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

St. Anthony Medical Center
Main and Franciscan Road
Crown Point, Indiana 46307

TELEPHONE NO.: AREA CODE (219) 738 2100

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Mr. Peter Seghi

TELEPHONE NO.: AREA CODE (219 738 2100

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. XX RENEWAL OF LICENSE NO. 13-15933-01

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

Leon E. Kinasiewicz, M.D.- All except
J. K. Dixit M.D. - Groups I, II, III, In
Vitro Studies-Xenon-133
A.S. Kim M.D.- Groups I, II, III, Xenon-133
Doyle L. Simmons, M.D. Group VI

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.)*

RSO: Frances L. Moser, PhD
Alternate RSO: Leon E. Kinasiewicz, M.D.

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 each
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000 each
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 total

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	100

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
Americium - 241	Sealed Source Amersham Corp. Model AMC 24	15	Calibration, motion correction for Siemens Gammasonics 495/4300 C Source assembly

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OCT 23 1984
REGION III

NRC FORM 313M (9-81)

CONTROL NO. 77675

OCT 23 1984

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REG3 LIC30
13-15933-01 PDR

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; XX and Appendix O *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE See attached list License#13-15933-01	
	Supplements A & B Attached for Each Individual User; and
X	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	
X	Appendix D Procedures Followed for Survey Instruments; or Form Attached *(Check One)*
	Equivalent Procedures Attached; and
X	Appendix D Procedures Followed for Dose Calibrator; or Form Attached *(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)*	
	Appendix F Procedures Followed; or
X	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
	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; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	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	Siemens	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

RECEIVED BY LFMB
Date 10/29/84
Log 84-26
By P Tu
Orig. To
Action Compl.

Applicant
Check No. 14021
Amount Fee Category 580
Type of Fee 7C Ren
Date Check Rec'd 10/29/84
Received By

25. FOR PRIVATE PRACTICE APPLICANTS ONLY N/A

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 Human Uses.... Other, renewal

(2) LICENSE FEE ENCLOSED: $ $580

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Peter G. Rogan

(1) NAME *(Type or Print)* Peter G. Rogan, PhD

(2) TITLE President & Chief Executive Officer

c. DATE

NRC FORM 313M (9-81)

CONTROL NO. 77675

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.

ITEM 7. Medical Isotopes Committee

Names and Sepcialies:

Physician's and Physicist's Curriculum Vitae are attached.

Leon E. Kinasiewicz, Chairman	Nuclear Medicine, Radiology
Peter Seghi	Administration Vice President in charge of Professional Services
Aloys M. Rieser, Jr., M.D.	Pathology
Doyle L. Simmons, M.D.	Radiation Therapy
Sheldon Kahn, M.D.	Internal Medicine
Frances L. Moser, PhD	RSO, Radiation Safety Radiological Physics
Carl Wheeler	Administration Manager of Nuclear Medicine

DUTIES:

Duties as Appendix B. Also per the ALARA PROGRAM (appendix O)

The Medical Isotopes Committee serves as the Radiation Safety Committee and fulfills the duties and purposes in Regulatory Guide 8.18-2.6 (attached) and Appendix O of Regulatory Guide 10.8 (attached).

ITEM 7

CURRICULUM VITAE

NAME:	Leon E. Kinasiewicz, M.D.
ADDRESS:	St. Anthony Medical Center Main at Franciscan Road Crown Point, Indiana 46307
DATE OF BIRTH	January 31, 1934
BIRTHPLACE	Gary, Indiana
EDUCATION	1962 B.S. Pharmacy Purdue University Lafayette, Indiana
	1966 M.D. Indiana University School of Medicine Indianapolis, Indiana
INTERNSHIP	1966-1967 South Bend Memorial Hospital South Bend, Indiana
RESIDENCIES	1967-1970 Radiology University of Minnesota Hospital Minneapolis, Minnesota.
MILITARY	United States Air Force - 1953-1957 Honorable Discharge
POSTGRADUATE EDUCATION	1974 Nuclear Medicine University of Minnesota Minneapolis, Minnesota
	1974 Xeroradiography Hutzel Hospital Detroit, Michigan
	1976 Nuclear Medicine Central Chapter of Nuclear Medicine Chicago, Illinois
	1976 Computerized axial tomography George Washington & Utah Universities
LICENSURE AND BOARDS	Indiana Minnesota California
	Certified by American Board of Radiology-1971
	Certified by American Board of Nuclear Medicine - 1976
PROFESSIONAL SOCIETY MEMBERSHIP:	American College of Radiology American Medical Association

ITEM 7

CURRICULUM VITAE

NAME:	Aloys M. Rieser, Jr., M.D.
ADDRESS:	St. Anthony Medical Center Main at Franciscan Road Crown Point, Indiana 46307
DATE OF BIRTH	April 17, 1936
BIRTHPLACE:	St. Louis, Missouri
EDUCATION:	1958 B.S. St. Louis University St. Louis, Missouri 1962 M.D. St. Louis University St. Louis, Missouri
INTERNSHIP:	1962 - 1963 St. Louis University Hospital Group St. Louis, Missouri
RESIDENCIES:	1963 - 1966 South Bend Medical Foundation South Bend, Indiana
MILITARY:	United States Army Medical Corp 1966-1968
LICENSURE:	Indiana Missouri
CERTIFICATION:	American Board of Pathology - Anatomical and Clinical - 1969
PROFESSIONAL SOCIETY MEMBERSHIP:	American Society of Clinical Pathologists Clinical and Anatomical Pathology College of American Pathologists A.A.B.P.

ITEM 7

DOYLE LEE SIMMONS
Curriculum Vitae

10-8-34	Born at Memphis, TX.
1952-56	Texas Technological College, Lubbock, TX.
1956-60	University of Texas Southwestern Medical School, Dallas, TX, M.D. degree.
1960-61	Internship--Rotating General--St. Joseph Hospital, Fort Worth, TX.
1961-62	US Public Health Service Hospital, New Orleans, LA. Responsible for out-patient Pediatrics.
1962-63	US Public Health Service Indian Hospital, Lawton, OK.
1963-64	General Practice, Eden, TX.
1964-67	Radiology Residency, Baylor University Affiliated Hospitals, Houston, TX.
1967	Pathology Fellowship, three months, Armed Forces Institute of Pathology, Washington, DC.
1967-68	Instructor in Radiology, Baylor University College of Medicine, Houston, TX.
1968	Certified in Radiology, American Board of Radiology.
1968-81	Private Practice of Radiology, predominantly Radiation Therapy, Albuquerque, NM: 1971-80 Member Hospital Staff Executive Committee; January, 1979--December, 1980 President of Hospital Medical Staff.
1982-83	Therapeutic Radiology Residency, Indiana University, Indianapolis, IN.
10-83	Satisfactorily completed written therapy boards.
10-1-83	Assistant Professor of Radiation Oncology, Indiana University, Indianapolis, IN.
Memberships	American Society of Therapeutic Radiologists American College of Radiology American Medical Association
Address	9996 Cedar Point Drive (317)846-8440 (home) Carmel, IN 46032 (317)264-2524 (office)

Doyle L. Simmons

ITEM 7

CURRICULUM VITAE

NAME: Frances L. Vollert Moser

DATE AND PLACE OF BIRTH: May 5, 1943
Spokane, Washington

EDUCATION:

University of Chicago, Chicago, Illinois
Degree: B.S., Physics 1965

University of Chicago, Chicago, Illinois
Degree: M.S., Physics 1967

University of Chicago, Chicago, Illinois
Degree: Ph.D., Physics 1977
Enrolled 1967-72
All Ph.D. requirements met (except publication), 1972
Thesis published, diploma awarded, 1977.

University of Chicago, Chicago, Illinois
Medical Physics, Department of Radiology
Program: 3 year Post Doctoral Training/Research Program in Medical Physics (the Physics of Diagnostic Radiology, Nuclear Medicine, Radiation Therapy and Health Physics) 1973 - 1976
Degree: Post Doctorate, Medical Physics

PROFESSIONAL EMPLOYMENT:

Radiological Physicist, Department of Radiology, St. Anthony's Medical Center, Crown Point, Indiana May 14, 1984 to date.

Medical Radiation Physicist, Hinsdale Sanitarium and Hospital, Department of Radiology, and M.D. Radiologists, Hinsdale, Illinois. October 1979 to May, 1984.

Radiation Therapy Physicist, Assistant Professor, Northwestern Memorial Hospital, Chicago, Illinois. February 1976 to September 197

Research Associate with rank of instrutor, University of Chicago, Department of Radiology and Franklin McLean Memorial Research Institut (F.M.I.), Chicago, Illinois. June 1974 - January 1976.

Post-Doctoral Fellow in Medical Physics, University of Chicago, Franklin McLean Memorial Research Institute and the Department of Radiology, Chicago, Illinois. 1973 - 1974.

Research Assistant, Enrico Fermi Institute, University of Chicago, Chicago, Illinois. 1968 - 1972.

Teaching Assistant and Laboratory Instructor for senior undergraduate in atomic physics course. 1965 - 1966.

PROFESSIONAL SOCIETIES AND CERTIFICATION:

Certified by the American Board of Radiology in Therapeutic Radiologic Physics, 1977.
American Physical Society.
American Association of Physicists in Medicine
Radiological Society of North America
American College of Radiology
American Endocurie Society

ITEM 7

MOSER

INSTITUTIONS: Listed as Radiation Safety Officer/Qualified Expert Physicist on Illi nois State and NRC licences and served on Isotope Committees while employed at the following institions:

Oak Park Hospital, Oak Park, Illinois (NRC #12-00912-03) 1976-78

Northwestern Memorial Hospital, Chicago, Illinois (NRC #12-02501-04) 1976-78

St. Mary of Nazareth Hospital, Chicago, Illinois 1976-78

Hinsdale Hospital, Hinsdale, Il. Deputy Radiation Safety Officer for Therapy. 1978-84.

ITEM 7 cont

2.6 Radiation Safety Committee

Part 35 requires that a radiation safety committee be appointed to supervise the institution's radiation safety program. Typical functions and responsibilities of the committee are given in Regulatory Guide 10.8. The RSO, who is required to be a member of the committee, may either serve as chairman or assist the chairman in preparing for and conducting meetings and maintaining committee records.

Meetings of the committee should be held at least quarterly. Every member of the committee should be invited to each meeting.

The purposes of the meetings should include:

a. Discussing any radiation safety problems requiring a general solution;

b. Determining whether current procedures are maintaining exposures ALARA;

c. Considering new proposals for the use of radioisotopes and evaluating the safety of those uses and the qualifications of the users; and

d. Auditing the radiation safety program to ensure that it meets all the goals presented in Sections C.2.1 through C.2.5 and all pertinent regulations.

All radiation safety committee meetings should be documented by a record of minutes approved by committee members and filed as part of the radiation safety record system within 60 days following each meeting.

ITEM 7 cont

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

_____

(Licensee's Name)

_____

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

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

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

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

2. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

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

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

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

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

[1] Private practice physician licenses do not include an RSC.

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

c. Review of ALARA Program

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

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).[3]

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

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

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

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

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

b. Education Responsibilities for ALARA Program

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

(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

[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 investigations.

ITEM 7 cont

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

5. **Persons Who Receive Occupational Radiation Exposure**

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

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

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

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

Table O-1

	Investigational Levels (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 § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

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

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table O-1 values for the Investigational Level I.

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

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

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

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

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

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

The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official[4]

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

_____

Signature

_____

Name (print or type)

_____

Title

Institution (or Private Practice) Name and Address:

_____

_____

_____

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

ITEM 8. TRAINING AND EXPERIENCE

The physicians listed as users on our present license are to be retained on our renewal for the same Groups listed on our present license. Per 10.8 p. 4, we list here the license number under which they were previously authorized as physician users. Physician users are summarized here in tabular form.

NAME	AUTHORIZED GROUPS	LICENSE # UNDER WHICH THEY WERE PREVIOUSLY AUTHORIZED
Leon E. Kinasiewicz, M.D.	I, II, III, IV, V, *in vitro* studies Xe-133	13-15933-01
J.K. Dixit, M.D.	I, II, III, *in vitro* studies and Xenon-133	13-15933-01
H.S. Kim, M.D.	I, II, III, Xenon-133	application for 13-15933-01 is pending
Doyle L. Simmons, M.D.	VI	application for 13-15933-01 is pending

ITEM 8 cont.

NRC FORM 313M SUPPLEMENT A
(9-81)

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
Frances L. Moser, PhD	N/A

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiological Physics	December, 1977
Previous RSO positions NRC	License #12-00912-03, #12-02501-04, #12-03536-03	

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES N/A

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)* N/A

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

ITEM 8 cont

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
Leon E. Kinasiewicz, M.D.	IN.

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Nuclear Medicine	Nuclear Medicine	December, 1976
American Board of Radiology	Radiology	June, 1971

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES N/A

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)* N/A

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

ITEM 9

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Victoreen

Manufacturer's model number: 470A CutiePie

Number of instruments available: 1

Minimum range: 0 mR/hr to 3 mR/hr

Maximum range: 0 mR/hr to 10^6 mR/hr = 1000R/hr

b. Manufacturer's name: Victoreen

Manufacturer's model number: Model 6B GM Counter

Number of instruments available: 1

Minimum range: 0 mR/hr to 0.5 mR/hr

Maximum range: 0 mR/hr to 50 mR/hr

2. Dose calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-6A

Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Scintillation Camera	Siemens	ZLC750S
Tomographic Scanning Camera	Siemens (Searle)	Pho/Con 192
Mobile Camera	Picker	Dyna Camera 4
Gas Delivery & Trap System	RadX	Model 120, Venti 1-Con 200A
Fibrinogin Deep Vein Thrombosis Detector	Actus	FP200

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

Adac Nuclear Medicine Computer System		
Well Counter/NaI Crystal/Scaler	Nuclear Chicago	Stock 1#008725-034
Ionization Chamber Dosimetry System	Victoreen	500 - Electrometer
(May be useful for inter comparisons)		30-361 Chamber

ITEM 10

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

__X__ 1. Survey instruments will be calibrated at least annually and following repair.

__X__ 2. Calibration will be performed at two points on each scale used for radiation protection purposes, i.e., at least up to 1 R/hr.

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

3. Survey instruments will be calibrated

_____ a. By the manufacturer

__X__ b. At the licensee's facility

(1) Calibration source Cs 137

Manufacturer's name Radiation Therapy Recourses Inc.
Model no. 67-802, 67-803, 67-804, 67-805 as needed
Activity in millicuries 25.6, 38.4, 51.1, 63.8, respectively
or
Exposure rate at a specified distance * Please see below.
Accuracy ± 5%
Traceability to primary standard Yes, certificate supplied by Radiation Therapy Resources Inc. These sources not purchased yet as Group VI Licensure is pending.

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

or

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

OR: __X__ c. By a consultant or outside firm

(1) Name Health Physics Associates

(2) Location Northbrook, IL.

(3) Procedures and sources

__X__ have been approved by NRC and are on file in License No. 12-09160-03

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

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

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

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

* Respectively 8.5, 12.7, 17, 21 mr/hr at 1 meter, combined as needed.
For example: 2 x 63.8 mCi sources yield 1.05 R/hr at 20 cm.

ITEM 10 FORM TO BE USED FOR 3b LICENSE CALIBRATIONS

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments:

Nuclide	Activity or Exposure Rate at Specified Distance	Calibration Accuracy

Calibration Source:

Calibrated by _____ Date _____

ITEM 10

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

X Other* (specify) Calibrated Source Supplied by Sencor International, Inc. 50 mCi Tc99m

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	.5	± 5
Ba-133	0.1-0.5	.250	± 5
Cs-137	0.1-0.2	.205	± 5
Ra-226	1-2		

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

or

_____ Equivalent procedures are attached.

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

ITEM 11

The diagram of the nuclear medicine facility is attached. The letters A-H indicate locations where surveys and wipes are taken at least weekly.

a) We do not use Tc-99m generators at present.

b) Non-refrigerated radiopharmaceuticals are stored behind a wall of 2 inch thick lead bricks. The L-Shield provides additional shielding. Sealed low level check sources are stored in Nuclear Associates 53-500 storage facility with a 1/16" Pb lining and a 1/4" Pb door. The Nuclear Associates 53-376 refrigerator is lined with 1/8" lead on the sides and 1/16" lead on the rear.

c) Most radioactive waste, including syringes, is returned to Syncor International, Inc., our radiopharmaceutical supplier. Radioactive material that is being held until it decays to background level is stored in the hot laboratory behind walls of 2" to 4" thickness of lead bricks.

d) Preparation and dispensing of Group III kit radiopharmaceuticals is done behind a lead glass L-block.

The work areas and storage area are well removed from unrestricted areas. Room surveys, surveys of adjacent areas, inspections, and calculations based on weekly mCi loads confirm that exposure levels are well below the permissable levels.

Long handled forceps are used for handling sources. As mush as possible sources are handled behind a lead glass L-block. Lead shielded syringes are used. Three fans in the nuclear medicine department ensure good air flow.

A fume hood is available for use in the hospital laboratory. For cases where a hood would be required the RSO would case by case designate the work area as a restricted area, perform surveys and wipes, and perform clean up as needed before restoring the areas to unrestricted areas. Therefore we have done no cases of the type requiring a hood and do not anticipate accepting such cases. Therapeutic doses of I-131 will be routinely administered in capsule form.

Item 11

DAILY RADIATION SURVEY AND WIPE TESTS

Locations:	SURVEY	WIPE TEST
A	_____	_____
B	_____	_____
C	_____	_____
D	_____	_____
E	_____	_____
F	_____	_____
G	_____	_____
H	_____	_____

Refrigerator: _____

norm : 38° F. [± 5]

Processor: _____

norm : 89° F. [± 2]

DATE _____

TECH _____

Item 11 Dept. of Nuclear Medicine
St Anthony's Medical Center
Crown Point, Ind.

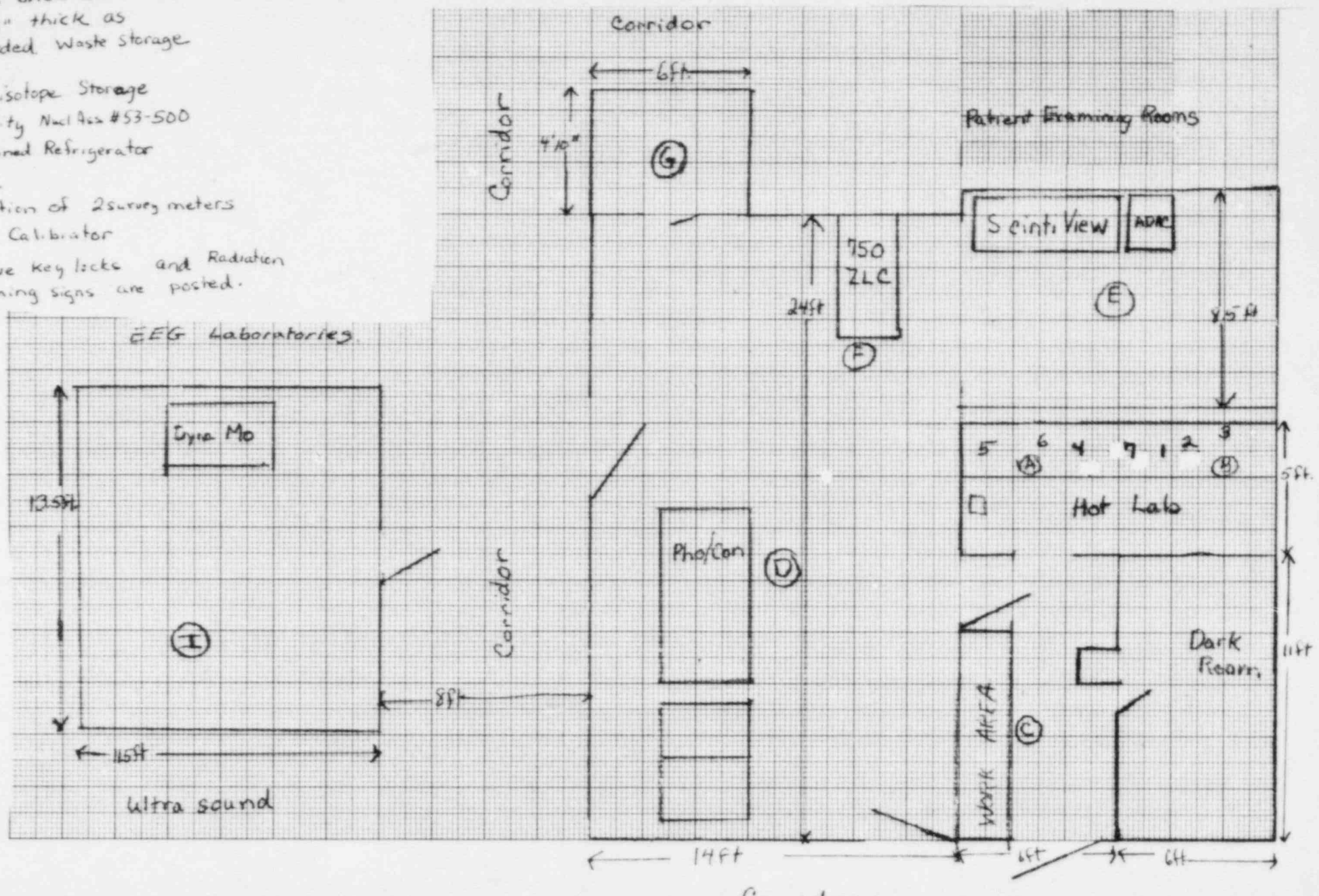
Drawing of facility
Not to scale
Thicknesses of walls not shown Distance and local lead shielding are used in protection evaluation calculations.

Location

1. Lead Brick wall 2" thick
   Isotope storage
2. Lead Brick wall
   2"-4" thick as
   needed Waste Storage
3. Radioisotope Storage
   Facility Nucl Reg #53-500
4. Lead-lined Refrigerator
5. Sink
6. Location of 2 survey meters
7. Dose Calibrator

Doors have key locks and Radiation Warning signs are posted.

Ⓐ-Ⓗ Location where wipes are taken, minimum interval weekly.
Ⓐ-Ⓗ Location of daily surveys.



ITEM 12 PERSONNEL TRAINING PROGRAM

All Nuclear Medicine Personnel receive training in radiation safety and protection, new procedures and new instrumentation at a minimum of 2 hours per quarter.

All radiation therapy personnel receive training in radiation safety and protection, safe handling of radioactive materials, new procedures and new instrumentation at a minimum of 2 hours per quarter.

Other personnel, i.e. nursing, housekeeping and security are instructed in items listed in Section 19.12 of 10 CFR part 19. This instruction is yearly, unless otherwise needed. All instruction will be conducted by the RSO radiological physicist, the physician in charge of Nuclear Medicine or Radiation Therapy, the Chief Nuclear Medicine Technologist, the Director of Radiation Therapy Technologists, or commercial representatives.

The Medical Isotopes Committee and RSO review programs and procedures per the Alara program Appendix O and may recommend training to specific groups per specific topics based on their monitoring of need.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY OF 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 Personnel

FROM: John Jones, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIO[illegible]MATERIAL

Any packages containing radioactive material that arrive [illegible]:[illegible]m. and [illegible]a.m. or on Sundays shall be signed for by the Security guard 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 hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: _____

OFFICE PHONE: _____

HOME PHONE: _____

** Submit a copy of your own institution's memorandum.

ITEM 13

MEMORANDUM FOR: Security Personnel

FROM: Peter G. Rogan, Pres. Exec. Dir.

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 9:00 p.m. and 6 a.m. or on Sundays shall be signed for by the Security guard 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 hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER: Frances L. Moser, PhD

OFFICE PHONE: 219-738-2100

HOME PHONE: 815-741-8828

CONTROL NO. 77675

ITEM 14

Our routine radioactive shipments do not exceed Type A Quantity limits. For completeness we include in our Procedure Manual that Appendix F procedures should be followed when Type A quantity limits are exceeded. (Attached).

Our routine procedure and forms are attached.

Item 14 cont

ST. ANTHONY MEDICAL CENTER

PROCEDURE FOR RECEIPT, STORAGE AND RETURN OF RADIOACTIVE MATERIALS OBTAINED FROM AN OUTSIDE NUCLEAR PHARMACY OF ROUTINE NUCLEAR MEDICINE QUANTITY ("TYPE A")

1. Cases/packages will be visually inspected for damage. If the case/package looks as if it has been dropped and/or damaged in any way, it will NOT be opened and the Nuclear Pharmacy and Radiation Safety Officer will be called immediately.
2. If the case/package passes visual inspection, a surface monitoring will be done with the geiger counter and the results recorded in the log.
3. Upon opening of the case/package, the individual dose will be placed in the appropriate area. (Isotopes requiring refrigeration will be placed in the lead lined refrigerator and all other doses will be placed behind the lead bricks in the HOT lab.)
4. After the use of any dose, the record copy of the dose label will be filled out with the patient's name, placed in the log book and the date, time of injection, amount of injection and initials of the Technologist will be entered in the appropriate place in the Isotope Log Record.
5. At the end of the work day all remaining unused doses will have their record copy of the dose label placed in the log book.
6. At that time all labels for that day will be stamped with the disposal stamp.
7. All doses, used and unused, will then be placed back in the original shipping cases and the Nuclear Pharmacy will pick them up for disposal.

Item 14 cont

RADIOACTIVE PACKAGING

INSPECTION

DATE:_____ TECH:_____

SUPPLIER:_____ RADIOACTIVE LABLE:_____

CONDITION OF PACKAGE:_____ PACKAGE COUNT:_____

BACKGROUND:_____

DATE:_____ TECH:_____

SUPPLIER:_____ RADIOACTIVE LABLE:_____

CONDITION OF PACKAGE :_____ PACKAGE COUNT:_____

BACKGROUND:_____

DATE:_____ TECH:_____

SUPPLIER:_____ RADIOACTIVE LABLE:_____

CONDITION OF PACKAGE :_____ PACKAGE COUNT:_____

BACKGROUND:_____

LABLE I : surface levels are 0.5 mr/hr or less

LABLE II: surface levels are between 0.5mr/hr and 10 mr/hr

LABLE III: surface levels are between 10 mr/hr and 200 mr/hr

DATE	TIME	AMOUNT	TECH	DATE	TIME	AMOUNT	TECH

Item 14 cont.

DATE	TIME	AMOUNT	TECH	DATE	TIME	AMOUNT	TECH

DATE	TIME	AMOUNT	TECH

DATE	TIME	AMOUNT	TECH

DATE	TIME	AMOUNT	TECH

DATE	TIME	AMOUNT	TECH

ITEM 14

ST. ANTHONY MEDICAL CENTER
PROCEDURE MANUAL DEFINITION
TYPE A QUANTITY LIMITS

Different procedures for processing radioactive packages apply depending on the quantity of radioactive materials in the package.

The NRC has defined "Type A Quantity Limits" in paragraphs 20.205(a) (1) and (c) (1) of 10 CFR Part 20. This publication is kept in the Nuclear Medicine Department and in the RSO office.

Some examples of Type A quantity limits are:

1. Less than 10 mc of radioactive materials consisting solely of tritium, C-14, Sulfur-35, or Iodine-125.

2. Packages containing only radioactive materials as gases or in special form.

3. Packages containing only radionuclides with half-lives less than 30 days and a total quantity no more than 100 mci.

4. Per Regulatory Guide 10.8 20 Ci for Mo99 and Tc99m.

Use this procedure for packages containing more than "Type A" quantity limits of radioactive material (more than 20 ci of Tc 99m).

Use this procedure for all packages to be used for therapeutic uses of radionuclides and sealed sources.

APPENDIX F

Item 14 cont.

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 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.

      (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 and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

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

Use this procedure for packages containing more than "Type A" quantity limits of radioactive material (more than 20 ci of Tc 99m).

Use this procedure for all packages to be used for therapeutic uses of radionuclides and sealed sources.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1. P.O. No.: _____ Survey Date _____ Time _____

   Surveyor _____

2. CONDITION OF PACKAGE:

   _____ O.K. _____ Punctured _____ Status _____ Wet

   _____ Crushed _____ Other

3. RADIATION UNITS OF LABEL: _____ Units (mR/hr)

4. MEASURED RADIATION LEVELS:

   a. Package surface _____ mR/hr

   b. 3 feet or 1 meter from surface _____ mR/hr

5. DO PACKING SLIP AND VIAL CONTENTS AGREE?

   a. Radionuclide _____ yes _____ no, difference _____

   b. Amount _____ yes _____ no, difference _____

   c. Chem Form _____ yes _____ no, difference _____

6. WIPE RESULTS FROM:

   a. Outer _____ CPM = _____ DPM

      eff = ( )

   b. Final source container _____ CPM = _____ DPM

      eff = ( )

8. SURVEY RESULTS OF PACKING MATERIAL AND CARTONS _____ mR/hr, CPM

9. DISPOSITION OF PACKAGE AFTER INSPECTION _____

10. IF NRC/CARRIER NOTIFICATION REQUIRED, GIVE TIME, DATE, AND PERSONS NOTIFIED.

_____

Signature Date

ITEM 18

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

__X__ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

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

__X__ Other (specify): Returned to the supplier for disposal.

2. Mo-99/Tc-99m generators will be (check as appropriate)

__X__ Returned to the manufacturer for disposal.

_____ 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.**

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

_____ Other (specify): _____

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

__X__ Held for decay* until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

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

__X__ Other (specify): Returned to the supplier for disposal.

4. The commercial waste disposal service used will be

Syncor International Corporation (Name) Dyer, IN Chicago, IL (City, State)

NRC/Agreement State License No. 12-19333-01MD

For products supplied by Syncor

4. (Continued)

All radioactive waste is either held for decay or returned to the manufacturer, Syncor International Corporation. We do not currently need to use waste disposal service. If waste disposal is required only an NRC licensed waste disposal service would be used.

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

**These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

ITEM 19

The room survey form and a supplementary, equivalent nursing instructions form is attached.

Item 19

ST. ANTHONY MEDICAL CENTER

SURVEY DATE_____ ROOM_____

SOURCES_____ STRENGHT(mCi Totel)_____

INSERTED_____ REMOVAL_____

NAME_____ HOURS_____

AREA SURVEY

POSITION	DOSE RATE (mrem/hr)	HOURS ALLOWED	MPD	REMARKS
1 Meter				
Chair (6')				
Doorway				
Adj. Walls				
N				
S				
E				
W				
Floor				
Ceiling				

CHECK LIST:

Warning on door

Warning on chart

Nursing instructions on chart

Sketch

SURVEY BY_____

EVALUATION_____
Radiation Safety Officer

ITEM 19

ST. ANTHONY MEDICAL CENTER
DEPARTMENT OF RADIATION THERAPY
NURSING CARE FOR PATIENTS WITH THERAPEUTIC RADIONUCLIDES

RADIONUCLIDE: _____ QUANTITY _____ mCi.

INSERTED IN: (part of body) _____

INSERTED ON: _____ AT _____

EXPOSURE RATE AT ONE METER FROM PATIENT _____ mR/hr.

1. No patient is to be released from the hospital without Radiation Safety approval.

2. Patients are normally treated in a private room with the bed at least three feet from inside walls. Ambulatory patients are to remain in the room and they are to sit at least three feet from the inside walls.

3. Visitors shall remain at least _____ feet from the patient. No visitor shall remain in the room for more than _____ hours a day. Visitors are encouraged to visit by phone. No visitors are to be less than 18 years of age or pregnant.

4. No nurse or other attendant shall remain in the room or in close proximity to the patient for more than a total of _____ hours per day. Pregnant nurses or attendants shall not be assigned to this patient.

5. Ambulatory patients may use private toilet facilities in the normal way. Nurses handling bed pans should wear rubber gloves; they should wash the gloves before removing, remove in a sterile manner, and wash hands again.

6. If the patient soils the bed linen, floor, etc. by vomiting or incontinence within _____ hours of the administration of the dose, do not attempt to clean up. Notify the administering physician and the Radiation Safety Officer, Ext. 1471.

7. In the event of death, immediately notify the Radiation Safety Officer and the Radiation Therapy Department Ext. 1471. Do not remove the body from the room without the approval of the Radiation Safety Officer.

8. Personnel monitoring is required for all nurses providing extended personal care to patients.

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

IF THERE ARE ANY QUESTIONS RELATED TO THESE INSTRUCTIONS, PLEASE CONTACT THE DEPARTMENT OF RADIATION THERAPY OR RADIATION SAFETY OFFICER EXT. 1471.

(IMPRINT PLATE)

_____
Radiation Safety Officer

_____ M.D.
Radiotherapist

ITEM 20

Therapeutic uses of sealed sources procedures have been submitted as an amendment. We repeat the same material here for completeness.

a) Attached is a drawing of the source storage room. The storage safe and L-shield will be used as primary shielding and their thicknesses are specified on the write-up, item 20b. Two inch thick lead brick and lifshitz metal will be used as needed so that the exposure at the work areas will be below permissable levels for radiation workers and the exposure rate in the hall will be below the level permissable for the general public. The initial quantity of Cs137 to be procurred is well below the storage capacity of this safe.

The storage room will be kept locked at all times. Entrance will be by key only. Only the radiation therapist, the radiation safety officer and administration will have a key to this room.

b) Sources are handled with long forceps and other specified source handling tools. As much as possible, sources are handled behind the L-block in the Cesuim Storage Room. The Radiation Safety Manual includes safety rules for handling sources. In addition, only trained persons, the certified radiation therapist, the radiation safety officer and registered therapy technologists wi-l handle sources.

c) Monitoring of extremities will be by TLD ring badges. The radiation therapists and the radiation safety officer will be assigned ring badges. Registered therapy techonologists who are authorized to handle sources will be specifically designated as such by the Therapist, so that ring badges can be ordered.

d) Sources are transported in a specialized carrier with 1" of lead protection and pushed on a long handled cart.

e) Source removal and return are logged into a bound log book. Entries include patient name, and room number, sources removed by source type and strength, sources used, sources removed unused (date and time) and sources returned used (date and time).