhaust system. The exhaust rate from the camera room is 400 cfm continuously with a fresh air supply of 300 cfm. There is no recirculation of exhausted air. The room is under negative pressure. In the event of accidental release of Xe-133 the high-speed exhaust of 800 cfm will be activated. Xenon, as well as contaminated tubing, face masks, etc., will be stored in the (hot lab) which is under negative pressure. The hot lab has an exhaust rate of (150 cfm. In the event of accidental release of Xe-133 the high-speed exhaust of 500 cfm will be activated.

C. The ventilation system will be checked semiannually to assure that no change in exjuast rate has occurred and that rooms are at negative pressure.

III. Procedures For Routine Use:

A. The dose will be prepared and assayed in the dose calibrator, if possible. Shielding of the dose will be maintained at all times up to patient administration, except during identification and assay. The room doors will be adjusted so a sensible draft is felt at their opening. Unnecessary personnel, except as required, will be excluded from the imaging room. Finger badges

and whole body film badges will be worn by all personnel handling Xenon-133. Patients will be instructed as to the procedure and trial runs will be conducted if at all possible.

B. Face masks, along with a Xenon rebreathing system (Pulmonex A-130-500 or equivalent) will be used to administer and collect the dose of Xenon. Tubing and valves will be inspected prior to use to assure continuity.

IV. Emergency Procedures:

A. In the event a dose of Xenon is accidentally released into the camera room or hot lab, the rooms will be evacuated until levels of concentration of Xenon have been reduced to 1×10^{-5} uCi/ml, provided patient condition will permit. The camera room door will be guarded against inadvertant entry.

B. The room evacuation interval will be (15) minutes per the following:

Room Volume: 3360 cu.ft. $\times$ 2.83×10^{4} ml/ft^3 = 9.5×10^{7}ml

Room Clearance Rate: 800 cfm

Dose: 20,000uCi

Initial Concentration (C_o): $\frac{20{,}000\text{uCi}}{9.5 \times 10^{7}\text{ml}} = 2.11 \times 10^{-4}$uCi/ml

Clearance (λ): $\frac{800\text{ cfm}}{3360\text{ cu.ft.}} = 2.38 \times 10^{-1} = 23.8\%$

Final concentration (c) is as follows:

$C = C_o e^{-\lambda t}$

$= 2.11 \times 10^{-4}\text{uCi/ml} \times e^{-(.238)(15\text{ min})}$

$= 2.11 \times 10^{-4}\text{uCi/ml} \times e^{-3.57}$

$= 2.11 \times 10^{-4}\text{uCi.ml} \times 028$

$= 5.91 \times 10^{-6}$uCi/ml which is substantially lower than 1×10^{-5}uCi/ml maximum limit for Xe-133 in a restricted area.

V. Air Concentration in Restricted Areas:

A. Estimated usage of (80)mCi per week.

B. Assume 20% Xenon loss during use and storage

C. Exhaust system operates at (800 cfm continuously.)

The average concentration will be:

(A) Activity = 80mCi/wk x .20 x 1 x 10^3uCi/mCi = 16,000uCi/wk

(V) Exhausted Volume = 400 cfm x 2.83 x 10^4ml/ft^3 x 60 min/hr x 40 hr/wk = 2.70 x 10^{10}ml/wk

$$C = \frac{A}{V} = \frac{16{,}000\text{uCi/wk}}{2.70 \times 10^{10}\text{ml/wk}} = 5.93 \times 10^{-7}\text{uCi/ml}$$

This is less than 1 x 10^{-5} uCi/ml permitted by 10 CFR 20.103.

VI. Air Concentrations In Unrestricted Areas:

A. It is assumed that 20% of the used Xenon will be vented outside and that the exjaust rate will be (400) cfm continuously.

(A) Activity = 80mCi/wk x .20 x 1 x 10^3uCi/mCi = 16,000 uCi/wk

(V) Volume = 400 cfm x 2.83 x 10^4ml/ft^3 x 60 min/hr x 168 hr/wk - 1.14 x 10" ml/wk

$$C = \frac{A}{V} = \frac{16{,}000\text{uCi/wk}}{1.14 \times 10^{11}\text{ml}} = 1.40 \times 10^{-7}$$

This value is less than the 3 x 10^{-7}uCi/ml limit for unrestricted areas.

B. After every 20 procedures, the trapping efficiency of the charcoal trap will be evaluated by holding a low level G-M survey meter on contact with the inlet tube to the trap during the equilibrium phase

of the study. When the maximum reading is reached, the probe will be placed on the exhaust tube. If the maximum exhaust reading exceeds 10% of the inlet reading during the washout phase, taking background into consideration, that trap will be considered to be saturated and cartridge will be replaced.

C. Saturated charcoal traps will be stored (in the fume hood) for decay. After decay, a survey will be performed using a low level G-M survey meter on contact with the unshielded column. If the reading is equivalent to background, the column will be disposed.

Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

Bartholomew County Hospital
(Licensee's Name)

3/8/85
(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 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 judgement, 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.

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1 Private practice physician licenses do not include a RSC.

II. 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 assure 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 authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

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

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

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle 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 paragraph VI).[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.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

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

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

b. Education Responsibilities for an ALARA Program

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

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

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[3]The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection", serve as check points above which the results are considered sufficiently important to justify further investigation.

c. Cooperative Efforts for Development of ALARA Procedures

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

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the 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, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

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

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

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he surpervises.

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

V. Persons Who Receive Occupational Radiation Exposure

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

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

VI. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practive) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

TABLE 1

		Investigational levels - (mrems per calendar quarter)	
		LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	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 is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I 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. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each 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, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form MRC-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 Committee 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. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's 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 Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official[4]

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

Robert S. Borczon

Signature

Robert S. Borczon

Name (print or type)

Executive Director

Title

Institution (or Private Practice) Name and Address:

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