Defiance Hospital
1206 East Second Street / Defiance, Ohio 43512 / Telephone (419) 782-6955

April 16, 1985

U.S. Regulatory Commission
Region 111
799 Roosevelt Road
Glen Ellyn, Illinois 60137

RE: Control Number 77113 - License Number 34-15654-01

Dear Sir:

Enclosed is the additional information requested for your review of our license application renewal.

Sincerely,

Mike Reichfield
Asst. Administrator

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 pionts on each scale used for radiation protection purposes.

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 ± 20% if a calibration chart, graph, or responce factor is prepared, attached to the instrument, and used to correct readings to within ± 10%. 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

X b. By an outside consultant: Schneider and Wuerst, Inc.
304 Mulberry St.
Perrysburg, Ohio 43551

1. Calibration source:

Manufacturer's name Radium Chemical Company

Model No. 10 mg.

Activity 10 needles at 10 mg. Ra each

Accuracy plus/minus 5%

Traceability to primary standard see Item 10 page 2

X 2. The calibration procedures in section 1 of Appendix D will be used.

X 3. The "Certificate of Instrument Calibration" is shown on page 3 of Item 10.

Radium Sealed Source Calibration

Date: October 13, 1983 By: Andrew J. Schneider

Instrument Used: RadX, Mark V, s/n 3314-71-PS

Calibrated on January 25, 1983

SOURCE	MEASURED ACTIVITY (mCi)	
Ra-226 needles	#5	10.4
Nominal Activity of 10 mg each	#6	10.5
Number Indicates	#7	10.0
Location in Radium Safe	#8	10.4
	#13	10.5
	#14	10.2
	#15	10.4
	#16	10.5
	#21	10.5
	#22	10.3
Average Activity (mCi)		10.37 + 0.16

ITEM: 10
DATE: 4-15-85

CERTIFICATE OF INSTRUMENT CALIBRATION

HOSPITAL: _____ DEPT. _____

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

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

Comments: _____

_____

_____

_____

	Nuclide	Activity	Calibration Accuracy
Calibration Source:	_____	_____	_____
	_____	_____	_____

Low energy (Co-57) response factor is _____

Calibrated by _____ Date _____

Reference readings: with 0.2 mCi Cs-137 source in styrofoam holder.

Date	Reading	Notes	By
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

ITEM: 10
DATE: 4-15-85

Item 10: Calibration of Instruments

A. The dose calibrator will be calibrated as follows:

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

Nuclide	Manufacturer	Model #	Activity (mCi)
Cs-137	Mallinckrodt	045-4DZ	1.0 on 5-1-74
Co-57	Amersham	CTC-VI	5.527 on 3-1-83
Co-60	NEN		Approx. 0.200

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standards 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 displaed by the dose calibrator must agree with the stated assay within ± 5%. This error may increase to ± 10% but correction factors will be determined. If the unit displays readings with an error greater than ± 10%, it will be repaired or adjusted.

b) The dose calibrator will be checked for constancy each day of use. This will be accomplished using the 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.

The acceptable range of error for the constancy checks may be extended to ± 10%, however correction factors will be determined. If variation greater than ± 10% are noted, the unit will be repaired or adjusted.

c) The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the first elution from a new Mo/Tc generator. After assay of the entire

contents, the concentration will be determined and an aliquot containing 40 mCi will be drawn. The aliquot will be assayed for agreement with the calculated activity. In this way, the accuracy of the unit will be assured in the measurement of activities from the maximum on hand to the quantity approximating the maximum dose used for a patient study.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check can 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 eluant can be determined by dividing the displayed activity by the volume in the syringe. A 40 mCi aliquot contained in the proper volume can be withdrawn from the elution vial and used for the linearity test. In this way, the accuracy of the dose calibrator will be assured in the measurement of activities approximating the maximum doses used for patient studies.

The linearity test will be continued by repeating the assay of the 40 mCi aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is less than 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 patient studies. In the event Technetium generator systems are not used, the linearity test described above will be performed using a source (instant technetium or radiopharmacy supplied) with an activity equal to or exceeding the maximum anticipated activity received for the performance of the clinical studies.

The above linearity test 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% but may increase to 10% between which correction factors will be determined. If measurements indicate an error greater than ± 10% the unit will be adjusted or repaired.

d) The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or linear repair or replacement. This test will be performed by placing an amount of activity of Tc-99m in a vial made of the same material and in the same volume as the Co-57 standard. This vial will be assayed. Aliquots of activity will be removed using syringes and volumes representative of those to be used and drawn for patient studies. In addition, aliquots will be drawn and transferred to kit vials representative of those kits to be employed in synthesizing various Technetium compounds. The syring aliquots and kit vials will be assayed.

The stock vial volume will be returned to its original volume using water after each withdrawal. The activity reduction in the stock vial determined on re-assay will be assumed quantitively transferred to the syringe aliquot or the kit vial. Correction factors for various geometries will be determined if the calculated vs. measured activities exceed ± 2% and will be considered in the setting of dose schedules for Technetium-99m.

Initial geometrical correction factors will be established for other nuclides beside Tc-99m which will be received bearing a manufacturer's assay. These sources, in such configuration as capsules, ampules, cartridges & etc, will be assayed and the initial correction factors will be established for source to be received in geometries such as capsules, ampules, cartridges, etc. These correction factors will be determined using the displayed assay vs. the manufacturer's assay at the time of receipt.

Acceptable correction factors may be on the order of ±50% due to the unusual configurations associated with these geometries. The manufacturer's assay will be assumed to be correct, however, and the correction factor will be used only as a constancy value to be compared to future shipments of these nuclides. In the event the constancy value varies by greater than ±10%, the dose calibrator will be adjusted or repaired.

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 one or more of the following plans:

1- A substitute dose calibrator will be acquired.

2- A new dose calibrator will be purchased and the present one will be used as a back-up.

3- Technetium eluents will be assayed and the Mo-99 contaminent will be determined using a dose calibrator located at the nearest cooperating institution 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 2.0mR/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.

B. Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and uniform flood check will be performed each day of use. A quarterly calibration and preventive maintenance program is done by the manufacturer.

Item 21: Procedures and Precautions for Use of Radioactive Gases

1. Quantities to be used: 10 Patients/week
   10 mCi/patient
   5200 mCi/year
   Possession Limit: 200 mCi

2. Xenon will be used in the single camera room as shown on the drawing in Item 11. Xenon will be stored in the fume hood in the hot lab in its shielded lead shipping container. Spent Xenon filters (from the delivery system) will also be stored in the fume hood behind lead bricks.

   The hot lab fume hood will run 168 hours per week at 600 CFM. The camera room will exhaust 168 hours per week at a rate of 600 CFM. There will be no recirculation of the exhaust air from the hot lab hood or the camera room. The air supply to the hot lab will be 550 CFM, the air supply to the camera room will be 550 CFM. The remainder, (100 CFM) will be provided by leakage around the door. The nuclear medicine area will be under negative pressure. The exhaust for the nuclear medicine area will be vented outside through a stack which is located 35 feet horizontally away and 20 feet above the nearest air intake for the hospital.

   The air flow rates into and out of the nuclear medicine area will be measured semiannually to assure that they are as stated above.

3. Procedure for Routine use:
   a. Peak the gamma camera for Xenon. Set stool in front of camera and bring over Pulmonex system. Turn on oxygen 3 to 5 psi. Bring in patient, close all doors, and plug in Pulmonex. Position patient in front of camera. Instruct patient as to what he/she will be doing. Have a trail run with the mask and nose clips. Be sure to check seal and air flow. Turn on Pulmonex system by setting the time to 14 minutes. Set Pulmonex to 2 and allow a small amount of O_2 into the bag (¼ full), attach Xenon gun or hose. Air flow at 20. Next have the patient take in a deep breath, blow it out, and take in another deep breath while injecting the Xenon. The patient should hold his breath while the pictures are started. Continue with rebreath. If using the Xenon injection system, be sure to hold in the button until Xenon is seen in the lungs. Air flow to 60. Turn the handle of the Pulmonex to 3 to start washout. If the patient's bag gets too full, turn up the air flow of the motor located in the lower trap. After the study is completed, turn off the Pulmonex. Views: initial breath, 3 rebreaths, and 3 washouts or until lungs are clear.

b. The Xenogard (or equivalent) air monitor will be used to measure the concentration of Xenon in the room air. The air monitor will be used each day Xenon is in the department and during each ventilation study. The results of the monitoring will be recorded.

We are presently using the manufacture's instructions for checking our Xenogard air monitor. The machine was calibrated at the factory. To ensure the machine is still calibrated we test the machine each day it is used for consistency of sensitivity. The procedure used is as follows: The Xenogard air monitor is turned on. A Cs-137 Check Source (Mallinckrodt 045-4DZ) is placed on top of the instrument directly over the label which reads "Place Check Source Here". The meter reading with the check source in place is recorded. Any significant change in the reading may indicate a need for recalibration. If any question arises concerning the overall calibration accuracy of the Xenogard, the unit is returned to the factory (Victoreen Inc.) for recalibration.

c. The Xenon-133 traps will be tested monthly for trapping efficiency with the XenGard (or equivalent) monitor.

d. Manufacturers instructions will be followed.

4. Emergency Procedures

If there is an accidental release of Xe-133, the following procedures will be done:

a. Notify all persons in the area to evacuate the room. Take survey meter out of room with you.

b. Notify the Radiation Safety Officer.

c. The door will be sealed with wide adhesive tape and locked to prevent entry.

d. The room will not be re-entered for 27 minutes. This will permit 10 air changes in the Nuclear Medicine area. Immediately upon entering the room, the XenGard will be checked to assert that the Xe-133 air concentrations are below the MPC.

5. Air Concentrations of Xe-133 in Restricted Areas

a. Hot Lab and Camera Room

100 mCi per week
0.25 escape fraction
1200 exhausted

$C = (A \times F)/V$

$C = (100\ mCi/week \times 1000\ uCi/mCi \times 0.25)/(1200\ CFM \times 2.854 \times 10^{8}\ ml/wk\ CFM)$

$C = 7.5 \times 10^{-8}\ uCi/ml$ which is below the MPC for restricted areas.

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DATE: 4-15-85

6. Air Concentration of Xe-133 in unrestricted areas

   a. The majority of Xe-133 used for ventilation studies will be absorbed on traps of the delivery system. Assuming an escape fraction of 0.25:

      $C = (A \times F)/V$

      $C = (5200\ mCi/year \times 1000\ uCi/mCi \times 0.25)/$

      $(1200\ CFM \times 1.44 \times 10^{10}\ uCi/ml)$

      $C = 7.5 \times 10^{-8}$ uCi/ml which is below the MCP for unrestricted areas.

   b. A Xenogard (or equivalent) air monitor will be used to test for efficiency of the Xenon traps of the delivery system. All manufacturers instructions will be followed. Saturated Xenon filters will be returned to the Radiopharmacy for disposal.

Survey Meters:

Presently we are receiving all our radiopharmaceuticals from Syncore. We wish to retain approval for the use of a Mo-99/Tc-99m generator. We will purchase a Victoreen 488 survey meter (measuring exposure rates from 0.05mR/hr to 1 R/hr) or its equivalent prior to ordering any Mo-99/Tc-99m generator.

ITEM: 9
DATE: 4-15-85

Item 17: Area Survey Procedures

1. All elution, preparation, and injection areas will be surveyed daily with our survey meter and decontaminated if necessary. 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.

2. Area surveys using the survey meter and wipe tests using a well counter (the well counter is found in the laboratory) will be performed weekly or in any case where contamination is suspected. If well counter is unavailable the survey meter may be substituted for the wipe test counting. (The information for wipe tests using the survey meter is found in Item: 14, Step: 5, Dated: 4-15-85.)

3. The weekly 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.

4. 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 of 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.

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

Item 14: Procedures for Safely Opening Packages Containing Radioactive Materials

It is the policy and procedure of this department to follow the steps listed below when receiving a radioactive package;

1. Visually inspect package for any signs of damage. If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Measure exposure rate at 3 feet from the case surface and record reading. If more than 10 mR/hr, stop procedure and notify Radiation Safety Officer.
3. Measure surface exposure rate and record reading. If more than 200 mR/hr, stop procedure and notify Radiation Safety Officer.
4. Put on gloves.
5. Open case and wipe external surface of each lead container with a cotton swab. The wipe tests are analyzed using the survey meter and then recorded. If any reading are above background level, the package will be treated as contaminated.

   Information for wipe tests using survey meter:
   a. Sensitivity is 0 to 800 cpm on "Low" Range.
   b. Efficiency is approximately 2% at 600 Kev and 5% at 100 Kev.
   c. Wipes are counted in low background area (counter space, Item: 11).
   d. Beta shield is removed before counting wipes.
   e. The wipe is held 1 cm or less from the beta window protective grid.
   f. The response time is 5 sec. (Medium Selection). Wipes are held at the counting position for no less than 10 seconds.
   g. Decontamination is performed if any reading is above background level.
6. Check all Record of Receipt slips and compare with order requisition. Check that shipment does not exceed possession limits. Inspect lead containers for breakage and loss of liquid.
7. Monitor the case for contamination and store for repackaging. All lead containers received (used and unused) will be returned to the radiopharmacy.

Note: If a package is found to be contaminated, treat it like a spill and follow the Emergency Procedures (Appendix H). These procedures are posted on the bulletin board by the hot lab.
The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet.

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	ICN Dosimetry Service	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST	X	FILM	ICN Dosimetry Service	Monthly
		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: 170.31 - 7B

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Mike Reichfield

(1) NAME *(Type or Print)* Mike Reichfield

(2) TITLE Acting Administrator - Defiance Hosp.

c. DATE 5-11-84

NRC FORM 313M (9-81)

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 pionts on each scale used for radiation protection purposes.

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 ± 20% if a calibration chart, graph, or responce factor is prepared, attached to the instrument, and used to correct readings to within ± 10%. 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

X b. By an outside consultant: Schneider and Wuerst, Inc.
304 Mulberry St.
Perrysburg, Ohio 43551

1. Calibration source:

Manufacturer's name Radium Chemical Company

Model No. 10 mg.

Activity 10 needles at 10 mg. Ra each

Accuracy plus/minus 5%

Traceability to primary standard see Item 10 page 2

X 2. The calibration procedures in section 1 of Appendix D will be used.

X 3. The "Certificate of Instrument Calibration" is shown on page 3 of Item 10.

Radium Sealed Source Calibration

Date: October 13, 1983

By: Andrew J. Schneider

Instrument Used: RadX, Mark V, s/n 3314-71-PS

Calibrated on January 25, 1983

SOURCE	MEASURED ACTIVITY (mCi)	
Ra-226 needles	#5	10.4
Nominal Activity of 10 mg each	#6	10.5
Number Indicates	#7	10.0
Location in Radium Safe	#8	10.4
	#13	10.5
	#14	10.2
	#15	10.4
	#16	10.5
	#21	10.5
	#22	10.3
Average Activity (mCi)		10.37 ± 0.16

ITEM: 10
DATE: 4-15-85

CERTIFICATE OF INSTRUMENT CALIBRATION

HOSPITAL: _____ DEPT. _____

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

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

Comments: _____

_____

_____

_____

	Nuclide	Activity	Calibration Accuracy
Calibration Source:	_____	_____	_____
	_____	_____	_____

Low energy (Co-57) response factor is _____

Calibrated by _____ Date _____

Reference readings: with 0.2 mCi Cs-137 source in styrofoam holder.

Date	Reading	Notes	By
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

ITEM: 10
DATE: 4-15-85

Item 10: Calibration of Instruments

A. The dose calibrator will be calibrated as follows:

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

Nuclide	Manufacturer	Model #	Activity (mCi)
Cs-137	Mallinckrodt	045-4DZ	1.0 on 5-1-74
Co-57	Amersham	CTC-VI	5.527 on 3-1-83
Co-60	NEN		Approx. 0.200

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standards 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 displaed by the dose calibrator must agree with the stated assay within ± 5%. This error may increase to ± 10% but correction factors will be determined. If the unit displays readings with an error greater than ± 10%, it will be repaired or adjusted.

b) The dose calibrator will be checked for constancy each day of use. This will be accomplished using the 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.

The acceptable range of error for the constancy checks may be extended to ± 10%, however correction factors will be determined. If variation greater than ± 10% are noted, the unit will be repaired or adjusted.

c) The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the first elution from a new Mo/Tc generator. After assay of the entire

contents, the concentration will be determined and an aliquot containing 40 mCi will be drawn. The aliquot will be assayed for agreement with the calculated activity. In this way, the accuracy of the unit will be assured in the measurement of activities from the maximum on hand to the quantity approximating the maximum dose used for a patient study.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check can 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 eluant can be determined by dividing the displayed activity by the volume in the syringe. A 40 mCi aliquot contained in the proper volume can be withdrawn from the elution vial and used for the linearity test. In this way, the accuracy of the dose calibrator will be assured in the measurement of activities approximating the maximum doses used for patient studies.

The linearity test will be continued by repeating the assay of the 40 mCi aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is less than 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 patient studies. In the event Technetium generator systems are not used, the linearity test described above will be performed using a source (instant technetium or radiopharmacy supplied) with an activity equal to or exceeding the maximum anticipated activity received for the performance of the clinical studies.

The above linearity test 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% but may increase to 10% between which correction factors will be determined. If measurements indicate an error greater than ± 10% the unit will be adjusted or repaired.

d) The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or linear repair or replacement. This test will be performed by placing an amount of activity of Tc-99m in a vial made of the same material and in the same volume as the Co-57 standard. This vial will be assayed. Aliquots of activity will be removed using syringes and volumes representative of those to be used and drawn for patient studies. In addition, aliquots will be drawn and transferred to kit vials representative of those kits to be employed in synthesizing various Technetium compounds. The syring aliquots and kit vials will be assayed.

The stock vial volume will be returned to its original volume using water after each withdrawal. The activity reduction in the stock vial determined on re-assay will be assumed quantitively transferred to the syringe aliquot or the kit vial. Correction factors for various geometries will be determined if the calculated vs. measured activities exceed ± 2% and will be considered in the setting of dose schedules for Technetium-99m.

Initial geometrical correction factors will be established for other nuclides beside Tc-99m which will be received bearing a manufacturer's assay. These sources, in such configuration as capsules, ampules, cartridges & etc, will be assayed and the initial correction factors will be established for source to be received in geometries such as capsules, ampules, cartridges, etc. These correction factors will be determined using the displayed assay vs. the manufacturer's assay at the time of receipt.

Acceptable correction factors may be on the order of ±50% due to the unusual configurations associated with these geometries. The manufacturer's assay will be assumed to be correct, however, and the correction factor will be used only as a constancy value to be compared to future shipments of these nuclides. In the event the constancy value varies by greater than ±10%, the dose calibrator will be adjusted or repaired.

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1- A substitute dose calibrator will be acquired.

2- A new dose calibrator will be purchased and the present one will be used as a back-up.

3- Technetium eluents will be assayed and the Mo-99 contaminent will be determined using a dose calibrator located at the nearest cooperating institution 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 2.0mR/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.

B. Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and uniform flood check will be performed each day of use. A quarterly calibration and preventive maintenance program is done by the manufacturer.

Item 21: Procedures and Precautions for Use of Radioactive Gases

1. Quantities to be used: 10 Patients/week
   10 mCi/patient
   5200 mCi/year
   Possession Limit: 200 mCi

2. Xenon will be used in the single camera room as shown on the drawing in Item 11. Xenon will be stored in the fume hood in the hot lab in its shielded lead shipping container. Spent Xenon filters (from the delivery system) will also be stored in the fume hood behind lead bricks.

   The hot lab fume hood will run 168 hours per week at 600 CFM. The camera room will exhaust 168 hours per week at a rate of 600 CFM. There will be no recirculation of the exhaust air from the hot lab hood or the camera room. The air supply to the hot lab will be 550 CFM, the air supply to the camera room will be 550 CFM. The remainder, (100 CFM) will be provided by leakage around the door. The nuclear medicine area will be under negative pressure. The exhaust for the nuclear medicine area will be vented outside through a stack which is located 35 feet horizontally away and 20 feet above the nearest air intake for the hospital.

   The air flow rates into and out of the nuclear medicine area will be measured semiannually to assure that they are as stated above.

3. Procedure for Routine use:
   a. Peak the gamma camera for Xenon. Set stool in front of camera and bring over Pulmonex system. Turn on oxygen 3 to 5 psi. Bring in patient, close all doors, and plug in Pulmonex. Position patient in front of camera. Instruct patient as to what he/she will be doing. Have a trail run with the mask and nose clips. Be sure to check seal and air flow. Turn on Pulmonex system by setting the time to 14 minutes. Set Pulmonex to 2 and allow a small amount of O_2 into the bag (½ full), attach Xenon gun or hose. Air flow at 20. Next have the patient take in a deep breath, blow it out, and take in another deep breath while injecting the Xenon. The patient should hold his breath while the pictures are started. Continue with rebreath. If using the Xenon injection system, be sure to hold in the button until Xenon is seen in the lungs. Air flow to 60. Turn the handle of the Pulmonex to 3 to start washout. If the patient's bag gets too full, turn up the air flow of the motor located in the lower trap. After the study is completed, turn off the Pulmonex. Views: initial breath, 3 rebreaths, and 3 washouts or until lungs are clear.

b. The Xenogard (or equivalent) air monitor will be used to measure the concentration of Xenon in the room air. The air monitor will be used each day Xenon is in the department and during each ventilation study. The results of the monitoring will be recorded.

We are presently using the manufacture's instructions for checking our Xenogard air monitor. The machine was calibrated at the factory. To ensure the machine is still calibrated we test the machine each day it is used for consistency of sensitivity. The procedure used is as follows: The Xenogard air monitor is turned on. A Cs-137 Check Source (Mallinckrodt 045-4DZ) is placed on top of the instrument directly over the label which reads "Place Check Source Here". The meter reading with the check source in place is recorded. Any significant change in the reading may indicate a need for recalibration. If any question arises concerning the overall calibration accuracy of the Xenogard, the unit is returned to the factory (Victoreen Inc.) for recalibration.

c. The Xenon-133 traps will be tested monthly for trapping efficiency with the XenGard (or equivalent) monitor.

d. Manufacturers instructions will be followed.

4. Emergency Procedures
If there is an accidental release of Xe-133, the following procedures will be done:

a. Notify all persons in the area to evacuate the room. Take survey meter out of room with you.

b. Notify the Radiation Safety Officer.

c. The door will be sealed with wide adhesive tape and locked to prevent entry.

d. The room will not be re-entered for 27 minutes. This will permit 10 air changes in the Nuclear Medicine area. Immediately upon entering the room, the XenGard will be checked to assert that the Xe-133 air concentrations are below the MPC.

5. Air Concentrations of Xe-133 in Restricted Areas

a. Hot Lab and Camera Room

100 mCi per week
0.25 escape fraction
1200 exhausted

$C = (A \times F)/V$

$C = (100\ mCi/week \times 1000\ uCi/mCi \times 0.25)/(1200\ CFM \times 2.854 \times 10^{8}\ ml/wk\ CFM)$

$C = 7.5 \times 10^{-8}\ uCi/ml$ which is below the MPC for restricted areas.

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6. Air Concentration of Xe-133 in unrestricted areas

   a. The majority of Xe-133 used for ventilation studies will be absorbed on traps of the delivery system. Assuming an escape fraction of 0.25:

      $C = (A \times F)/V$

      $C = (5200\ mCi/year \times 1000\ uCi/mCi \times 0.25)/$

      $(1200\ CFM \times 1.44 \times 10^{10}\ uCi/ml)$

      $C = 7.5 \times 10^{-8}$ uCi/ml which is below the MCP for unrestricted areas.

   b. A Xenogard (or equivalent) air monitor will be used to test for efficiency of the Xenon traps of the delivery system. All manufacturers instructions will be followed. Saturated Xenon filters will be returned to the Radiopharmacy for disposal.

Survey Meters:

Presently we are receiving all our radiopharmaceuticals from Syncore. We wish to retain approval for the use of a Mo-99/Tc-99m generator. We will purchase a Victoreen 488 survey meter (measuring exposure rates from 0.05mR/hr to 1 R/hr) or its equivalent prior to ordering any Mo-99/Tc-99m generator.

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Item 17: Area Survey Procedures

1. All elution, preparation, and injection areas will be surveyed daily with our survey meter and decontaminated if necessary. 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.

2. Area surveys using the survey meter and wipe tests using a well counter (the well counter is found in the laboratory) will be performed weekly or in any case where contamination is suspected. If well counter is unavailable the survey meter may be substituted for the wipe test counting. (The information for wipe tests using the survey meter is found in Item: 14, Step: 5, Dated: 4-15-85.)

3. The weekly 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.

4. 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 of 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.

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

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DATE: 4-16-85

Item 14: Procedures for Safely Opening Packages Containing Radioactive Materials

It is the policy and procedure of this department to follow the steps listed below when receiving a radioactive package;

1. Visually inspect package for any signs of damage. If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Measure exposure rate at 3 feet from the case surface and record reading. If more than 10 mR/hr, stop procedure and notify Radiation Safety Officer.
3. Measure surface exposure rate and record reading. If more than 200 mR/hr, stop procedure and notify Radiation Safety Officer.
4. Put on gloves.
5. Open case and wipe external surface of each lead container with a cotton swab. The wipe tests are analyzed using the survey meter and then recorded. If any reading are above background level, the package will be treated as contaminated.

   Information for wipe tests using survey meter:
   a. Sensitivity is 0 to 800 cpm on "Low" Range.
   b. Efficiency is approximately 2% at 600 Kev and 5% at 100 Kev.
   c. Wipes are counted in low background area (counter space, Item: 11).
   d. Beta shield is removed before counting wipes.
   e. The wipe is held 1 cm or less from the beta window protective grid.
   f. The response time is 5 sec. (Medium Selection). Wipes are held at the counting position for no less than 10 seconds.
   g. Decontamination is performed if any reading is above background level.
6. Check all Record of Receipt slips and compare with order requisition. Check that shipment does not exceed possession limits. Inspect lead containers for breakage and loss of liquid.
7. Monitor the case for contamination and store for repackaging. All lead containers received (used and unused) will be returned to the radio-pharmacy.

Note: If a package is found to be contaminated, treat it like a spill and follow the Emergency Procedures (Appendix H). These procedures are posted on the bulletin board by the hot lab.
The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet.

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24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	ICN Dosimetry Service	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST	X	FILM	ICN Dosimetry Service	Monthly
		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: 170.31 - 7B

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Mike Reichfield

(1) NAME *(Type or Print)* Mike Reichfield

(2) TITLE Acting Administrator - Defiance Hosp.

c. DATE 5-11-84

NRC FORM 313M (9-81)