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.*

Rec'd 12/24/85

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

St. Charles Hospital
2600 Navarre Ave.
Oregon, Ohio 43616

TELEPHONE NO. AREA CODE 419 698 7225

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

Same as 1.a.

Check No. 5580
Amount: Fee $150.00
Type of Fee amend
Date Check Rec'd 12/24/85
Received by

2. PERSON TO CONTACT REGARDING THIS APPLICATION

David Close, Consultant
Nuclear Medicine Associates

TELEPHONE NO. AREA CODE 216 641 5799

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 34-15072-01
c. ☐ RENEWAL OF LICENSE NO.

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

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.)*

Samuel Hancock, M.S.
See license #34-15184-01

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		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		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		

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

The purpose of this amendment application is to amend Items #5, 9, 10, 17, 18, 21 and 24 as per the enclosed and Items #14, 15 and 19 in part as per the enclosed addendums. These changes reflect the improved revision of the radiation safety program for the hospital.
In addition, we would like to amend Item #4 to add Daniel Singer,M.D. for Groups I, II, III and IV, and Xenon-133 for blood flow and pulmonary function studies.

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	15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*
8. TRAINING AND EXPERIENCE	☐ 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)*	☐ Appendix I Procedures Followed; or
☒ Appendix C Form Attached; or	☒ Equivalent Procedures Attached
☐ List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☒ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☐ Equivalent Information Attached
☒ Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☒ Appendix K Procedures Followed; or
☒ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	20. THERAPEUTIC USE OF SEALED SOURCES
☐ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☐ 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)
☐ Detailed Information Attached	☒ 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
	☐ Detailed Information Attached
☐ 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

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

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

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

26. CERTIFICATE

(This item must be completed by applicant)

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

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

(1) LICENSE FEE CATEGORY: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
X William Jenks

(1) NAME *(Type or Print)*
X

(2) TITLE
X Asst. Administrator

c. DATE
X

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.

INDIVIDUAL USERS

Authorization is requested for Daniel Singer, M.D. for Groups I, II, III, and IV, and Xenon-133. For training and experience refer to NRC License No. 34-15184-01 for Flower Memorial Hospital, Sylvania, Ohio.

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Prepared 8/7/85
License # 34-15072-01

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

      Manufacturer's model number: E 520

      Number of instruments available: 1

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

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

   b. Manufacturer's name: Victoreen

      Manufacturer's model number: CDV-700

      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(s)

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-30

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Scintillation Camera	G.E.	400 ZS
Uptake Probe	Tennelec	948

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

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Prepared: 8/7/85
Lic. # 34-15072-01

CALIBRATION OF INSTRUMENTS

A. Survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within ± 20% of the reading displayed after calibration, the instrment will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy. They will consist of:

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3 - 5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1 - 0.5 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1 - 0.3 mCi	100 uCi or more	Within ± 5%

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standard sources.

3. The calibration procedure will be as follows:

a. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5 of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo-Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within ± 5%. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less that 200 mCi will be drawn and used. The reduced amount will

then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum on hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 5%. If test result error exceeds ± 5%, arrangements will be

made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck Kit from Calcorp, Inc. The manufacturer's instructions for use dated 3/2/82 will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed ± 2%.

In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be

shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within ± 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse analyzer will be calibrated using Tc-99m or Co-57 and a uniform flood check will be performed each day of use.

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

3. Uptake probes will be calibrated each day of use with a long lived reference standard such as Cs-137 or Ba-133.

ADDENDUM ITEM #14

The procedure for safely opening packages containing radioactive materials as outlined in Appendix F, Licensing Guide 10.8 will be subscribed to with the following exceptions. The procedures shall not be applicable to prepackaged in vitro kits received without evidence of shipping damage except that radiation labels will be obliterated. Evaluation of final source container wipe smears will be performed with a survey meter listed in Item #9 of license application.

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ADDENDUM ITEM #15

General rules for the safe use of radioactive materials, as outlined in Appendix G of the Licensing Guide will be subscribed to at this institution. Additionally, authorization is requested to dispose of the following records subsequent to NRC inspection of these records.

1. Dose calibrator accuracy, constancy and linearity checks.
2. Survey meter calibration records.
3. Instrument calibration and quality assurance records. (e.g., camera, well, uptake probe, etc.)
4. Records of training for occupational and nonoccupational personnel.
5. Radiation Safety Committee minutes.

Provided that:

1. The record was examined during a routine NRC inspection.
2. The record is in excess of two years from the date of generation.
3. Disposal of the record does not conflict with the requirements of other state and federal agencies.

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AREA SURVEY PROCEDURE

A. Routine elution, preparation and designated injection areas will be surveyed daily with a G-M survey meter and decontaminated, if necessary.

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

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

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

2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a low level G-M survey meter.

The procedure will be as follows:

a. Perform wipe tests.
b. Place smear(s) in a "baggy" or disposable glove.
c. Adjust response time to the longest time constant, if applicable.
d. Select most sensitive range.
e. Turn beta shield on probe to open position.
f. Wait until reading stabilizes.
g. Read and record background.
h. Place smear in contact with open position of probe.
i. Wait until the reading stabilizes.
j. Read and record wipe results.

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

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

1. Location, date and type of equipment used.

2. Name of person conducting the survey.

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

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

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

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

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of:

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

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

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

2. Mo-99/Tc-99m generators will be:

__X__ A. Returned to manufacturer for disposal.

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

___ C. Disposed of by commercial waste disposal service.

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

3. Other solid waste will be:

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

___ B. Disposed of by commercial waste disposal service.

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

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ADDENDUM ITEM #19

The procedures and precautions for radiopharmaceutical therapy as described in Appendix K of Regulatory Guide 10.8 will be implemented with the following exceptions:

For I-131 Therapy

1. The urine will not normally be collected when patients are treated with I-131.

2. Only patients containing > 30 mCi must be hospitalized. If a patient is hospitalized with < 30 mCi, radiation safety procedures shall be applied until such time as the residual activity in the patient is < 8 mCi. (Reference: NCRP #37).

3. Liquid sources will be opened in a vented hood if available. Gloves, tongs, and lead shielding will be utilized by personnel handling I-131 sources.

4. Liquid I-131 sources received in closed remote displacement containers designed for direct oral administration to a patient will be treated with the same radiation safety precautions as are employed in the use of capsules containing this radionuclide. Devices equivalent to the Oral Radioisotope Administration Set #32-27 available from Paramedical Inc., Watertown, Massachusetts, will be used for this purpose.

5. The criteria and procedures for a personnel bioassay program will be as described in Regulatory Guide 8.20, September, 1979.

For P-32 Therapies

1. Nursing instructions as defined in Appendix K shall not apply to P-32 except in the colloidal form in which case the nurse will be advised to observe the wound and report any drainage to the Radiation Safety Officer. The RSO will be responsible for the supervision of changing the dressings.

ITEM #21

Procedures and Precautions for Use of Xenon-133

I. Quantities to be used:

A. Patient Information

1. 10 Studies per week
2. 15mCi per study

B. Possession Limit: 500mCi

II. Use and Storage Areas:

A. The camera room and adjoining hot lab are used for the storage and use of Xenon. Storage of Xenon is in the fume hood located in the hot lab. This same fume hood also is used to store tubing, face masks and etc., that have been contaminated until the Xenon has decayed. Saturated charcoal filters will be stored here also.

B. The camera room is exhausted through a ceiling grill at the rate of 450 cfm. This exhaust operates continuously. The hot lab is exhausted through the fume hood at a rate of 300 cfm. The fume hood is on at all times that Xenon is in storage. A high speed is available on the fume hood (550cfm). There is no recirculation of the air exhausted from these rooms. There are no other exhausts from these rooms.

C. The camera room is under negative pressure at all times. The hot lab is under negative pressure when the fume hood is on. The ventilation will be checked semi-annually to assure the exhaust rates have not decreased and the rooms remain under negative pressure.

III. Procedures for Routine Use:

A. The dose will be prepared and assayed in the dose calibrator. Shielding of the dose will be maintained at all times up to patient administration, except during identification and assay. Unnecessary personnel except desired observers will be excluded from the camera room during Xenon use. Patinets will be instructed as to the procedure and trial runs will be conducted if possible. Finger badges will be worn by all personnel handling Xenon. The camera room door will be closed if possible.

B. Face masks along with a Xenon rebreathing system and charcoal Xenon gas trap (Pulmonex 130-500 or equivalent) will be employed.

The face mask covers both nose and mouth. Mouth piece and nose clamp may be used as necessary. Tubing and valves, etc. will be inspected prior to use to assure continuity.

IV. Emergency Procedures:

In the event a dose of Xenon is accidentally released into the camera room, the room will be evacuated until levels have been reduced to 1×10^{-5} uCi/ml. Removal of personnel from the room will be effected if the patient's condition permits. The time required for this evacuation is 20 minutes.

Room volume = 2858 cu.ft. = 8.09×10^{7} ml.

Clearance rate (λ) = $\frac{450 \text{ cfm}}{2858 \text{ cu.ft.}} = 0.157 \text{ min.}^{-1}$

Initial concentration (C_o) = $\frac{15{,}000 \text{uCi}}{8.09 \times 10^{7} \text{ml}} = 1.85 \times 10^{-4}$ uCi/ml

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

= $1.85 \times 10^{-4} e^{-.157 \times 20}$

= 1.85×10^{-4} (.0433)

= 8.01×10^{-6} uCi/ml

Prior to re-entry, a measurement will be made using a low level G-M near the floor. A reading equivalent to background shall be considered as evidence that the ventilation has cleared the room of Xenon as calculated.

V. Air Concentrations in Restricted Areas:

It is assumed here that the exhaust runs at 450 cfm continuously and that 20% of the used Xenon escapes due to leakage, trap pass-through and patient associated losses. It is also assumed that 10 studies are performed per week at 15mCi per study.

Activity (A) = 10×15 mCi $\times 0.2 \times 10^{3}$ uCi/mCi

= 3×10^{4} uCi/week

Volume (V) = 450 cfm x 60 min/hr x 40 hrs/wk x 2.83×10^{4} ml/cu.ft

= 3.06×10^{10} ml/week

Concentration = $\frac{A}{V}$

= $\frac{3 \times 10^{4} \text{ uCi/week}}{3.06 \times 10^{10} \text{ml/week}}$

= 9.80×10^{-7} uCi/ml

This value is significantly less than the 1×10^{-5} uCi/ml limit. Operation of the fume hood will reduce this value further.

VI. Air Concentrations in Unrestricted Areas:

A. It is assumed that 20% of the used Xenon, as described above, will be vented outside the hospital. It is again assumed the exhaust runs at 450 cfm continuously.

$$\text{Activity (A)} = 3 \times 10^{4} \text{ uCi/week}$$

$$\text{Volume (V)} = 450 \text{ cfm} \times 1.7 \times 10^{6} \text{ ml/hr/cfm} \times 168 \text{ hr/wk}$$

$$= 1.29 \times 10^{11} \text{ ml/week}$$

$$\text{Concentration} = \frac{A}{V}$$

$$= \frac{3 \times 10^{4} \text{ uCi}}{1.29 \times 10^{11} \text{ ml}}$$

$$= 2.33 \times 10^{-7} \text{ uCi/ml}$$

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

B. After every 20 procedures, the trapping efficiency of the charcoal trap will be evaluated. This will be performed by connecting a Xenogard Xenon-133 Room Air/Trap Monitor to the exhaust of the trap. The charcoal will be replaced if the trap exhaust concentration exceeds 5×10^{-3} uCi/ml. The manufacturer's instructions for use will be followed when operating the Xenogard. Records will be maintained.

As an alternative procedure, the trapping efficiency of the charcoal trap will be evaluated by holding a low level G-M on contact with the inlet tube to the trap during the equillibrium mode. The probe will be placed on the exhaust tube. If the maximum exhaust reading during the washout phase exceeds 10% of the inlet reading, taking background into consideration, the trap will be considered to be saturated and the cartridge will be replaced.

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