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

Holy Cross Parkview Hospital
1401 North Michigan Street
Plymouth, Indiana 46563

TELEPHONE NO. AREA CODE 219 936 - 3181

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

Same as 1.a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

John D. Scheu, Ph.D.
808 E. Jefferson Blvd., South Bend, IN

TELEPHONE NO.: AREA CODE 219 287 - 4146

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 13-18880-01

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

See attachment #1

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.)*

W. S. Tirman, M.D.

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	Mo99/Tc99m 3000mCi
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	50mCi
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
Co-57	As a solid in a plastic vial.	5mCi	Calibration of dose calibrator.

Feb 13 III
Applicant Marshall County/Parkview
Check No. 020185 $580 ~~Check 2/12/85~~
Amount/Fee Category ~~$~~ 7C see 2/20/85 telecon record
Type of Fee Rep
Date Check Rec'd 2/12/85
Received By ... 2/12/85

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8506040736 850510
REG3 LIC30
13-18880-01 PDR

FEE EXEMPT

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
X	Equivalent Duties Attached **See Attachment #2**	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
X	Supplements A & B Attached for Each Individual User; and **See attachment #1**		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
X	Appendix C Form Attached; or **See Attachment #3**	X	Equivalent Procedures Attached **See Attachment #9**
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or **See Attachment #10**
X	Appendix D Procedures Followed for Survey Instruments; or **See Attachment #4** *(Check One)*		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix D Procedures Followed for Dose Calibrator; **with one exception, see attachments 5A & 5B.**		Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached **See Attachment#6**		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached **See Attachment #7**		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached **See Attachment #8**		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
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached		Detailed Information Attached

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24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R. S. Landauer Jr. and Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R. S. Landauer Jr. and Company	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: Renewal-Human Use of Byproduct Material

(2) LICENSE FEE ENCLOSED: $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Martin P. Braaksma

(1) NAME *(Type or Print)* Martin P. Braaksma

(2) TITLE Executive Director

c. DATE 1-25-85

RECEIVED
FEB 01 1985
REGION III

NRC FORM 313M (9-81)

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ATTACHMENT 1

Item 4. Individual Users.

The following individuals have been previously listed on license number 13-18880-01 as individual users.

W. S. Tirman, M.D.
J. R. Lionberger, M.D.

ATTACHMENT 2

Item 7. Radiation Safety Committee

The duties/responsibilities of the radiation safety committee will include those specified in Appendix B of Regulatory Guide 10.8 with the exception stated below.

Meeting Frequency

The radiation safety committee will meet once in each calendar quarter to review radiation exposures and carry on other points of business; however, this meeting can take the form of a letter sent to each committee member if no other business is to be conducted except for review of the quarterly exposure records. The Chairman of the committee will make this decision when preparing the agenda for a meeting. If he/she finds that there is not sufficient business to warrent a physical gathering of the committee, he/she will send out a letter to each member. The letter will report on the radiation exposure of the nuclear medicine staff and offer an invitation to have a gathering of the committee if any committee member has business to conduct. These leters will be filed for NRC inspection.

ATTACHMENT 3

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Eberline

   Manufacturer's model number: 520

   Number of instruments available: 1

   Minimum range: 0.1 mR/hr to _____ mR/hr

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

   b. Manufacturer's name: _____

   Manufacturer's model number: _____

   Number of instruments available: _____

   Minimum range: _____ mR/hr to _____ mR/hr

   Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator

   Manufacturer's name: Capintec

   Manufacturer's model number: CRC-5

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	General Electric	Maxicamera II
Thyroid Uptake Probe	Nuclear Data	System ND62T

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

   1. Calicheck Dose Calibration Linearity Test Kit
   2. Airflow meter, Dwyer Controls Gages, Model # 480
   3. Access to a Multichannel Analyzer-NaI Detector (Nucleus Inc. #256)

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ATTACHMENT 4

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

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

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

3. Survey instruments will be calibrated

X a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

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

____ (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.

X c. By a consultant or outside firm

(1) Name James E. Durlocher Certified Radiological Physicist Or Enviromental Health & Safety University of Notre Dame

(2) Location 6741 Allisonville Road Indianapolis, IN 46220 NRC# 13-07215-01 Notre Dame, Indiana 46556 NRC# 13-01983-15

(3) Procedures and sources

X have been approved by NRC and are on file in License No. #13-07215-01 #13-01983-15

____ 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 5A

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

X Other* (specify) First elution from new Mo-99/Tc-99m generator when possible or first elution of a Mo-99/Tc-99m generator on any given day in which the activity assayed will be equivalent to the maximum activity used for that period of time.

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy ±
Co-57	3-5	3.2 mCi	±4.3%
Ba-133	0.1-0.5	.200mCi	±5.0%
Cs-137	0.1-0.2	.183mCi	±4.3%
Ra-226	1-2		

C. X The procedures described in Section 2 of Appendix D will be used for calibration of the dose calibrator. With equivalent procedure used for Linearity testing, see Attachment 5B.

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.

10 8-30

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Item 10
1-15-87

Item 10 Equivalent Procedure for Checking Calibrator Linearity

As an alternative procedure for dose calibrator activity linearity check a device called "Calicheck" manufactured by Calcorp, Inc. will be used. The manufacturer's instructions for use will be followed and test results will be recorded and retained for inspection. The "Calicheck Kit" has been calibrated and calibration factors have been generated. Included, find the calibration factors, the manufacturer's calibration instructions and the procedure that will be used in checking the calibrator's linearity.

MARSHALL COUNTY PARKVIEW HOSPITAL
MCPH

219 936-3181
1401 N. MICHIGAN ST
PLYMOUTH, INDIANA 46563

PARKVIEW HOSPITAL
Kit Calibration
(Linearity)

Kit Serial No. 175

February 22, 1982

Tubes A		Displayed B		Calibration Factors C
Black Only / Black Only	*	248 mCi / 248 mCi	=	1.00
Black Only / Black & Red	=	248 mCi / 135 mCi	=	1.84
Black Only / Black & Orange	=	248 mCi / 71 mCi	=	3.49
Black Only / Black & Yellow	=	248 mCi / 19.7 mCi	=	12.59
Black Only / Black & Green	=	248 mCi / 5.8 mCi	=	42.76
Black Only / Black & Blue		248 mCi / 1.8 mCi	=	137.78
Black Only / Black & Purple		248 mCi / 0.[illegible] mCi	=	496

*Or following repair of dose calibrator or Calicheck Kit. In all instances these factors can only be determined following proof of activity linearity by standard techniques.

* *

SOURCE CONFIGURATION

___ Syringe

_X_ Vial

KEEP THIS FORM FOR FUTURE REFERENCE!

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Section III
CALIBRATION OF CALICHECK

OBJECTIVE:

To generate calibration factors for each tube in the Calicheck Kit, thereby expressing the amount of attenuation by each tube.

PREPARATION:

All radiation sources in the vicinity of the dose calibrator should be shielded to avoid erroneous readings. Further, the instrument may be sensitive to dosed patients in the vicinity. Move the patients to another location before you start. Both the "Kit Calibration" and the "Activity Linearity Procedure" must be performed in an environmentally stable background.

Syringe hangers and vial holder assemblies supplied with Capintec, Nuclear Associates, and some Picker dose calibrators must be removed. Molded chamber liners as supplied by RadX and some Picker dose calibrators must be lifted out. Calicheck will not fit the Mediac dose calibrators because the chamber diameter is too small.

The calibration source that is used should be the largest activity measured in the dose calibrator. This would normally be the Monday morning elution in the case of the generator, or the largest dose obtained from your radiopharmacy.

In order to use Calicheck, a source of Tc-99m must be placed into the central black tube. If the source is in a top loading lead elution shield, use extension tongs to transfer the source. If the source is in a bottom loading elution shield, remove the base cover, put the open end of the black tube to the bottom of the lead shield and allow the source to slide down into the black tube by tilting the tube at an angle. The center

tube accommodates vial sizes up to 20 ml. and syringes up to 10 ml. Proper technique dictates that when using a syringe, a clean needle be used and it should be no longer than 1½" in length. When the black tube is inserted into the dose calibrator, it should be done carefully with the open end in the upward position. The black tube must remain in the dose calibrator throughout all steps in the calibration cycle. Once the source is placed in the dose calibrator, the source must be kept in exactly the same position throughout the test to insure consistent geometry.

If the unit has a manual range adjust, adjust the range as necessary to acquire three significant figures for each reading.

When the activities displayed are at the uCi level (e.g., when the blue and possibly purple tubes are in place), dose calibrator displays may "float" or vary on successive measurement. Be sure to record an average figure on your data sheets. Record all values on the data sheets in the same units, either mCi or uCi.

Once the procedure is started, do not stop. All readings should be recorded within a matter of minutes. Otherwise, the short half life of Tc-99m will introduce unacceptable error.

CALIBRATION PROCEDURE: (To be performed only once.)*

1. Remove any syringe hanger or chamber liner, if necessary, from dose calibrator.

2. Set dose calibrator to measure Tc-99m.

*Or following repair of dose calibrator or Calicheck.

3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" in all ranges, zero on one range and record values on all other ranges, to add or subtract from final results when those ranges are used.

4. Place calibration source into black tube and insert black tube into dose calibrator CAREFULLY with the open end in the upward position. Read displayed activity.

5. Record reading in appropriate positions on Data Sheet #1 "Kit Calibration". (8 entries. See example)

Carefully ensure that, in the following steps, each tube is firmly seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record reading as the appropriate denominator on Data Sheet #1, Kit Calibration Form.

7. Replace red tube with orange tube. Record.

8. Replace orange tube with yellow tube. Record.

9. Replace yellow tube with green tube. Record.

10. Replace green tube with blue tube. Record.

11. Replace blue tube with purple tube. Record.

12. Remove the Calicheck assembly and place source in a shielded container. Place Calicheck in storage container provided.

Section IV

ACTIVITY LINEARITY PROCEDURE

OBJECTIVE:

To determine if a dose calibrator can respond linearly to a variety of levels of radioactivity via the Calicheck Technique.

PREPARATION:

Same as described under "Calibration of Calicheck". See page 4. Use the same source configuration as used in that calibration procedure.

PROCEDURE:

1. Remove any syinge hanger or chamber liner, if necessary from dose calibrator.
2. Set dose calibrator to measure Tc-99m.
3. Adjust zero, background, etc., if applicable. Check zero on each range. If background is not "zero" on all ranges, zero on one range and record values on all other ranges to add or subtract from final results when those ranges are used.
4. Place source to be used for the activity linearity procedure into the black tube and insert tube into the dose calibrator CAREFULLY with the open end in the upward position.
5. Record "displayed activity" on "Black Only" on Data Sheet #2 ("Dose Calibrator Activity Linearity Check").

Carefully ensure that, in the following steps, each tube is seated against the lead at the base of the black tube.

6. Place red tube in the dose calibrator over the black tube. Record "displayed activity" on Black & Red blank on Data Sheet #2.
7. Replace red tube with orange tube. Record on "Black & Orange" blank.
8. Replace orange tube with yellow tube. Record on "Black & Yellow" blank.

9. Replace yellow tube with green tube. Record on "Black & Green" blank.
10. Replace green tube with blue tube. Record on "Black & Blue" blank.
11. Replace blue tube with purple tube. Record on "Black & Purple" blank.
12. Remove Calicheck assembley and place source in shielded container.

DATA TREATMENT OF DATA SHEET #2: (To be completed each calendar quarter)

1. Enter appropriate Calibration Factors from Data Sheet #1 for your dose calibrator in Column C.

2. Multiply the value in Column B by the corresponding value in Column C to determine product of each entry for Column D. Record values. (Ideally, these values will all be the same.)

3. Add all products in Column D and divide by 7 to determine the mean value. Multiply the mean by 1.05 and 0.95 as indicated. These define the upper and lower limits of ± 5% variation.

If all values in Column D fall between these two limits, your dose calibrator has acceptable activity linearity. The test is complete, unless additional readings are required to check the microcurie range. If so, continue the determination by withdrawing an aliquot containing 2-3 mCi more activity than the displayed activity in the last measurement. The test is then repeated (Data Sheet #2 only), using the same source configuration as that used in determining the calibration factor on Data Sheet #1.

If any values in Column D fall outside the limits, repeat the study to rule out possible variations in the initial data. Consistent results that are outside the limits indicate that the instrument is exhibiting non-linearity. Corrective action is indicated.

DATA SHEET #2 (to be completed each quarter)

DOSE CALIBRATOR ACTIVITY LINEARITY CHECK

Dose Calibrator _____ Date _____

Model _____ Technologist _____

Source Configuration _____ (must be the same as on Data Sheet #1)

> All readings must be taken at the lowest range setting available and converted to mCi units.

A TUBE COLOR	B DISPLAYED ACTIVITY		C CALIBRATION FACTOR		D PRODUCT OF B X C
Black Only	_____ mCi	x	1.00	=	_____
Black & Red	_____ mCi	x	_____	=	_____
Black & Orange:	_____ mCi	x	_____	=	_____
Black & Yellow:	_____ mCi	x	_____	=	_____
Black & Green :	_____ mCi	x	_____	=	_____
Black & Blue :	_____ mCi	x	_____	=	_____
Black & Purple:	_____ mCi	x	_____	=	_____
				SUM =	_____

MEAN = $\frac{\text{SUM}}{7}$ = _____

x1.05 = _____ = UPPER LIMIT*

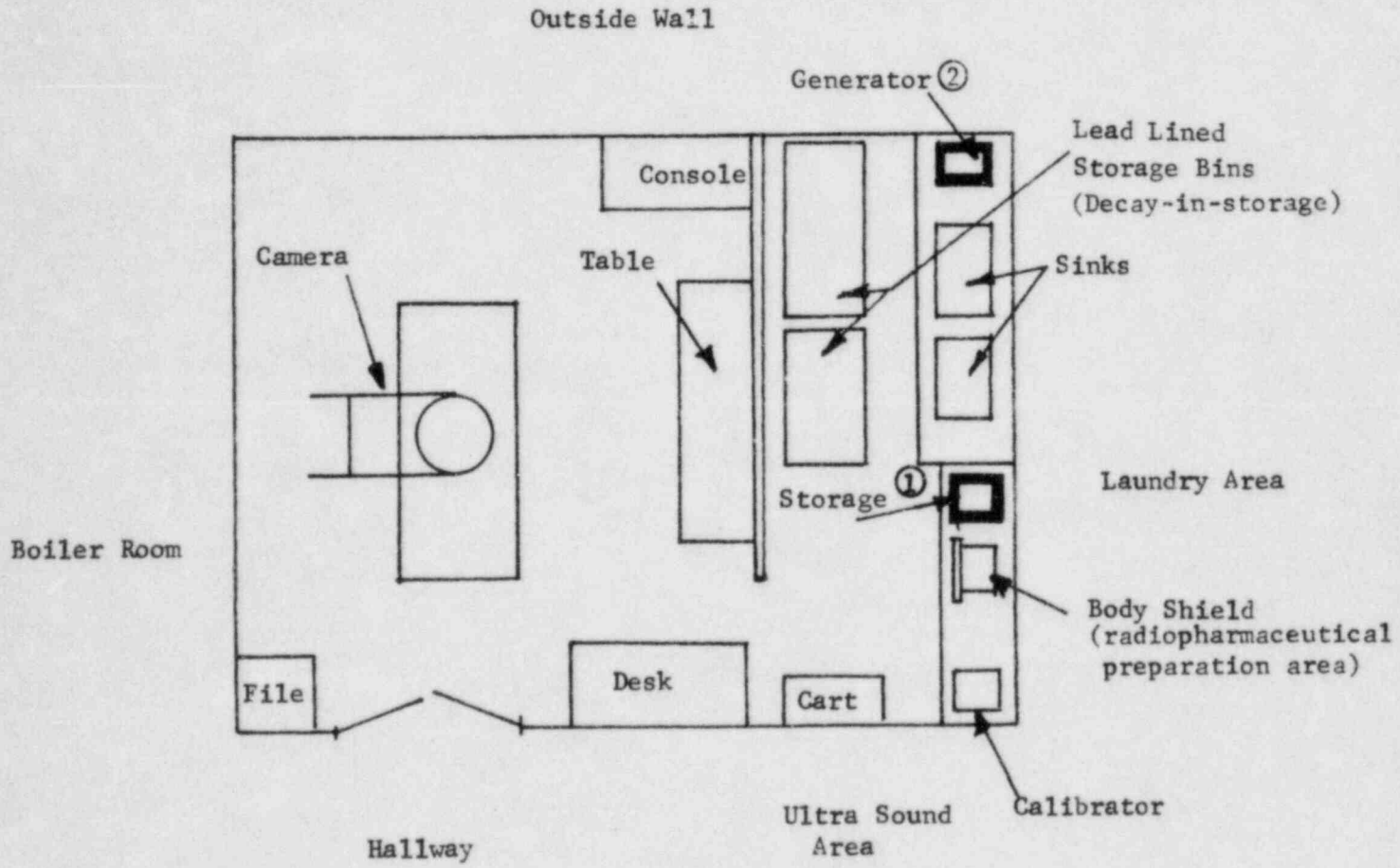
x0.95 = _____ = LOWER LIMIT*

Compare Column D data to upper and lower limits to confirm linearity.

*Instead of a variation in the Column D data of ± 5%, your radioactive material license may allow a difference of ± 10% in the test results. If so, multipliers of 1.10 and 0.90 can be used to determine the upper and lower limits.

ATTACHMENT 6

DEPARTMENT OF NUCLEAR MEDICINE



Scale ½"=1'

1. Lead brick shielding
2. " " "

ATTACHMENT 7

Item 12 Personnel Training Program

A. Radiation Workers: Individuals who work with radioactive materials(e.g., technologists) or with patients who have received therapeutic amounts of radioactive materials(e.g., nurses) will be instructed at the time of orientation with yearly reviews on matters concerning:

1. Pertinent NRC regulations.
2. The Institution's radiation exposure policy.
3. Radiation safety practices.
4. Potential hazards associated with radioactive material.
5. Rules and regulations of the licensee.
6. Emergency procedures.
7. Obligation to report unsafe conditions to the radiation safety officer.
8. Right to know their radiation exposure levels and the results of any bioassays done.
9. The location and availability of the NRC license, notices, and pertinent rules and regulations.

B. Ancillary Personnel (e.g., Clerical, nursing, housekeeping, security personnel) whose duties may require them to work in the vicinity of radioactive materials will be instructed at the time of orientation with yearly reviews on matters concerning:

1. Where radioactive materials are stored and used.
2. The meaning of posted signs.
3. The patential hazards associated with radioactive materials.
4. Emergency procedures.
5. Who to call for assistance and/or information

ATTACHMENT 8

Item 13. Procedure for Odering and Receiving Radioactive materials

1. All orders for radioactive materials are to be placed by the Chief Nuclear Medicine Technologist or persons designated to order by the same.

2. Only those materials and quantities authorized by the license are to be ordered; not exceeding possession limits.

3. Proper records will be maintained to identify the radioactive material ordered, quantity, supplier, etc and the verification of receipt.

4. During normal working hours, carriers will be instructed to deliver radioactive materials directly to the Radiology Department.

5. Packages delivered during nuclear medicine personnel off duty hours will be accepted and signed for by any of the following individuals: radiographer on duty, emergency room staff, or security personnel. Packages will be accepted in accordance with the procedures outlined in the attached memorandum.

HOLY CROSS
PARKVIEW HOSPITAL
1401 N. MICHIGAN ST., PLYMOUTH, INDIANA 46563 (219) 936-3181

MEMORANDUM

Memorandum For: Radiographers, Emergency Room Personnel, and Security Personnel.

From: W. S. Tirman, M.D., Radiation Safety Officer

Date: 1-20-85

Subject: Receipt of Packages Containing Radioactive Materials.

Packages containing radioactive materials that arrive when nuclear medicine personnel are off duty can be accepted and signed for by the radiographer on duty, emergency room personnel, or security personnel. After inspecting the outside of the package for wetness or signs of damage, take it immediately to the Nuclear Medicine Department. Unlock the door, place the package on the floor outside of the hot lab, and re-lock the door.

If the package is wet or appears to be damaged, immediately, contact one of the individuals listed below. Ask the carrier to remain at the hospital until it can be determined that neither the carrier or the delivery vehicle are contaminated.

Mr. Charles Kling 784-3435
Dr. Wallace Tirman 936-6127
Dr. John D. Scheu 291-9532

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ATTACHMENT 9

Item 17. Area Survey Procedures

Appendix I of Regulatory Guide 10.8 will be followed as written except for 4b and 6 which will read as follows.

4.b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be as follows:

1. Absorbent paper will be used to wipe containers and counters using moderate pressure.

2. A properly calibrated G-M survey meter with the beta shield removed will be used for detection of any contamination.

3. The meter will be taken to an area of low background activity and set on low range.

4. The wipe paper being evaluated will be placed as close to the probe as possible without making contact. It will be held there for 30 seconds and removed. This will be repeated twice.

5. If the meter registers activity above background, the paper will be considered contaminated and decontamination of the area will take place.

6. Area will be cleaned if the survey meter registers activity above background upon wipe testing.

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APPENDIX I

AREA SURVEY PROCEDURES

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

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

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

4. The weekly and monthly surveys wil onsist of:

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

   b. A series of wipe tests to measure c amination levels. The method for performing e tests will be sufficiently sensitive to detect 0 dpm per 100 cm^2 for the contaminant invol . Wipes of elution and preparation areas or her "high background" areas will be removed t low background area for measurement.

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

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

   b. Name of person conducting the survey.

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

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

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

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

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

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

ATTACHMENT 10

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).

_X_ Other (specify) Held for decay until background levels are reached.

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

_X_ Returned to the manufacturer for disposal.

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

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

_____ Other (specify): _____

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

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

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

_____ Other (specify) _____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

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

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

CONTROL NO. 78240

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Holy Cross Parkview Hospital

(Licensee's Name)

1-15-85

(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.

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

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.

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

CONTROL NO. 78240

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 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	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 0-1:

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 0-1 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 0-1.

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.

Martin P. Braaksma
Signature

Martin P. Braaksma
Name (print or type)

Executive Director
Title

Institution (or Private Practice) Name and Address

Holy Cross Parkview Hospital
1401 North Michigan Street
Plymouth, Indiana 46563

[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.