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

South Shore Hospital
8015 South Luella Ave.
Chicago, IL 60617

TELEPHONE NO.: AREA CODE (312) 778 - 0810

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

Same as 1,a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Stan Buhr or Jim Mikowski
Standard Nuclear Consultants, Ltd.
TELEPHONE NO.: AREA CODE (312) 344 - 7308

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 12-05257-02

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

Stanley H. Gumbiner, M.D.
Jaspal Singh, M.D., Surinder K. Parmar, M.D.
Parvez Hussain Shirazi, M.D.
Don R. Santschi, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Surinder K. Parmar, 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		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	2000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
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
N/A			

RECEIVED BY LFMB
Date 4/26/85
Log 033
By Brown

Applicant
Check No. 21334
Amount Fee Category 4580/MC
Type of Fee Renewal
Date Check Rec'd 4/26/85
Received By Brown

RECEIVED
APR 22 1985
REGION III

8507230399 850708
REG3 LIC30
12-05257-02 PDR

NRC FORM 313M (9-81)

Forwarded 4/29/85

APR 22 1985

CONTROL NO. 78770

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

(Some portions of the Guide have been revised slightly as shown in the attachments to more closely describe our program.)*

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
X	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*		X	Appendix I Procedures Followed; or
X	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES N/A	
X	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS N/A	
			Detailed Information Attached
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached		Detailed Information Attached

*Pages which are unchanged from the 10.8 guide are not attached to the NRC copies of this application.

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

This institution is also committed to the ALARA program set forth in the attached Appendix O.

We plan to use I-131 therapy doses only in capsule form. If it ever becomes necessary to use liquid I-131 therapy doses, we will perform bioassays in accordance with NRC Regulatory 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)* John D. Harper

(1) NAME *(Type of Print)* John D. Harper

(2) TITLE Administrator

c. DATE April 17, 1985

RECEIVED APR 22 1985 REGION III

CONTROL NO. 78770

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 45[illegible] (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 (3) 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 specialties of the committee members will be documented at the hospital, will be updated as necessary, and will be available for inspection.

APPENDIX B

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

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

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

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

NAME OF AUTHORIZED USER	AUTHORIZATION
Stanley H. Gumbiner, M.D.	All
Jaspal Singh, M.D.	All
Parvez Hussain Shirazi, M.D.	All
Surinder K. Parmar, M.D.	All
Don R. Santschi, M.D.	Groups I, II,III and Xenon-133

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Wm. B. Johnson

      Manufacturer's model number: GSM-5

      Number of instruments available: 1

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

      Maximum range: 0 mR/hr to 20 mR/hr

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: 740-F

      Number of instruments available: 1

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

      Maximum range: 0 mR/hr to 2500 mR/hr

2. Dose calibrator

   Manufacturer's name: Nuclear Associates

   Manufacturer's model number: Rad Cal II

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Picker	4/15
Uptake Probe	Picker	Spectroscaler 4

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

   Pulmonex, Model 130-500 Xe-133 Dispensing/Trapping system

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

__X__ a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

or

__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 Standard Nuclear Consultants, Ltd.

(2) Location 1340 Balmoral Ave., Westchester, IL 60153

(3) Procedures and sources

__X__ have been approved by NRC and are on file in License No. 12-20362-01

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

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

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

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

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

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

B. Sources Used for Instrument Accuracy and Constancy Tests ***

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

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.

** We also request authorization to use an alternate method of performing dose calibrator linearity checks using a "Lineator" device (Atomic Products Corp., Center Moriches, NY) or a "Calicheck" system (Calcorp). We confirm the manufacturer's product literature will be followed with respect to use, calculations, and replacement of damaged parts.

*** For constancy tests, we will use a Cs-137 source of 100 µCi or more to check the Cs-137 setting as well as the other commonly used radionuclide settings. The shorter half-lives of Ba-133 and Co-57 make frequent decay corrections necessary and we therefore do not feel they are practical for this use.

Assay Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

** 4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

** 5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

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

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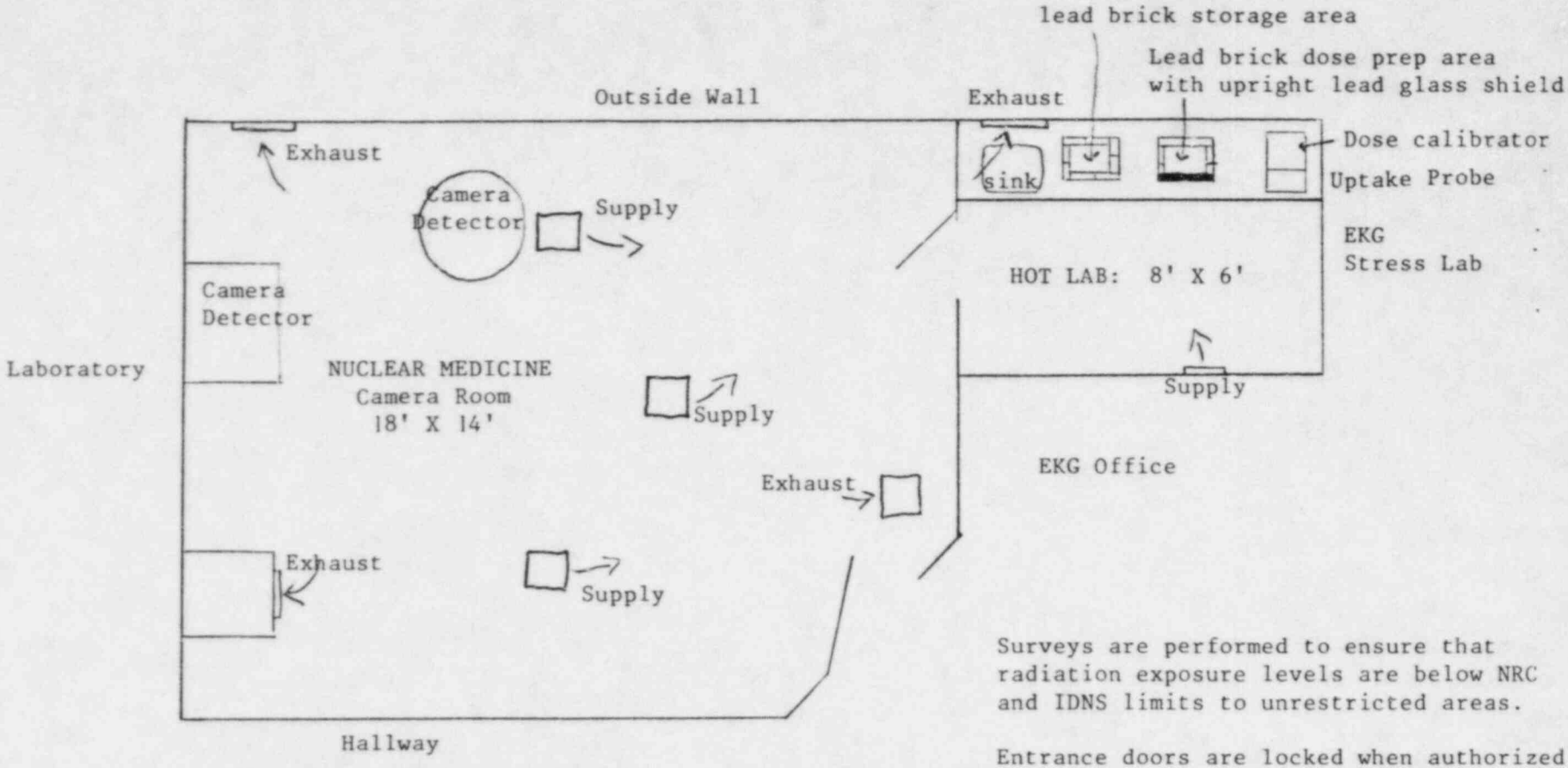
* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

**As an alternative to graphing these results, we find we find we can more accurately determine the %error by the following equation: $\frac{\text{Calculated activity - Measured Activity}}{\text{Calculated Activity}} = \%\text{error}$

SOUTH SHORE HOSPITAL
Chicago, Illinois



Surveys are performed to ensure that radiation exposure levels are below NRC and IDNS limits to unrestricted areas.

Entrance doors are locked when authorized personnel are not present to restrict access to the radioactive materials.

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 by 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 F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 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 shield and remove wipe to low background area. Check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

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

      (1) If contaminated, treat as radioactive waste.

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

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

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

APPENDIX I

AREA SURVEY PROCEDURES

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

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

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

4. The weekly and monthly surveys will consist of:

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

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

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

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

   b. Name of person conducting the survey.

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

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

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

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

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

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

** At times when a well counter is not available for assaying wipes, the following method may be performed, using a low level g.m. survey meter. We confirm the following points:

A. The detector wall thickness will be 30 mg/cm^2 or less.

B. The instrument will be capable of detecting 0.1 mr/hr or less.

C. The approximate response time of the survey meter used will be 30 seconds or less. The wipes will therefore be held at the open window of the detector for about 30 seconds to ensure any contamination present may be detected.

D. Wipes will be assayed in a low background area.

*** When a survey meter is used to assay the wipes, any readings over background radiation levels (rather than 200 dpm/100 cm^2) will be used as the action level for cleaning the area.

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.

__N/A__ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

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

__X__ Returned to the manufacturer for disposal.

__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 generators will be disposed of as normal trash.**

__N/A__ 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.

__N/A__ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

*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 21

Procedures and Precautions for Use of Radioactive Gas (Xe-133)

1. Quantities to be used:

We expect the number of patients undergoing Xe-133 lung ventilation studies to average 3 or less per week, with an average of 15 millicuries of Xe-133 to be used per patient. We request a possession limit of 100 millicuries.

2. Equipment and ventilation:

Xe-133 will be used and stored only in the nuclear medicine area of the hospital (see attached sketch). The Xe-133 will be stored in the manufacturer's shielded shipping container in the lead brick storage area of the hot lab. The Xe-133 will be used in the camera room and will be administered to the patient using an NRC approved dispenser system such as the New England Nuclear "Calidose" dispensing system and an Atomic Products Pulmonex Xe-133 delivery unit and gas trap. The system is shielded to minimize radiation exposure to operating personnel. Other shielded dispensing units may be used as they become available from other manufacturers, and approved by your agency.

The total combined exhaust from the camera room and hot lab will be maintained at a rate of at least 400 cfm. The exhaust will also be kept at least 10% higher than the supply rates to ensure a negative pressure effect during use of Xe-133. These rates will be measured on a semi-annual frequency. The exhaust air is vented directly to the outside and the vent locations are shown on the attached sketch.

3. Procedures for routine use:

To minimize the escape of Xe-133 from the area, the entrance door to the nuclear medicine area will be kept closed and the door between the camera room and hot lab kept open during use and handling of Xe-133.

The Xe-133 will be received in precalibrated unit dose vials. All doses will be assayed in the dose calibrator prior to administration.

Patients will be instructed on the details of the procedures, emphasizing those steps in which their cooperation is needed.

Patients will be connected to the Xe-133 delivery system either by a face mask or by a mouthpiece with a nose clamp. The patient connection will be checked for leakage by feeling for air movement around the mask or mouthpiece as the patient exhales into the system prior to administration of the gas. To minimize the chances of having to discontinue the study prior to completion, the patient will first be given a chance to become acclimated to the system before the gas is administered.

The lung ventilation procedure consists of breath holding, equilibrium and wash-out phases. During the wash-out phase, the air is drawn into the trap to remove the Xe-133.

Manufacturer's instructions for checking and changing the CO2 and moisture absorbers will be followed. The system will also be visually checked periodically to ensure all connections are intact.

4. Emergency procedures:

In the event of accidental release of Xe-133, the room will be evacuated for approximately 30 minutes depending on the condition of the patient. A survey meter will be used upon reentry to ensure the Xe-133 has been cleared. With a room volume of approximately 2425 cubic feet and an exhaust rate of at least 400 cfm, we calculate one air turnover to be approximately 6 minutes

5. Air concentrations in restricted areas:

All reasonable precautions will be taken to minimize the release of Xe-133 into the room. There will, however, be some release from the delivery system and from patients. It is unlikely that these releases will exceed 25% of the Xe-133 used.

We can calculate the air concentration of Xe-133 in restricted areas (hot lab and camera room), as follows:

Assumptions:
3 patients/week
15 mCi/patient
45 mCi/week
25% escape into room
cfm minimum exhaust
1 cfm=6.797 X E7 ml/40 hour week

Therefore:

$$\frac{4.5 \times E4 \text{ uCi} \times 0.25}{400 \text{ cfm} \times 6.797 \times E7 \text{ ml}/40 \text{ hr week}/\text{cfm}} = 4.1 \times E-7$$

The calculated concentration of 4.1 X E-7 uCi/ml is well below the 10 CFR 20.103 limit of 1.0 X E-5 uCi/ml to restricted areas for Xe-133.

6. Air concentrations of Xe-133 in unrestricted areas:

As stated in item #5 above, the release of Xe-133 into the room is not likely to exceed 25% of the activity used. We can therefore calculate the maximum air concentratin of Xe-133 in unrestricted areas (point of release from the exhaust system), as follows:

A. 3 patients/week X 15 mCi X 1000 uCi/mCi X 52 weeks/year X 0.25

release fraction = 5.85 X E5 uCi activity released per year

B. 400 cfm X 1.484 X E10 ml/year/cfm = 5.94 X E12 ml/year air volume

C. 5.85 X E5 uCi / 5.94 X E12 ml/year = 1.72 E-7 uCi/ml air conc.

The air concentration of 1.72 X E-7 uCi/ml averaged over one year is less than the 10 CFR 20.103 limit of 3 X E-7 uCi/ml to unrestricted areas for Xe-133.

7. Monitoring of Xe-133 gas trap efficiency:

The efficiency of the Xe-133 trap will be monitored by measuring the activity in the rebreathing tube during the equilibrium phase, and exhaust port during the first minute of the washout phase. This measurement will be made every tenth patient study using the low level g.m. survey meter. The meter probe will be shielded from the patient while taking the readings. Exhaust port readings of less than 10% of the rebreathing tube reading, the charcoal filter will be replaced. The shielded, saturated traps will be stored in nuclear medicine until no detectable activity remains.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

SOUTH SHORE HOSPITAL

(Licensee's Name)

April 17, 1985

(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.

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.

John D. Harper
Signature

John D. Harper
Name (print or type)

Administrator
Title

Institution (or Private Practice) Name and Address:
South Shore Hospital
8015 South Luella Ave.
Chicago, IL 60617

[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.

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: 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 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 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.

James Mallaver:
These are the Item 13
pages which were missing
from the South Shore
Hospital renewal
application.
Thanks,
Stan Burke

18770