NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved OMB No. 3150-0041 Expires 8-31-82

INSTRUCTIONS - Complete Items 1 through 20 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 20 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 License 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 20 and the appropriate fee enclosed.

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

St. Luke's Regional Medical Center
2720 Stone Park Blvd
Sioux City, Iowa 51104

TELEPHONE NO.: AREA CODE (712) 279-3500

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

Same as 1a

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Stan A. Huber Consultants, Inc.
200 North Cedar Road
New Lenox, Il 60451

TELEPHONE NO.: AREA CODE (815) 485- 6161

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 14-18721-01

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 attached Item 8

5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual named in Item 8, describe training and experience as in Supplement A.)

O.E. Selander, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES			IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS		
10 CFR 35.100, SCHEDULE A, GROUP III	X	3000	GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200
10 CFR 35.100, SCHEDULE A, GROUP VI	X	2000			

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
NOT APPLICABLE			

8602240113 851018
REG3 LIC30
14-18721-01 PDR

CONTROL NO. 78593

Applicant Check # 10785
Amount and Category 150
Type of Fee IC Reg
Date Check Rec'd 1/9/85
Received By

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: October 1980

NOTE: All appendices referenced on this page are based on Regulatory Guide 10.8, Rev. 1, and are attached to this application. Some appendices have been slightly modified to reduce the regulatory burden.

7. MEDICAL ISOTOPES COMMITTEE

	Names and Specialties Attached; and
/	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached

8. TRAINING AND EXPERIENCE

X	Supplements A & B Attached for Each Individual User; and See attached Item 8
	Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

	Appendix C Form Attached, or
X	List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	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; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*

X	Appendix G Rules Followed; or
	Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

X	Appendix I Procedures Followed; or and
X	Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

	Appendix J Form Attached; or
X	Equivalent Information Attached

19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*

X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

	Detailed Information Attached; and
X	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

N/A	Detailed Information Attached

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

N/A	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

This institution is committed to the ALARA program set forth in Appendix O, attached to this application.

Based on the radionuclides and procedures to be used, the use of pocket dosimeters and bioassay services are considered not applicable for Groups I, II, and III.

For radionuclide therapy procedures, we confirm I-131 will be used in capsule form rather than liquid. Should administration of I-131 in liquid form ever be deemed medically necessary, we would limit personnel attending the admistration to a minimum. A 24-hour thyroid uptake would be performed on all personnel attending such a case and the results reviewed with them. The bioassay will follow action levels and follow-up actions listed in the NRC Reg. Guide 8.20, "Applications of Bioassay for I-125 and I-131".

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 Robert L. Peck

(1) NAME *(Type of Print)*
Robert Peck

(2) TITLE
Administrator

c. DATE
March 15, 1985

FORM NRC-313M (8-78)

CONTROL NO. 7859

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 Form NRC-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/MEDICAL ISOTOPES 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. a physician specialist* from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

*Some departments, such as the nuclear pharmacy, may not be under the supervision of a physician. In these cases, the supervisory paramedical professional will be a member of the committee.

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/MEDICAL ISOTOPES 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 and the conditions of the license.

3. Establish 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 inspection, 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 medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Ref: NRC 31 3M Item 8

TRAINING AND EXPERIENCE

Radiation Safety Officer

Radiation Safety Officer; Training, Duties & Availability:

a). Training:

The training and experience descriptions of the Radiation Safety Officer (R.S.O.) are appended to this application.

b). Duties:

The R.S.O. is responsible for the overall radiation protection program within the institution. The R.S.O. has authority to implement and enforce all NRC license stipulations and regulations pertaining to the institution on a daily basis and has authority immediately terminate any hazardous operation The R.S.O. responsibilities involve not only routine applications and occupational personnel within the restricted areas using radioactive materials in the institution but also all non-occupational personnel and visitors in non-restricted areas, as well as security and handling procedures from the time radioactive shipments arrive in the hospital, day or night, through the time all such sources are properly used or disposed. The R.S.O. must provide and document extensive education (initialy, as needed and at least annually) of all personnel and public who may come within the vicinity of radioactive materials.

c). Availability:

The R.S.O. must provide back-up 24 hours per day coverage during illness, vacations or emergency by providing Administration and the occupational personnel with the phone numbers of consulting physical scientists and the Regional NRC Division of Compliance.

NAME OF AUTHORIZED USER	AUTHORIZATION
O. E. Selander, M.D.	All
W. S. Thoman, M.D.	All
J. J. Goebel, M.D.	Diagnosis I-131 for therapy Group VI
D. L. Howard, M.D.	Diagnosis Use of I-131 for treatment of hyperthyroidism or cardiac dysfunction
Daryl C. Rife, M.D.	Groups I, II, and III Xenon-133 I-131 for therapy Phosphorus-32 for colloidal chromic phosphate for intracavitary treatment

FORM NRC-313M SUPPLEMENT A
(8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

CONTROL NO. 78593

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

b. NAME OF INSTITUTION

c. MAILING ADDRESS

d. CITY

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE

LEON BROWNING McNEALY, M.D.

Radiation Oncologist
Department of Radiation Oncology
Santa Monica Hospital Medical Center
Santa Monica, California

PERSONAL:

Date of Birth	September 14, 1940
Place of Birth	Houston, Texas
Home Address	3549 Veteran Ave. Los Angeles, CA 90034
Home Telephone	(213) 839-3057
Social Security	452-70-0308
Licensure	California GO44593
Office Telephone	(213) 319-4000 ext2206
Married	Wife, Sandra French Son, Kenneth (10)

EDUCATION:	Degree	Awarded
University of Texas Austin, Texas	B. of Journalism	1963
San Francisco State Univ. San Francisco, California	M.A. Counseling Psychology	1972
University of California Berkeley, California	M.S. Medical Science	1977
University of California San Francisco, California	M.D.	1979

POSTGRADUATE TRAINING:

Internship:	University of California San Francisco, California	1979-80
Residency:	Department of Radiation Oncology University of California, San Francisco	1980-83
Clinical Fellowship:	California Hospital Medical Center/USC	1983-84

TEACHING ACTIVITIES:

Psychiatry 100, 1977-82; Participated in special class for first year medical students The Difficult Patient.

Chancellor's Class, 1982-83; Participated in a series of one week classes for senior medical students designed to ease the transition from medical student to internship.

REFERENCES:

Dennis R. Hill, M.D.; Chief of Radiation Oncology, Ralph K. Davies Medical Center, Clinical Associate Professor UCSF, San Francisco, CA (415) 565-6200

Leopole T. Avallone, M.D.; Chief of Radiation Oncology, Santa Monica Hospital Medical Center, Santa Monica, Dalif. (213) 319-4000 x2206

Nergesh Surti, M.D.; Chief of Radiation Oncology, Letterman Hospital, San Francisco, CA (415) 561-3133

Emily Militzer, M.D.; Assistant Professor, Radiation Oncology, University of Southern CA Medical Center (213) 226-5031

Vaclav Klement, M.D.; Associate Professor, Radiation Oncology, University of Southern CA Medical Center (213) 226-5031

Ref: NRC 31 3M - Item 9

INSTRUMENTATION

a) Survey Meter(s)

One (1) Texas Nuclear Model Log Series, Serial B-516 gamma survey meter
Ranges .2 - 2; 2-20; 20-200; 200-2000 mR/hr

One (1) Picker CDV Serial 369084 Low level survey meter
Ranges 0-0.5; 0-5; 0-50 mR/hr

b) Dose Calibrator

One (1) Picker Model Isotope 632-507 dose Calibrator

c) Diagnostic Instruments

ADAC System I Computor
EDC Exercise Table
Accu-sync Gate
Dynamo Portable
ADAC Cam II
Picker Series 5 with ECT

d) Other

Radx Ventilator

Ref: NRC 31 3M - Item 10

CALIBRATION OF INSTRUMENTS

a). Survey Meter:

The survey meters will be calibrated at least annually, and after repairs, by any firm that is approved by the NRC for such calibrations. Instruments will be calibrated on at least two points on each scale range. Currently, our calibration service firm is Stan A. Huber Consultants, Inc., of New Lenox, Illinois, whose radiation sources and procedures are on file with the NRC under license #12-17503-01.

The licensee shall perform operational constancy checks on survey instruments before each day's use to ensure proper functioning of the devices. For any infrequently used meters, these reference source operational checks shall be taken at least quarterly, per NRC Regulatory Guide 10.8 (October 1980) Appendix D, Section 1, Item B.

b). Dose Calibrators:

We shall follow the calibration methods and frequencies for dose calibrators as defined in NRC Regulatory Guide 10.8, dated October 1980, Appendix D, Section 2, "Methods for Calibration of Dose Calibrator".

For the linearity test, we will use a vial of Tc99m whose activity is equivalent to the maximum anticipated activity to be assayed. For the accuracy test, Stan A. Huber Consultants, Inc., of New Lenox, Illinois, or other licensed calibration firms, will use the following sources under the authority of their NRC license:

Model NES-356, 200 microcuries of Cs-137 (high energy)

Model NES-352, 1 millicurie of CO-57 (low energy)

Model NES-358, 250 microcuries of Ba-133 (medium energy)

We use a NEN Model NES-356 Cs-137 standard, 200 microcuries, for our day-of-use dose calibrator constancy checks. Records of all tests and checks will be maintained.

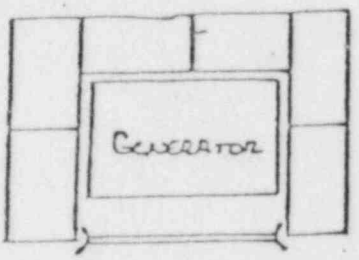
We request use of the "Calicheck" (CaliCorp) system or "Lineator" system (Atomic Products) as an alternate method of performing dose calibrator quarterly linearity checks. The product certifications for those devices are on file with the NRC.

FACILITIES AND EQUIPMENT

Shielding Around Generator:

The generator is shielded on the rear by a wall of standard size lead bricks (each 2" thick X 4" wide X 8" long). This wall is three (3) bricks (12") high and two (2) bricks (16") long. Immediately adjoining both sides of this rear wall are side walls of lead bricks of the same dimensions as the rear wall. The front of the generator area is shielded by an upright Protective Lead Barrier 15" high X 15" wide X 1/2" thick, to prevent direct exposure to personnel eluting the generator. The generator area location on the hot lab work bench is shown on the facility sketch. A top view of this arrangement is shown below.

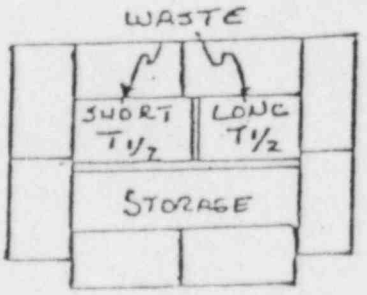
See (A) on attached sketch.



Storage and Waste Area Shielding:

The active storage/waste area is sheilded on all four (4) sides by standard size lead bricks as described above for the generator area shielding, except that a front lead brick wall is substituted for the protective lead barrier. This storage area is located on the hot lab area work bench as shown on the facility sketch. This lead brick storage area will be divided by plywood or similar material into three (3) compartments as shown on the diagram below. We do not anticipate the use of many long-lived radionuclides and the short-lived waste compartment contents can be more frequently surveyed for disposal to avoid waste accumulation or the need for any other radioactive storage or waste areas. A top view of the storage area shielding is shown below:

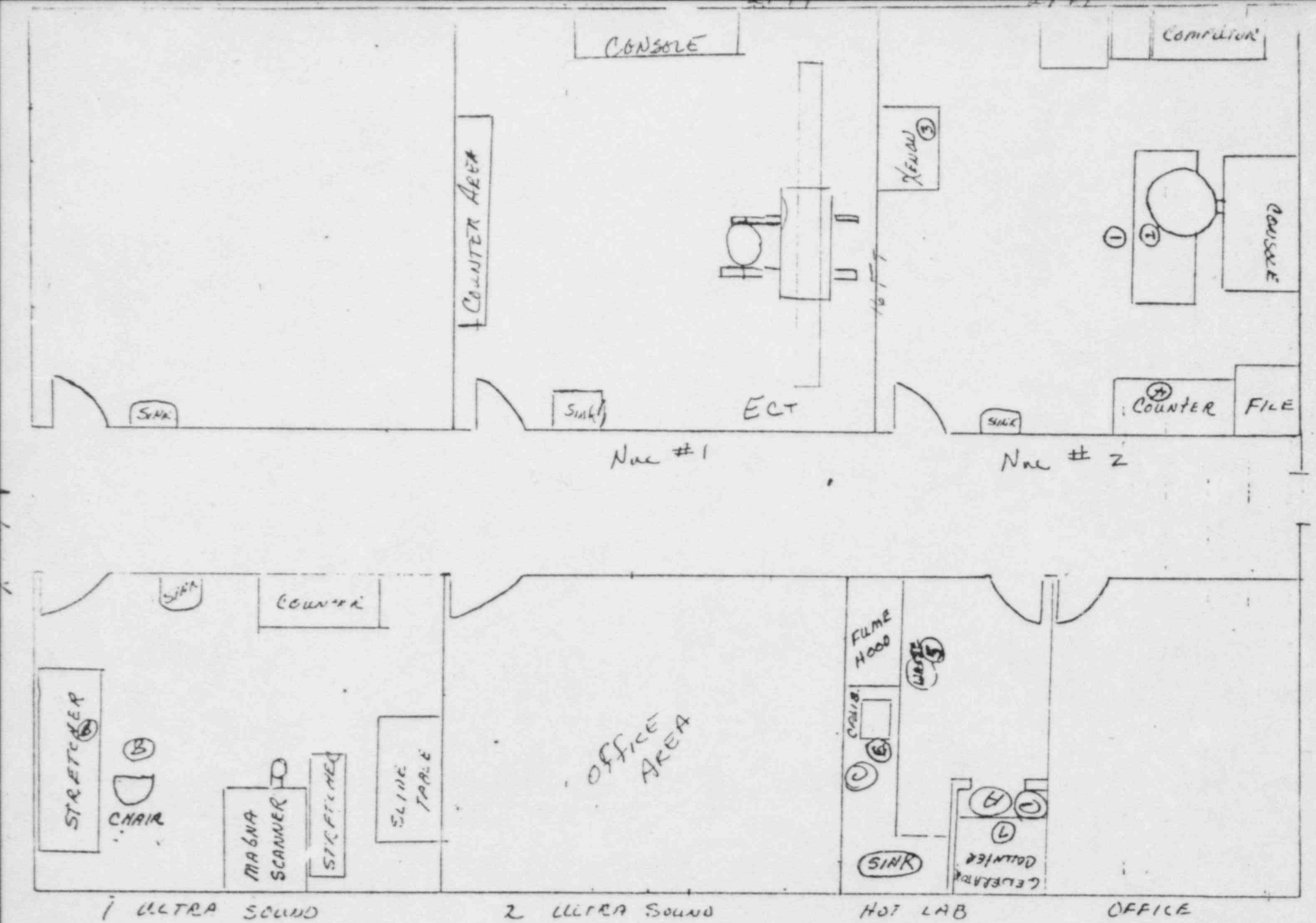
See (B) on attached sketch.



Dose Preparation Area:

The dose preparation area on the hot lab area work bench as shown on the facility sketch, is shielded in the front by an upright Protective Lead Barrier (15" X 15" X 1/2" thick). Disposable gloves, remote handling tongs (4" to 8" long), survey meters, plastic backed absorbent pads and all other ancillary supplies mentioned in NRC Regulatory Guide 10.8, dated October 1980, will also be on hand in this hot lab area.

Equivalent shielding to maintain minimal exposure levels may be used.



ST. LUKE'S MEDICAL CTR., SIOUX CITY, IA

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence, as required y 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY
RADIOACTIVE MATERIAL

1. The Supervisory Nuclear Medicine Technologist will place all orders for radioactive materials and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following.

   a. Ordering of routinely used materials

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc, will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty-hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

*In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE**MEMORANDUM

MEMORANDUM FOR: Security

FROM: Hospital Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 p.m. and 7 a.m. or on Sundays shall be signed for by the Security Supervisor on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged immediately contact the Radiation Safety Officer. Ask the carrier to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

**RADIATION SAFETY OFFICER _____

**OFFICE PHONE _____

**HOME PHONE _____

**On the actual memo that is used, this information will be filled in and updated as necessary.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIAL

Only trained Nuclear Medicine personnel are to open radioactive material shipments. These personnel have been instructed in the "Radioactive Shipment Receipt and Notification Procedures" which the Radiation Safety Officer has distributed to personnel who could possibly have contact with a radioactive shipment delivery.

The radioactive material shipments are to be opened in accordance with the NRC Regulatory Guide 10.8 dated October, 1980, Appendix F, "Procedures for Opening Packages Containing Radioactive Material".

The basic steps are:

a. Monitor the outside of the package and record the survey reading. The exterior reading limits and notification procedures are in the Appendix F guide. (200 mr/hr at surface and 10 mr/hr at 3 feet from the package surface.)

b. Wear gloves while opening the package behind the lead shield on the hot lab work bench.

c. Check packing material in accordance with the Appendix F guide referenced above. Record the inside packing material survey reading.

d. Report any leakage immediately to the Radiation Safety Officer who in turn will notify the supplier and/or NRC Division of Compliance.

e. Detain the driver or courier of the radioactive shipment if any package is apparently damaged or suspected as leaking, until the shipment is pronounced safe by the Radiation Safety Officer or the proper authorities have been notified. If the driver insists on leaving prior to this time, obtain the driver's name, company name, and phone numbers for any follow-up that may be needed.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

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

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

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

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

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

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

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

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

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

10. Never pipette by mouth.

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

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

13. Always transport radioactive material in shielded containers.

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

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

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

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

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

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

Major Spills

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

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

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

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

5. CALL FOR HELP: Notify the Radiaton 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: _____ See original application.

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

_____
_____
_____

*On the actual copy that is posted in the nuclear medicine department, this information will be filled in and updated as necessary.

APPENDIX I

AREA SURVEY PROCEDURES

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

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

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation level with a survey meter sufficiently sensitive to detect 0.1 mr/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

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

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

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

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

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

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

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

*For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

APPENDIX I

ALTERNATE WIPE TEST METHOD

Alternate method of assaying wipe test (smear test) samples for detecting surface contamination. Because of the relatively small quantities of radioactive materials used at our hospital, we feel the following procedure is sufficient to detect surface contamination levels:

a. Wipe test samples will be assayed by holding the smear immediately adjacent to the open window of our low level g.m. survey meter. Care will be taken to avoid contamination of the probe.

b. The smear will be held adjacent to the probe for approximately 30 seconds to ensure that any contamination over normal background levels will be detectable.

c. Normal background levels at our hospital are approximately 0.05 mr/hr. Any wipe test reading over that level will indicate the need to decontaminate the tested area.

Ref: NRC 313M - Item 18

WASTE DISPOSAL PROCEDURES

G. Unused sources and/or residues are decayed in the lead shielded hot lab storage area for a period of at least (10) half lives (fifteen (15) half lives in the case of Mo-99 and Tc-99m) and/or until radiation levels, as determined with a low level survey meter are found to be that of normal background readings (usually $\leq$0.05 mR/hr) before disposal as regular trash. In certain cases when the initial calibrated activity of a radionuclide is already low, the Radiation Safety Officer may authorize specific disposals before the ten half-lives have elapsed, as long as the surveyed source shows no detectable activity above background on the low level survey meter. Radiation labels are obliterated before such disposal. Surveys are performed with source shielding removed.

We may use any NRC licensed waste disposal service as a back-up method of disposal, especially if an accumulation of long lived waste would develop. We may also transfer radioactive materials to any appropriately licensed recipient.

H. Therapeutic doses of radiopharmaceuticals will be administered under the direct supervision of the licensed physician users. Nursing instructions from NRC Regulatory Guide 10.8, dated October 1980, Appendix K, "Radiation Safety Procedures for Therapeutic Use of Radiopharmaceuticals" will be followed.

I. Therapeutic use of sealed sources will be performed under the direct supervision of the licensed physician users. We will follow procedures and nursing instructions specified in NRC Regulatory Guide 10.8, dated October 1980, Appendix L.

*RADIATION SAFETY OFFICER: _____
ON DUTY PHONE: _____
HOME PHONE: _____

*On the actual copy that is posted in the nuclear medicine department, this information will be filled in and updated as necessary.

REF: NRC 313M - Item 19

We request exemption from following procedures specified in Appendix K, Regulatory Guide 10.8, dated October, 1980, for therapy patients who have received less than 30 mCi and do not require hospitalization because of the amount of radioactive material present. Occasionally, patients who have received less than 30 mCi doses must be hospitalized for other reasons and we do not feel the radiation hazards present in these cases and on such an infrequent basis warrants following the restrictive Appendix K procedures.

We will follow Appendix K procedures for cases where more than 30 mCi therapy doses have been administered.

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 §§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 paragraph 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,

---

*Be sure to submit a complete response to Item 19b in addition to referencing procedures in Appendix K.

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 of linen and floor. In any situation 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.

Date _____

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 _____ chart

_____ bed _____ 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

CONTROL NO. 78593

10.8-45

APPENDIX L

RADIATION SAFETY PROCEDURES FOR THERAPEUTIC USE OF SEALED SOURCES*

1. All patients treated with brachytherapy sources will be placed in a private room that has a toilet.

2. The patient's room will be properly posted or attended in accordance with §§ 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 sources are implanted. Exposure rate measurements will be taken at 3 feet (or 1 m) from the patient with sources implanted, at the patient's bedside, at 3 feet (or 1 m) from the bed, 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 and the exposure rate at 3 feet (or 1 m) from the patient on the patient's chart.

4. Immediately after sources are implanted, the form "Nursing Instructions for Patients Treated with Brachytherapy Sources" will be completed and attached to the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraphs 20.105(b)(1) and (b)(2) of 10 CFR Part 20.

6. Nurses caring for brachytherapy patients will be assigned film or TLD badges. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient. Pocket dosimeters may be assigned in addition to a film or TLD badge.

7. At the conclusion of treatment, a survey will be performed in accordance with paragraph 35.14(b)(5)(vii) of 10 CFR Part 35 to ensure that all sources other than permanent implants have been removed from the patient and that no sources remain in the patient's room or in any other area occupied by the patient. At the same time, all radiation signs will be removed and all film and TLD badges assigned to nurses will be collected. If the patient is to be discharged, the final survey will also include a notation on the patient's chart that the activity remaining in the patient meets conditions for release from the hospital.

8. Instructions to Nurses

   a. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these instructions before administering to the patient. The Radiation Safety Officer should be contacted to answer any questions about the care of these patients in regard to radiation safety precautions.

   b. Nurses should spend only the minimum time necessary near a patient for routine nursing care. Obtain and wear a film or TLD badge or a pocket chamber as instructed by the Radiation Safety Officer.

   c. When a nurse is assigned to a therapy patient, a film or TLD badge should be obtained immediately from the Radiation Safety Officer or his designee. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged among nurses.

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

   e. 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 Radiation Therapy, the Radiation Safety Officer, or the Nuclear Medicine Department at once.

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

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

   h. 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 Radiation Safety Officer or his designee.

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

   i. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, or utensils unless specifically ordered, but these items should be saved for a check with a radiation survey meter to ensure that no sources have been inadvertently displaced into them.

*Be sure to submit complete responses to Items 20a through 20f in addition to referencing procedures in Appendix L.

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

k. These patients must stay in bed unless orders to the contrary are written. In any event, patients will remain in their assigned rooms during the treatment period.

l. 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.

m. Visitors should sit at least 3 feet (or 1 m) from the patient and should remain no longer than the time specified on the form posted on the patient's door and on his chart.

n. No nurse, visitor, or attendant 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.

o. Emergency Procedures

(1) If an implanted source becomes loose or separated from the patient, or

(2) If the patient dies, or

(3) If the patient requires emergency surgery, immediately call _____

_____

Telephone No. (days) _____

(nights) _____

p. At the conclusion of treatment, call the Radiation Safety Officer to (1) survey the patient and room, (2) count the radiation sources to be sure that all temporary implants have been removed prior to discharging the patient, and (3) record a summary of the final survey results on the patient's chart. If any permanent implants are to remain in the patient, the Radiation Safety Officer will brief the patient on precautions for minimizing radiation exposure to others after discharge from the hospital.

_____ 15. All items must remain in the room until approved for disposal by the Radiation Safety Officer or his designee.

_____ 16. Contact the Radiation Safety Office when temporary sources (nonpermanent implants) are removed to perform a survey to be sure all sources are removed from the patient, to do a physical source count, and to be sure no sources remain in the room.

_____ 17. Contact the Radiation Safety Office when the patient is discharged to survey the room prior to its assignment to another patient.

_____ 18. Other instructions.

RSO

Name On-duty, Off-duty Telephone Numbers

CONTROL NO. 7859.3

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH BRACHYTHERAPY SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope and 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

(Comply with all checked items.)

_____ 1. Wear film or TLD badge.

_____ 2. Wear pocket chambers for supplementary personnel monitoring of individual tasks.

_____ 3. Wear rubber gloves.

_____ 4. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 5. Place laundry in linen bag and save.

_____ 6. Housekeeping may not enter the room.

_____ 7. Visiting time permitted: _____

_____ 8. Visitors must remain _____ from patient.

_____ 9. Patient may not leave the room.

_____ 10. Patient may not have visitors.

_____ 11. Patient may not have pregnant visitors.

_____ 12. Patient may not have visitors under 18 years of age.

_____ 13. Patient must have a private room.

_____ 14. A dismissal survey must be performed before the patient is discharged.

REF: NRC 313M - ITEM 20

THERAPEUTIC USE OF SEALED SOURCES

The following information is submitted as additional information concerning Therapeutic Use of Sealed Sources:

1. A diagram of the storage area, including shielding specifications, is attached. The area is locked at all times when occupational personnel are not present, to prevent access by unauthorized personnel.

2. Only the licensed nuclear physician users handle sealed sources. The radiation safety principles of time, distance, and shielding are used in all phases of such handling.

3. Instructions for nurses are detailed in NRC Regulatory Guide 10.8, Appendix L, and the additional instructions for nursing personnel, which are attached to this application.

4. Ring badges are worn by personnel handling sealed sources.

5. The sealed souces are transported in their lead shielded transport/shipping container (description submitted with renewal application) from the storage area to the area of use by the licensed physician user and returned by him to storage.

6. Inventory procedures include a physical count of sources checked out and returned, as well as radiation surveys, to ensure all sources are accounted for after treatment.

7. A dismissal survey, including radiation survey of patient and room after removal of sources, is performed to ensure that all sources have been removed from the patient and from those areas the patient occupied.

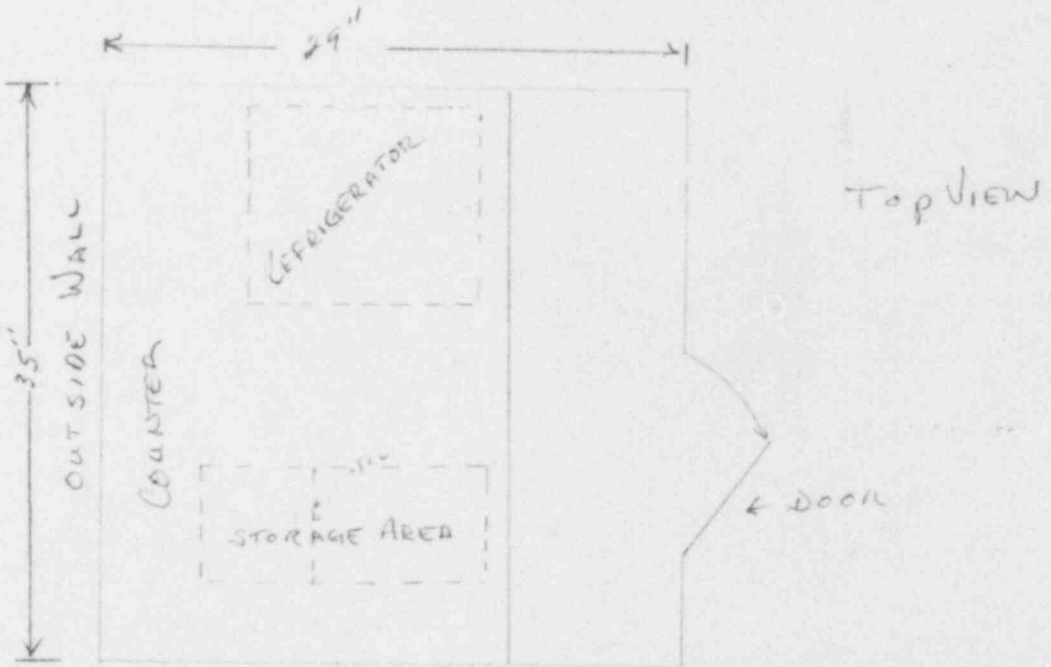
Diagrahm of the Storage area for Radioactive Materials

This area is for the storage of all the radioactive materials used in the Nuclear Medicine Department.

Tthe walls are all lead lined and the door is also lead lined. The door to this area is also locked when the department is not open.

Below the counter is a lead lined storage box and there is also a lead lined refrigerator.

Item #1

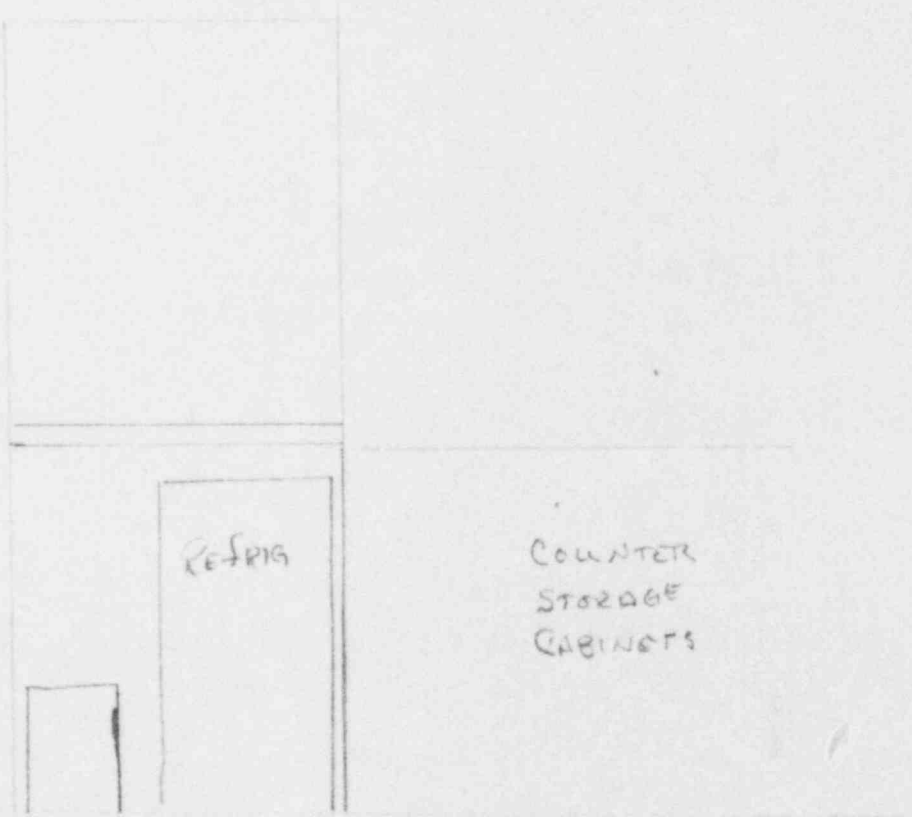


Top View

HOT LAB

THERE ARE ALSO THREE LEAD LINED SLIDING PANELS THAT ARE IN FRONT OF THE LOWER AREA. THEY ARE CLOSED WHEN THE AREA IS USED DURING NORMAL WORKING HOURS

I think



FRONT VIEW

Sealed Source Transport System

The sealed source transport system will be the container the container that is supplied with the materials. The anly sealed source that is used at this time is the I-125 Seeds.

The MIK Injector gun that is used for inserting the seads will be loaded behind a shielded barrier. All seeds will be returned to the Nuclear medicine department.

Item #5

CONTROL NO. 78593

328

St. Lukes Medical Center
2720 Stone Park Blvd.
Sioux City, Iowa 51104

Supporting Documentation for Use of Xe-133

Date: March 15, 1985

In support of our request to use Xe-133 for lung ventilation procedures, we submit the following information as outlined in Appendix M, "Procedures and Precautions for Use of Radioactive Gases", of Regulatory Guide 10.8.

1. Quantities to be used:

   a. (1) We anticipate the maximum annual number of Xe-133 patient studies to be 150 for an average weekly total of 3 patients.

   (2) At 20 mCi/patient, our average weekly utilization of Xe-133 would be 30 mCi.

   b. We request a possession limit of 200 mCi to provide for Xe-133 decaying in storage and for shipments whose calibration dates are several days after receipt.

2. Use and Storage Areas

   a. Attached is a facility sketch showing the areas in which we plan to use and store the Xe-133. Vent locations and planned air flow rates are shown on the sketch. Xe-133 shipments will be stored in the lead shielded hot lab area.

   b. Air flow rates of the vents will be as follows:

   (1) Fraction of air recirculated into other areas of the facility = 0%.

   (2) Exhaust: At least 1606 cfm. This exhaust is direct to the outside and is at least 20 feet distant from the nearest hospital intake duct. No blocking objects will be placed in front of the exhaust vents.

   c. We confirm that total supply vent air in this location will be kept at least 10% below the total exhaust vent rates to ensure a negative pressure effect.

3. Procedures for routine use:

   a. NEN's "Calidose" dispensing system or other NRC licensed system will be used to inject precalibrated single dose Xe-133 into the Xe-133 delivery unit.

b. We plan to use an Atomic Products Model 127-313 Xenon gas trap system or similar NRC-approved Xenon-133 system for these procedures. (Descriptions attached.)

c. Entrance doors to the nuclear medicine area will be closed during any use of Xe-133 gas.

4. Emergency Procedures

In the event of an accidental release of Xe-133 into the room, we will temporarily evacuate the room(s) and reclose the entrance door for a period of 12.55 minutes (five room air exchanges). With a total exhaust rate of at least 1606 cfm and a total room volume of approximately 4032 cubic feet, we estimate one room air turnover to be a maximum of 2.51 minutes.

We confirm that a low level survey meter will be used to survey the affected area to confirm normal background readings prior to permitting reoccupation of the room.

5. Xe-133 Concentrations in Restricted Areas:

20.103 of 10 CFR 20 requires that Xe-133 concentrations, averaged over a 40 hour week for a calendar quarter do not exceed 1 x E-5 uCi.

a. The estimated weekly utilization (A) of Xe-133 in our facilities will be 30 mCi (see Item 1,a,(2) of this application).

b. The estimated fraction of Xe-133 lost (f) during these procedures and during storage is 0.20 (or 20%).

c. The minimum amount of air flow (V) necessary per week to dilute the Xe-133 to less than 1 x E-5 uCi/ml is calculated as follows:

$$A/V \times f \leq 1 \times E\text{-}5 \text{ uCi/ml}$$

or

$$V \geq \frac{A \times f}{1 \times E\text{-}5 \text{ uCi/ml}}$$

$$V \geq \frac{30 \text{ mCi} \times 1000 \text{ uCi/mCi} \times .20}{1 \times E\text{-}5 \text{ uCi/ml}}$$

$$V \geq \frac{6 \times E4 \text{ uCi}}{1 \times E\text{-}5 \text{ uCi/ml}}$$

$$V \geq 6 \times E9 \text{ ml/week}$$

Since 1 cfm = 6.797 x E7 ml/40 hr week, this translates to a required air flow rate of 8.82 cfm.

$$V \geq \frac{6 \times E9 \text{ ml/week}}{6.797 \times E7 \text{ ml/40 hr week/cfm}}$$

$$V \geq 8.82 \text{ cfm}$$

We confirm that the ventilation rate will be well over 8.82 cfm to maintain air concentrations of Xe-133 as low as reasonably achievable. These rates will be checked semi-annually to verify compliance with NRC limits.

6. Xe-133 Concentrations in Unrestricted Areas:

a. We will use a charcoal gas trap as our primary means of disposing of Xe-133. Since Xe-133 gas traps are not 100% efficient for trapping Xe-133, we use the following method to ensure that Xe-133 concentrations will not exceed the 10CFR 20.106 limit of 3 x E-7 uCi/ml, averaged over 1 year.

(1) As calculated in item 5,c., of this application, the estimated fraction of Xe-133 lost during use and storage is 6 x E4 uCi/week.

(2) This can be expressed in uCi/year as follows:

$$6 \times E4 \text{ uCi/week} \times 52 \text{ weeks/year} = 312000 \text{ uCi/year}$$

(3) 10CFR 20.106 requires that $C = A/V \leq 3 \times E\text{-}7$ uCi/ml

The required ventilation rate (V) to maintain concentrations below this level is therefore:

$$V \geq \frac{A}{3 \times E\text{-}7 \text{ uCi/ml}}$$

$$V \geq \frac{312000 \text{ uCi/year}}{3 \times E\text{-}7 \text{ uCi/ml}}$$

$$V \geq 1.04E+12$$

(4) This rate can then be translated to cfm as follows:

$$V \geq \frac{1.04E+12 \text{ ml/year}}{1.484 \times E10 \text{ ml/year/cfm}}$$

$$V \geq 70.08 \text{ cfm}$$

We confirm the ventilation rate will be greater than 70.08 cfm to maintain Xe-133 levels in unrestricted areas as low as reasonably achievable. The air flow rates will be remeasured semi-annually to verify compliance with NRC limits.

b. To monitor our Xe-133 gas trap exhaust (to ensure trapping efficiency) we will use either a commercially available trap monitor (such as a Atomic Products, Model 136-250 Xenalarm) (brochure attached) or will collect Xe-133 gas trap exhaust in a plastic bag and assay the Xe-133 content with ur gamma camera.

If we obtain a trap monitor, we confirm we will follow the manufacturer's instructions for use and calibration frequency of the instrument (at least annually).

The bag method will involve:

(1) Determining camera detection efficiency using a known source of Tc99m, Co-57, Xe-133, or other low energy radionuclide. Configuration of the source will be in the form of a flood phantom rather than a point source to approximate the geometry of the bag.

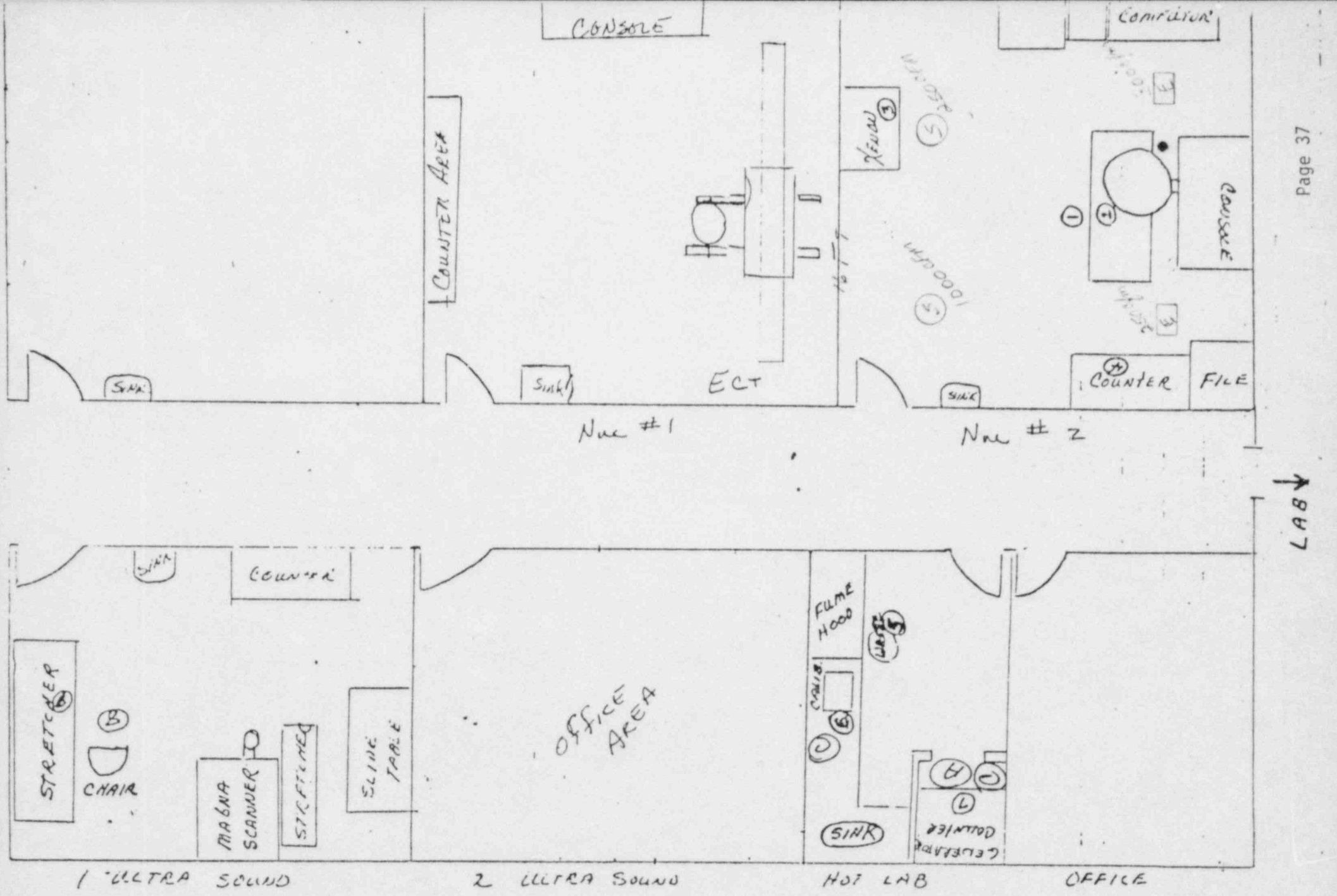
(2) Assaying a Xe-133 exhaust bag and calculating the quantity (activity) of Xe-133 leakage. The frequency of this check will be initially and at least monthly, or more frequently, if more than 30 Xe-133 studies are performed in a given month.

(3) Calculating whether or not the trap is at least 95% efficient by dividing trap leakage by administered activity.

(4) Manufacturers specify that charcoal traps are at least 98% efficient for trapping Xe-133. Therefore, we feel that 95% is a reasonable action level at which point the charcoal filters would need replacement.

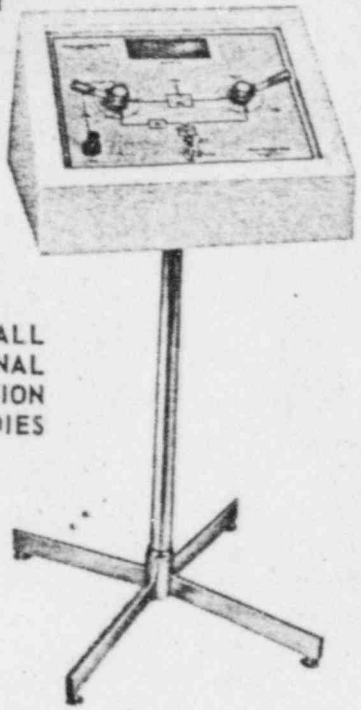
(5) The saturated filter will be removed and the portals will be tightly capped with rubber stoppers. In this manner, the cartridge will not leak since air is not flowing through the unit. The surface readings of the lead shielded "saturated" cartridge should not exceed normal background levels, as determined with a low level survey meter, or additional lead foil (1/8" thick) will be wrapped around the cartridge until this background reading is achieved. The unit will be stored in the hot lab storage area and allowed to decay. The attached sketches, descriptions of shielding, and previously defined calculations of average concentrations in air should serve to also cover this final phase of Xe-133 handling procedures.

We also confirm that all disposal items are to be surveyed with a low level g.m. survey meter to confirm exposure rates of normal background (less than 0.05 mr/hr) prior to disposal.



ST. LUKE'S MEDICAL CTR., SIOUX CITY, IA

XENON DELIVERY UNIT



PERFORMS ALL REGIONAL VENTILATION STUDIES

#130-330

The Model 130-133 Xenon Delivery Unit offers an uncomplicated and inexpensive method for delivering Xenon gas for regional ventilation studies. Designed for simple, efficient and reliable operation, the unit will perform rebreathing, washout, perfusion and single breath studies with a minimum of effort. Two valves mounted on the instrument panel direct air flow for the procedure desired.

A lead glass viewing window in the panel permits observation of the breathing bag. Oxygen is thus monitored at the initiation of the study and added if required during the procedure. A push button valve starts and stops the O_2 flow. A one-way valve allows resistance free breathing in equilibrium and washout cycle. Simple-to-follow panel instructions and full lead lining insure complete safety for patient and technician.

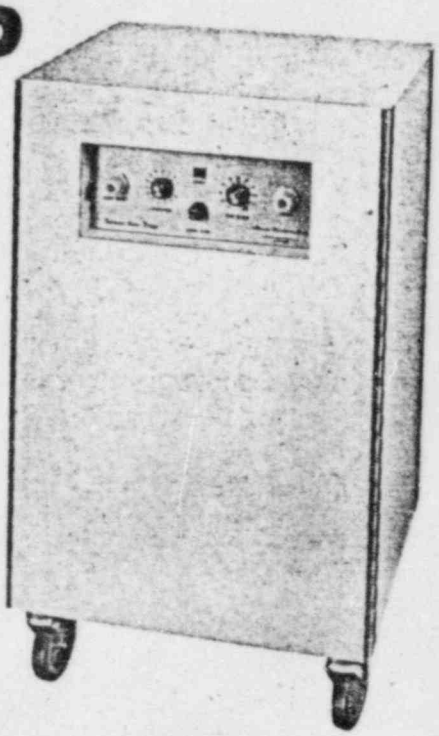
The unit will accept any commercially available Xenon source. The washout exit port can be easily vented to a trap, bag or hood. A CO_2 absorber cartridge is placed in line to prevent CO_2 build-up within the closed circuit. The cartridge is easily replaced between patient studies. A bacteria trap eliminates the need for sterilization. Each system includes complete instruction manual. Size 18" x 19" x 39".

130-330	Xenon Delivery Unit	$1195.00
130-550	Disposable Mouthpiece	1.95 ea.
130-740	Optional Stand	25.00
130-700	Disposable Bacteria Filter	3.25 ea.
139-101	Moisture Absorber (Drierite)	7.50 lb.
130-019	Soda Lime, CO_2 Absorber	5.25 lb.

XENON GAS TRAP

REMOVES XENON FROM EXHALED AIR

YEAR GUARANTEE ON CARTRIDGE



#127-313

Now Xenon can be efficiently removed from exhaled air without the awkwardness and expense of venting to the outside. Such venting is regulated and may be completely prohibited by NRC or state law. The Atomlab 127-313 lead shielded Xenon Gas Trap draws air through a bed of specifically compounded activated charcoal aggregate. As expelled air migrates through the cartridge, radioactive xenon adheres to the charcoal aggregate and eventually decays. The cartridge is designed, packed and mounted to give optimal adsorption efficiency and prevent "channelling" and "walling" of the gas. The trap effluent is virtually devoid of radioactivity. The patient output is gently drawn in by an induction vacuum pump; flow speed can be adjusted and monitored to assure patient comfort. A timing device allows the operator to choose the desired washout time (1 to 15 minutes) and automatically shut down when the study is completed. A pilot light indicates when the unit is in operation.

The model 127-313 Xenon Gas Trap can be easily integrated into any ^{133}Xe system or may be used independently as a patient exhalation unit. The 1/8" lead shielding makes external radiation levels negligible. A dessicant cartridge on the input line functions as a water trap.

SPECIFICATIONS

Size: 18"x19"x34"
Mobility: Rolls on 4" casters
Weight: 125 Lbs.
Finish: White Formica
Power: 115V.
Controls: On-Off/Timer switch, Pilot Light, Air Flow Controls

127-313	Xenon Gas Trap	$1195.00
127-318	Replacement Charcoal Cartridge	325.00
087-130	220V Converter	150.00

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

St. Luke's Regional Medical Center
(Licensee's Name)

3-85
(Date)

1. Management Commitment

a. We, the managment of this (medical facility, hospital, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)* and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, icluding ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

* Private practice physician licenses do not include an RSC.

2. Radiation Safety Committee (RSC)*

a. Review of Proposed Users and Uses

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

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

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

b. Delegation of Authority

(1)he judicious delegation of RSC authority is essential to the enforcement of an ALARA concept.

(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 necesary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA program

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

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).**

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

** 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 investigations.

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

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific proedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

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

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

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

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

b. Responsibility of Authorized User to Persons Under His/Her Supervision.

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

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

5. Persons Who Receive Occupational Radiation Exposure

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

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

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

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initial review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed on Table 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

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 required by 10.401 of 10 CFR part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

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 0-1 values for Investigational Level I.

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

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

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

The RSC will review the justification for and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official*

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

X Robert F. Peck
Signature

Robert F. Peck
Name (print or type)

Administrator
Title

Institution (or Private Practice) Name and Address:

St. Luke's Medical Center
2720 Stone Park Blvd
Souix City, Iowa

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