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

Suburban General Hospital
South Jackson Avenue
Bellevue, Pittsburgh, PA. 15202

TELEPHONE NO.: AREA CODE(412) 734 1800

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

John B. Mallon
President
TELEPHONE NO.: AREA CODE(412) 734-1800, Ext. 2111

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 37-15350-01

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

Wayne V. Greenberg, M.D., Director of Nuclear Medicine
Sanford Edberg, M.D., Drtr. of Laboratories

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.)*

Wayne V. Greenberg, M.D., Director of Nuclear Medicine

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
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	2300
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		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	400
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	200

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

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE

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

8. TRAINING AND EXPERIENCE

- Supplements A & B Attached for Each Individual User; and
- Supplement A Attached for RSO.

9. INSTRUMENTATION *(Check One)*

- ✓ Appendix C Form Attached; or
- List by Name and Model Number

10. CALIBRATION OF INSTRUMENTS

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

11. FACILITIES AND EQUIPMENT

- ✓ Description and Diagram Attached

12. PERSONNEL TRAINING PROGRAM

- ✓ Description of Training Attached

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

- ✓ Detailed Information Attached

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*

- ✓ Appendix F Procedures Followed; or
- Equivalent Procedures Attached

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

- ✓ Appendix G Rules Followed; or
- Equivalent Rules Attached

16. EMERGENCY PROCEDURES *(Check One)*

- ✓ Appendix H Procedures Followed; or
- Equivalent Procedures Attached

17. AREA SURVEY PROCEDURES *(Check One)*

- ✓ Appendix I Procedures Followed; or
- Equivalent Procedures Attached

18. WASTE DISPOSAL *(Check One)*

- ✓ Appendix J Form Attached; or
- Equivalent Information Attached

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

- ✓ Appendix K Procedures Followed; or
- Equivalent Procedures Attached

20. THERAPEUTIC USE OF SEALED SOURCES

- Detailed Information Attached; and
- Appendix L Procedures Followed; or *(Check One)*
- Equivalent Procedures Attached

21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)

- ✓ Detailed Information Attached

22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

- Detailed Information Attached

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

- ✓ Detailed Information Attached

24. PERSONNEL MONITORING DEVICE

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
	X	TLD	Landauer	monthly
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer	monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ~~ENCLOSED~~: $580. paid Oct. 23, 1984

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

John B. Mallon

(1) NAME *(Type or Print)*
John B. Mallon

(2) TITLE
President

c. DATE

NRC FORM 313M (9-81)

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

There is a general hospital radiation safety committee which has a responsibility for all radiation sources. The committee is chairred at the present time by E. R. Seitz, M.D., a radiologist. The members listed below, by name and specialty, form the core for meeting requirements of this license.

a. Committee's Duties and Responsibilities

The responsibilities, duties and meeting frequency (once per calendar quarter) will be as described in Appendix B.

b. Name and Specialty of Each Committee Member

The Committee shall be made up of at a minimum the following individuals:

1. A member of the hospital administration
2. The hospital radiation protection officer
3. The directors of the respective clinical laboratories involved in the use of radioactive materials

At the present time the Committee consists of the following individuals:

Name	Specialty
W. V. Greenberg, M.D.	Nuclear Medicine and Internal Medicine, RPO, Director
S. H. Edberg, M.D.	Pathology, Director
J. B. Mallon	Administration
J. A. Fragola, M.D.	Internal Medicine

The membership and composition of the Committee is subject to change without license amendment.

ITEM 8. TRAINING AND EXPERIENCE

W. V. Greenberg, M.D. Director of Nuclear Medicine	Previous License No. 37-15350-01
S. Edberg, M.D. Director of Laboratories	37-15350-01 1080

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victoreen

   Manufacturer's model number: 498

   Number of instruments available: 1

   Minimum range: 0 mR/hr to 1 mR/hr

   Maximum range: 0 mR/hr to 1000 mR/hr

   b. Manufacturer's name: Picker* Victoreen*

   Manufacturer's model number: 436 495

   Number of instruments available: 1 1

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

   Maximum range: 0 mR/hr to 50. mR/hr 0 - 500

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC 30-BC

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	Technicare	420/550
Gamma Camera	Technicare	438/560
Gamma Camera	Siemans	3132
Gamma Counter	Beckman	Biogamma II MB 1000
NaI Well	Picker	Spectra scaler - 4R
Uptake Probe	Picker	Spectra scaler - 4R

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

Xenon Monitor --Victoreen Model No. 36-751
Area Monitors--primalert 35 Model No. 05-437

*These two instruments are calibrated by comparison with a calibrated meter. Meter (a) is calibrated in accordance to Item 10.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

✓ 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

_____ 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 _____

_____ (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.

✓ c. By a consultant or outside firm

(1) Name See Attachment

(2) Location _____

(3) Procedures and sources

_____ have been approved by NRC and are on file in License No. _____

_____ 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.

ATTACHMENT D

ITEM 10. METHODS, FREQUENCY AND STANDARDS USED IN CALIBRATING INSTRUMENTS

Portable beta-gamma survey instruments are calibrated at least annually using Ra-226, Co-60, and/or Cs-137 NBS related sources corrected for decay and compared to readings made by Victoreen R-chamber measurements.

Procedure for portable beta-gamma instrument calibration using a Radium-226, Cesium-137, and/or Cobalt-60 source is enclosed with this attachment.

Approximate correction factors for the low energy response of the GM detectors will be determined by comparison with the manufacturer's energy calibration curves or by measurement of their response to sources of Tc-99m. The activity of the Tc will be determined using the dose calibrator. Point source dose rate constants will be used to check the meter response.

Nuclear Medicine uptake probes, scanners, and cameras are calibrated consistent with acceptable nuclear medicine clinical needs.

Calibrations of the survey instruments will be performed by the consulting health physicist,

Mr. Jerry C. Rosen
167 Richmore Drive
Verona, PA 15147

Copies of the calibration procedures are enclosed.

CALIBRATION OF SURVEY INSTRUMENTS

A. Sources

1. ICN Model CCSD-20E Irradiator containing 19.4 curies ^{137}Cs (as of 5/30/73), source w-748.
2. 2.2 curie sealed ^{60}Co as of 11/23/73 (no model or number).
3. 62.8 millicurie sealed ^{60}Co as of 11/16/77 (no model or number).
4. 9.9 $\pm$ 0.7% milligram sealed ^{226}Ra needle, NBS #47428 - 11/11/71.

7. J. L. Shepherd & Associates Model 78-2M calibrator S/N 9016 containing 1 curie ^{60}Co Gamma Industries type BDHP S/N 1698, and 25 mg ^{226}Ra U.S. Radium S/N TS-784.

B. Traceability - Source Outputs

The radium needle is traceable to NBS. The plutonium-beryllium sources' emissions are traceable to certificates provided by Monsanto. The Eberline sources also are traceable to certification provided on each of the 4 sources in the set.

The exposure rates from the gamma sources are measured at known distances using Victoreen Model 570 Condenser R-Meter and appropriate R-chambers which are NBS traceable by calibration at an approved Regional Calibration Facility. Distance versus mR/hr curves are plotted periodically to account for slight decay (or ingrowth) and to insure repeatability. These curves are used on a day-to-day basis for routine calibrations.

C. Method

1. Beta-Gamma

Instruments are normally calibrated according to manufacturers instructions. Typically the instrument is placed in a known field of radiation which approximates mid-range or slightly above and the meter is adjusted to within ± 10%. Then as a final linearity check, 2 points at approximately 1/3 and 2/3 full scale for each scale on each range are checked for exposure rate readings at known exposure rate distances. If true exposure rate versus meter reading exceeds ± 10%, a calibration graph is attached to the meter. When meter reading versus true reading exceeds ± 20%, the cause is investigated and instrument repair is initiated.

D. General

Calibrated instruments are supplied with a calibration form for all tested ranges, and are labeled with a calibration sticker. See attached form for sample of each.

RADIATION SURVEY INSTRUMENT CALIBRATION

Instrument_____ Date Calibrated_____

Model_____ Calibrated by_____

Serial Number_____ Source (1) _____

(2) _____

Internal Check Source Reads_____ (3) _____

Battery circuit check_____ (4) _____

(5) _____

Remarks_____ (6) _____

_____ (7) _____

Scale	Source Used	Source mr/hr	Instrument mr/hr

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

✓ Other* (specify) A Tc-99m source which exceeds the largest administered radiopharmaceutical dose

B. Sources Used for Instrument Accuracy and Constancy Tests

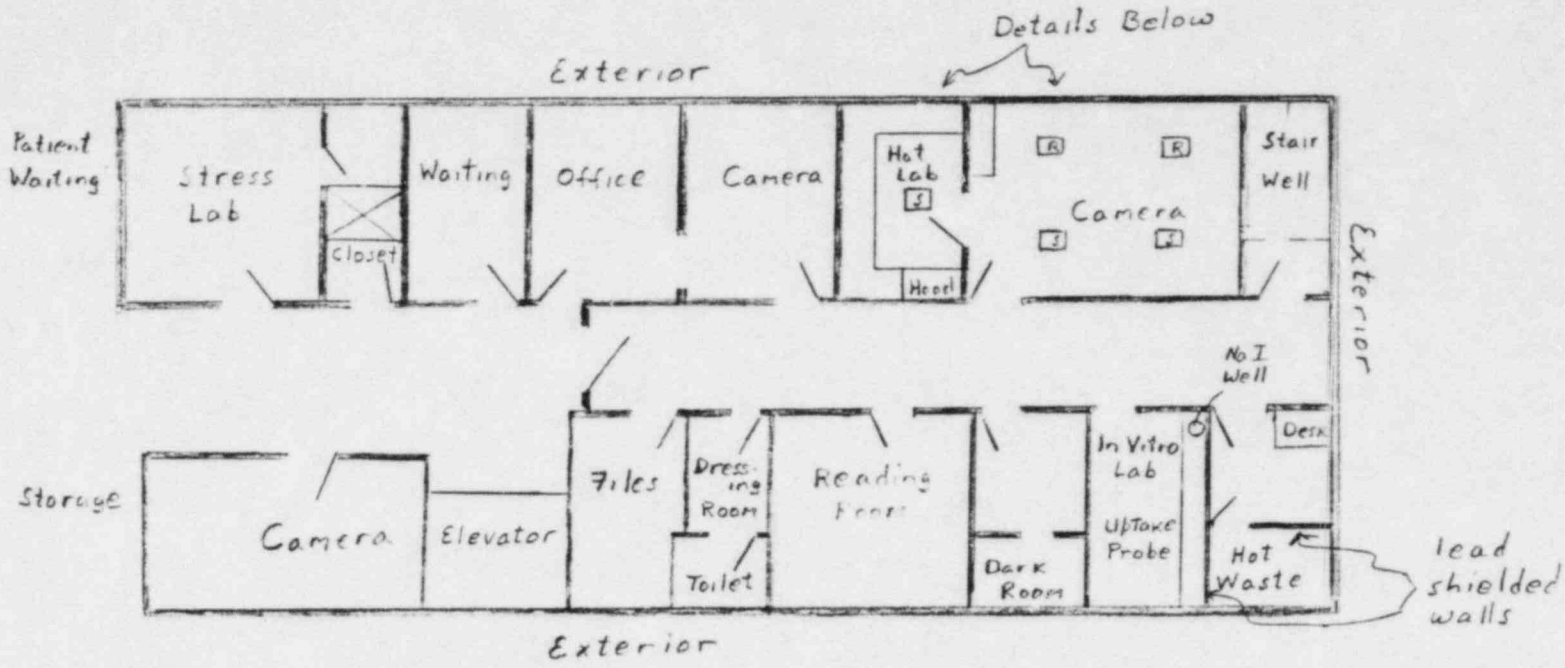
Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	≤5	5%
Ba-133	0.1-0.5	≤.250	5%
Cs-137	0.1-0.2	≤.199	5%
Ra-226	1-2		

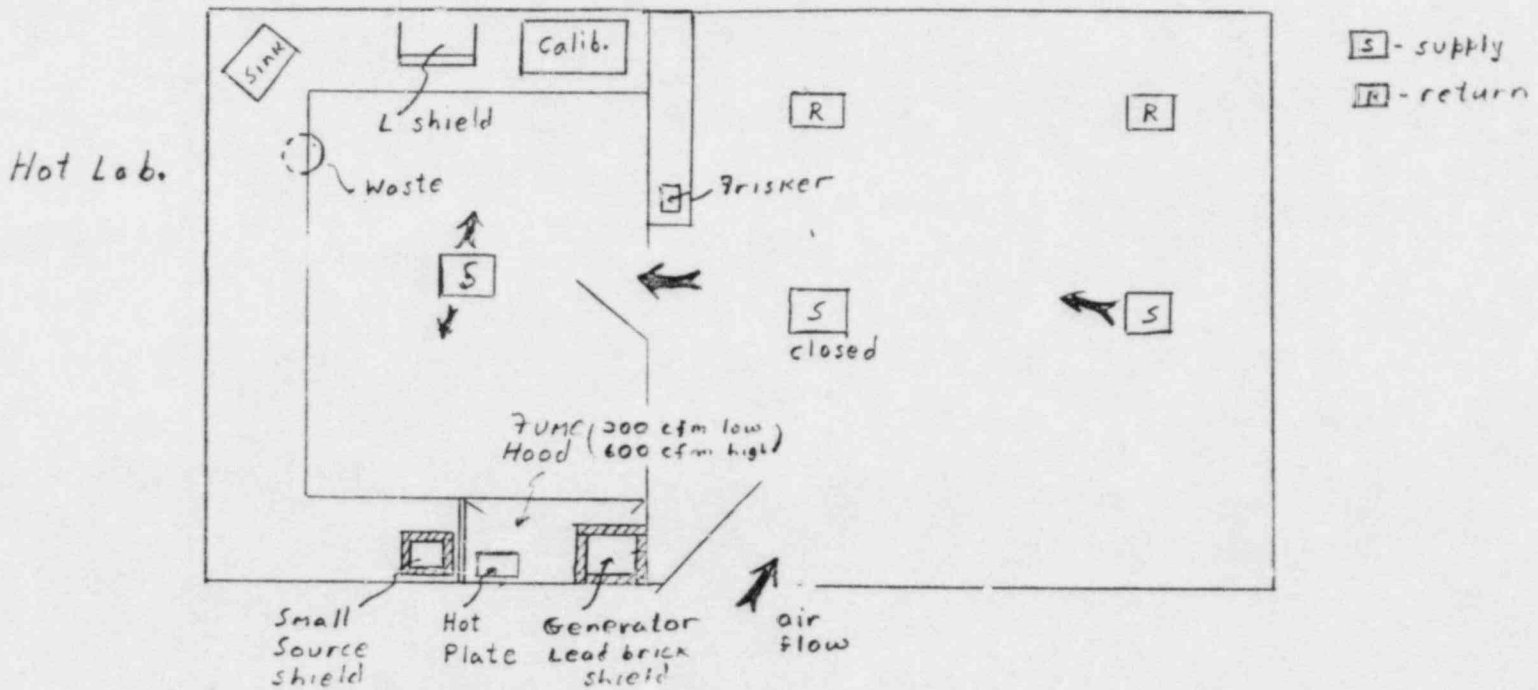
C. ✓ The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator

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 No 11.

2/19/85

ITEM 12. PERSONNEL TRAINING PROGRAM AND FREQUENCY

The primary use of radioactive materials is within the Department of Nuclear Medicine. This area is restricted to Nuclear Medicine personnel, patients undergoing diagnostic or therapeutic procedures. No other individuals frequent the area. Housekeeping personnel are only admitted to the area in the presence of departmental personnel and after all sources have been safely stored. Under these conditions training of personnel from outside the department is required only on a limited basis. No formal ongoing course work is required.

Department personnel are educated in the requirements of 10CFR, Part 19. The NRC regulations and a copy of the license are available in the department for their use. Radiation workers are instructed in appropriate techniques for performing radiation surveys and controlling contamination. Emergency procedures are clearly posted. The consulting health physicist makes routine inspections of the department and problems associated with the health aspects of radiation usage are open to discussion at that time. Time is made available to the technicians to participate in special seminars and training programs held in the Pittsburgh area.

ITEM 13. PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

1. The chief 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. Records will be maintained of all standing orders, special orders and receipts of radioactive materials.

   (a) All materials received, in use, or in storage will be labelled in a manner suitable to trace them to their original order.
   (b) Ordering of therapeutic agents will be done only under the written request of a physician. That request shall indicate the nuclide, compound, activity and intended use.

3. Delivery and Security

   (A) During Normal Working Hours

      1) Arriving shipments of radioisotopes are to be delivered promptly and directly to the Nuclear Medicing Laboratory.
      2) Packages of radioisotopes are not to be left unattended in unsecured areas; be sure that the package is delivered personally to the Nuclear Medicine Technician.
      3) In the event that a package of radioisotopes appears to be damaged, and particularly if there appears to be any leakage of the contents, do not deliver the package but proceed as follows:

         (a) Request that the person delivering the package remain until a radiation survey can be performed.
         (b) Notify the Nuclear Medicine Technician of the situation.
         (c) Do not allow anyone to touch the package or walk through areas where leakage may have occurred until a radiation survey has been performed.

   (B) During Off-Duty Hours

      See attachment

RADIOISOTOPE RECEIVING PROCEDURES

I. Delivery and Security

A. During Normal Working Hours

1. Arriving shipments of radioisotopes are to be delivered promptly and directly to the Nuclear Medicine Laboratory.
2. Packages of radioisotopes are not be be left unattended in unsecured areas; be sure that the package is delivered personally to the Nuclear Medicine Technician.
3. In the event that a package of radioisotopes appears to be damaged, and particularly if there appears to be any leakage of the contents, do not deliver the package but proceed as follows:
   (a) Request that the person delivering the package remain until a radiation survey can be performed.
   (b) Notify the Nuclear Medicine Technician of the situation.
   (c) Do not allow anyone to touch the package or walk through areas where leakage may have occurred until a radiation survey has been performed.

B. During Off-Duty Hours

1. Security personnel are to deliver all arriving shipments of radioisotopes promptly and directly to the Nuclear Medicine Laboratory. Place the package on the floor inside the Laboratory and be sure that the door is again locked.
2. In the event that a package of radioisotopes appears to be substantially damaged, and particularly if there appears to be any leakage of the contents, the package should not be delivered to the Laboratory or even handled. In such a situation proceed as follows:

REVIEWED	REVISED
1/84	1/84

(a) Request the person delivering the package to remain until a radiation survey can be performed.

(b) Notify the Director of Nuclear Medicine and/or the Radiation Physicist immediately.

(c) Do not allow anyone to touch the package or walk through areas where leakage may have occurred until a radiation survey has been performed.

II. Radiation Survey

A. Normal Packages

1. Promptly after delivery, if during normal working hours, or in the morning of the first work day following an off-hours delivery, the Nuclear Medicine Technician shall:

(a) Check the package visually for any damage.

(b) Measure the radiation exposure rate at the surface of the package and/or at one meter from the package and compare with similar measurements taken of comparable previous shipments.

(c) Wipe representative surfaces of the package with a filter paper or tissue and assay the wipe in the radiation dose calibrator.

(d) Record the results of the surveys in the appropriate logbook.

2. If a package appears to be damaged but no unusual radition levels or exterior contamination is detected, open the package carefully and inspect the contents for damage. Check inner containers for contamination by wiping and assaying in the dose calibrator. If no contamination is detected, proceed as with normal packages.

B. Damaged or Leaking Packages:

1. If called to check a package at the receiving dock, the Nuclear Medicine Technician shall:

   (a) Take the radiation survey meter, some filter papers or tissues for contamination wipes and some gloves to the receiving area.

   (b) Make a complete radiation survey and wipe the accessible surfaces to test for contamination. WEAR GLOVES; DO NOT HANDLE THE PACKAGE UNTIL SURE THAT NO CONTAMINATION IS PRESENT.

2. In any case where damage or leakage of the package contents appears to have occurred (as opposed to strictly superficial damage or spilling of some other material on the package), notify the Director of Nuclear Medicine and the Radiation Physicist immediately.

3. If unusually high radiation levels are detected but there is no evidence of contamination, move the package carefully to the decay storage vault; be very careful not to tilt or drop the package. After removal of the package, make a wipe test of the floor area where the package had been set and assay the wipe before permitting normal traffic through the area.

4. If contamination is detected on the package, do not handle or move it. Cover it with a plastic sheet (or a regular bed sheet, lab coat, etc.) and keep people away from it until the arrival of the Director of Nuclear Medicine or the Radiation Physicist. Ask anyone who may have touched the package or contaminated surfaces to remain in the immediate area until a thorough radiation survey can be performed.

III. Evaluation, Decontamination and Reporting

A. The Director of Nuclear Medicine, with the consultation of the Radiation Physicist, is responsible for evaluating abnormal situations, for conducting or supervising any required decontamination or remedial action, and reporting to regulatory agencies, if appropriate.

B. If removable contamination on the package exceeds 0.01 uCi (22,000 dpm) per 100 cm, immediately notify the final delivery carrier and the NRC Region I Office.

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)

✓ 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).

✓ Other (specify): In general, will be held for decay, assayed and discharged.

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

✓ 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)

✓ 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).

_____ Other (specify): _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

5. In the event that a commercial waste disposal service is needed, services of a company holding a currently valid license for possession and transportation of wastes will be obtained. The companies NRC/Agreement State License will be maintained as a part of the laboratory disposal records.

*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. USE OF RADIOACTIVE GASES

1. Quantities Used (design basis)
   a. 5 studies per week
      20 mCi Xe per patient
   b. possession limit - 200 mCi Xe-133

2. Xenon will be stored in the hood and used exclusively in the adjacent camera room. (See Item No. 11 for diagram).

   The enclosed diagram shows the location of supply and exhaust ducts in the Nuclear Medicine Department. The imaging room and hot lab are on an isolated air system with the exhaust air carried directly to the roof. The one supply air duct in the hot lab is closed so that air flows from the imaging room to the hot lab. With the face of the hood open to a height of one foot and the exhaust blower on low speed the measured face velocity is 180 fpm and the total flow is in excess of 600 cfm.

   There are two exhaust and two intake vents as indicated in the sketch of the imaging room. Supply vent #1 is closed and vent #2 is opened to provide sufficient circulation to prevent any dead pockets of air forming in the room. The flow in exhaust vents #1 and #2 is minimal with the major fraction of the exhaust flow from the imaging room to the hot lab. Measurements of air flow at the doors to the hot lab and imaging room confirm that the imaging room is operating at a negative pressure relative to the corridor and the hot lab negative relative to the imaging room. There is no air flow from these two rooms into any other portion of the building. These operating conditions will be confirmed on a routine schedule.

3. While xenon traps are expected to be used, no credit is taken for calculation purposes. A xenon monitor is available to monitor airborn activity during a study.

4. Air concentrations in restricted areas.

   Based on an exhaust rate of 600 cfm and the hot lab volume of 1300 cu. ft. a loss of 200 μCi of Xe-133 (a weeks estimated use) into the room would result in an initial concentration of 5.4×10^{-2} μCi/ml. With a mean residence time of 2.2 minutes it would take approximately 15 minutes to reduce the air concentration to one MPC_a (1×10^{-5} μCi/ml). For the loss of 10 millicuries, seven minutes would be required to reduce the air concentration to a level of one MPC_a. In neither case would the integral exposure exceed 20 MPC-hrs.

   A minimum of 600 cfm is exhausted from the imaging room (2700 cu. ft.) The release of 10 millicuries would result in an initial

concentration of 1.3×10^{-4} µCi/ml or 13 x MPC. With a mean residence time of 4.5 minutes an exposure of one MPC_a-hr could occur with no evacuation of the area. The time required to reduce the concentration to one MPC_a would be 12 minutes.

With a use of 200 mCi per week, A, and a ventilation rate of 4×10^{10} ml/week (600 cfm), V, then $A/V = 0.5 \times 10^{-5}$ µCi/ml. This is less than the acceptable concentration of 1×10^{-5} µCi/ml specified in Section 20.103 of 10CFR.

5. Emergency Procedures

Based on the above ventilation characteristics and estimated integral exposures the departmental emergency procedures will not specifically require evacuation for the release of a single dose in the area. For the release of multidose levels of xenon evacuation of the area for a period of 15 minutes will be recommended; however, the overall safety of the patient and the potential for other problems will take precedence over the evacuation.

6. Unrestricted areas

a. If xenon is released, a total flow rate of 2000 cfm or 6x10" ml/week is available at the discharge point on the roof with the hood operated at high speed. A loss of 100 µCi per week would result in a discharge of $<2 \times 10^{-7}$ µCi/ml.

b. Charcoal traps

Since adequate ventilation is available without the use of charcoal traps, no further calculations are given. The traps have a breakthrough monitor in line to avoid major losses. Saturated xenon filters will be stored in a cabinet under the hood in the hot lab. The filters are lead covered and should not require additional shielding when saturated. This will be confirmed by direct measurement. The filters will be sealed during storage for decay to prevent any offgassing. Prior to re-use the filters will be checked to guarantee that there will be no significant venting of residual xenon.

ITEM 23. OTHER PROCEDURES

a. Following administration of therapeutic quantities of I-131, uptake to the thyroid of the administering personnel will be checked within 24 hours. The thyroid uptake probe will be used for this purpose.

b. All sealed sources will be leak-tested at 6-month intervals in accordance with 10CFR 35.14d.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Suburban General Hospital

(Licensee's Name)

March 5, 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.

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.

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.

John B. Mallon

Signature

John B. Mallon

Name (print or type)

President

Title

Institution (or Private Practice) Name and Address:

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