

January 9, 1989

DEPARTMENT OF RADIOLOGY

Radiologists: Richard L. Taylor, M.D. M.Van Ooyen, M.D. Donald C. Parker, M.D.

Materials Licensing Section Division of Radiation Safety and safeguards United States Nuclear Regulatory Commission Region III 799 Roosevelt Rd. Glen Ellyn, Illinois 60137

Subject: Renewal of License

Gentlemen:

Please accept this letter as request for renewal of our Materials License #21-03194-01 as amended January 30th, 1984 and with current expiration date of March 31, 1989.

Please reference addendum copies of Amendment 21 and 22 of prior license.

We have reviewed the instructions for preparation of application for license renewal provided with the reminding letter and submitted data. We have reviewed the current license and there have been no changes in the types or uses of isotopes currently being used per our current license.

Equipment changes, see Addenum I.

We have reviewed documents submitted in the past and there are no significant changes excepting in the membership of the Radiation Safety Committee. Current membership of Radiation Safety Committee - see Addendum II.

We have reviewed the NRC regulations and there seem to be no significant changes or regulations which would affect our program.

Thank you for the review of renewal application.

Sincerely,

& Thank Waylor, W

Richard L. Taylor, M.D. Director - Department of Radiology, Radiation Safety Officer Bixby Medical Center 818 Riverside Ave. Adrian, MI 49221 517 263-0711

818 Riverside Avenue + Adrian, Michigan 49221 + 517/263-0711



CONTROL NO 8672 1

EMMA L. BIXBY HOSPITAL DEPARTMENT OF RADIOLOBY ADRIAN, MICHIBAN 49221

RICHARD L. TAYLOR, M.D.

M. VAN DOYEN, M.D. RADIDLOGIST

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January 30, 1984

Material Licensing Branch Division of Fuel Cycle and Material Safety United States Nuclear Regulatory Commission Washington, D.C., 20555

SUBJECT: APPLICATION FOR LICENSE RENEWAL

License # 21-03194-01 Expiration date: 03-31-84

We have reviewed our current License Amendment #20 dated October 30, 1978.

We have reviewed supporting documentations supplied at your request dated September 1978.

There have been changes in personnel of the Radiation Safety Committee and in the Supervisor-Technologist of the Nuclear Medicine Department modifying Item #7 and Item # 12 respectively. Supplementary information is attached.

We have reviewed NCR regulation 10 CFR part 35.

Not withstanding the above changes we would request that we may continue to operate under our current License # 21-03194-01 Amendment # 20 with changes as noted to personnel.

RECEIVED BY LEMB Richard L. Taylor, M.D. Chief, Department of Radiology Jare 102 S. Knew no com 39 Jay Kreazer, Vice President Orig. To Emma I. Bixby Hospital Action Comple Chesk No. A Tea Coladar RELEWEN 44

PERSONNEL TRAINING PROGRAM AND FREQUENCY

QUALIFICATIONS FOR NUCLEAR MEDICINE PERSONNEL:

- 1. High school graduate, or equivalent, and
- Certified by the American Registry of Radiologic Technologists or equivalent registry.
- At least three years of experience at combination of staff nuclear medicine technologist's level and gained experience and possesses capabilities determined to be adequate by the Radiology Medical Director and Department Manager.

NUCLEAR MEDICINE PERSONNEL:

- 1. Supervisor, Nuclear Medicine Technologist:
 - D. Alice Ford, R.T.R., Senior Technologist, trained at General Electric Nuclear Medicine Institute, Milwaukee, Wisconsin.
 - b. Post-graduate programs in Nuclear Medicine, sponsored by the Michigan Society of Radiologic Technologists.
 - c. Eight years experience in Nuclear Medicine.
- 2. Back-up Nuclear Medicine Technologist:
 - Chris Wrona, R.T.R., Senior Technologist, trained at Ceneral Electric Nuclear Medicine Institute, Milwaukee, Wisconsin. - 1981
- 3. Back-up Nuclear Medicine Technologist:
 - a. D.Jerry Wolcott, R.T.R., Radiology Department Manager, Post-graduate programs in Nuclear Medicine, sponsored by the American and Michigan Societies of Technologists.
 - Nuclear Medicine refresher courses, sponsored by the Various Radiopharmaceutical companies and equipment manufacturers.
 - c. Twenty five years experience in Nuclear Medicine under the supervision of Certified Radiologists.

All Nuclear Medicine Technologists perform the various Nuclear Medicine functions under the direction and supervision of Board Certified Radiologists.

Item # 12 January 30, 1984 a. Medical Isotopes Committee's Duties and Responsibilities for a Medical Isotope Committee will be as described in Appendix B to this guide.

b. The Medical Isotopes Committee will meet guarterly.

c. Radiation Safety Committee:

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Richard L.Taylor, M.D., Radiologist Marinus Van Ooyen, M.D., Radiologist Leonardo Baylon, M.D., Surgery Serafin Samson, M.D., General Practice Jay Kreuzer, Vice President, Administration Mohinder Chada, M.D., Pathology Ronald Isley, MD., Internal Medicine

> Item # 7 January 30, 1984

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UNITED STATES NUCLEAR REGULATORY COMMISSION WASHINGTON, D.C. 20555

EMMA L. BIXBY HOSPITAL DEPARTMENT OF RADIOLOGY 818 RIVERSIDE AVENUE ADRIAN MICHIGAN LICENSE: 21-03194-01 EXPIRATION DATE: 03/31/84 PRDGRAM CODE: 02120 NOTICE DATE: 01/09/84

SUBJECT: NOTICE OF EXPIRATION

YOUR NRC LICENSE SPECIFIED ABOVE WILL EXPIRE ON THE DATE SHOWN. IF YOU WISH TO CONTINUE YOUR PROGRAM, YOU MUST SUBMIT AN APPLICATION FOR LICENSE RENEWAL.

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IN THE PAST, WE HAVE REQUESTED THAT RENEWAL APPLICATIONS BE SUBMITTED IN THEIR ENTIRETY, WITH NO REFERENCES TO PREVIOUS SUBMITTALS. THIS ASSURED THAT COM-PLETE, UP-TO-DATE INFORMATION ON LICENSEE PROGRAMS WAS SUBMITTED AT LEAST EVERY FIVE YEARS. IF YOU SO CHOOSE, YOU MAY SUBMIT A COMPLETE, UP-TO-DATE RENEWAL APPLICATION IN DUPLICATE WITH FROPER FEE, AS HAS BEEN DONE IN THE PAST.

HOWEVER, IN ORDER TO SIMPLIFY THE LICENSE RENEWAL PROCEDURE AND SAVE PAPERWORK, YOU MAY WISH TO CONSIDER AN ALTERNATIVE WHICH WOULD ALLOW SUBMITTAL OF ONLY THE ESSENTIAL INFORMATION WHICH IS NECESSARY FOR US TO ASSESS YOUR CURRENT PROGRAM AND ANY CHANGES YOU MAY REQUEST. IF YOU CHOOSE THIS ALTERNATIVE, YOU SHOULD DO THE FOLLOWING:

- 1. REVIEW YOUR CURRENT LICENSE TO DETERMINE THAT THE INFORMATION CONCERNING THE RADIONUCLIDES, CHEMICAL AND/OR PEYSICAL FORMS OF THE RADIONUCLIDES, QUANTITIES YOU WISH TO POSSESS, AND USES FOR THE RADIONUCLIDES ACCURATELY REPRESENTS YOUR CURRENT AND ANTICIPATED PROGRAM. IDENTIFY ANY ADDITIONS, DELETIONS, OP OTHER CHANGES. FOR ADDITIONS OR OTHER CHANGES, YOU MUST PRE-PARE INFORMATION CONCERNING PERSONNEL, FACILITIES, EQUIPMENT, AND RADIATION SAFETY PROCEDURES APPROPRIATE FOR THE REQUESTED ADDITIONS OR CHANGES.
- 2. REVIEW THE DOCUMENTS YOU HAVE SUBMITTED IN THE PAST TO DETER-MINE THAT THE INFORMATION IN THEM IS UP-TD-DATE AND ACCU-RATELY REPRESENTS YOUR MANAGEMENT CONTROL PROGRAM, FACILITIES, EQUIPMENT, PERSONNEL, RADIATION SAFETY PROCEDURES, WASTE DIS-PDSAL PROCEDURES, LOCATION(S) OF USE, AND ANY OTHER INFORMATION PERTINENT TO YOUR PROGRAM. THE DOCUMENTS WHICH YOU CONSIDER TO BE THOSE WHICH REPRESENT YOUR CURRENT PROGRAM SHOULD BE IDENTIFIED. ANY OUT-OF-DATE AND SUPERSEDED DOCUMENTS SHOULD BE IDENTIFIED. ANY OUT-OF-DATE AND SUPERSEDED DOCUMENTS SHOULD ALSO BE IDENTIFIED. (THOSE DOCUMENTS WHICH YOU HAVE SUBMITTED IN THE PAST WHICH ARE PART OF YOUR LICENSE ARE REFERENCED IN YOUR CURRENT LICENSE.) CHANGES SHOULD BE MADE IN THE DOCU-MENTS, AS NECESSARY, TO REFLECT YOUR CURRENT PROGRAM.

LICENSE NO: 21-03194-01

- 3. REVIEW NRC REGULATIONS TO ASSURE THAT ANY CHANGES IN THE REGU-LATIONS ARE APPROPRIATELY COVERED IN YOUR PROGRAM DESCRIPTION. IN PARTICULAR, YOU SHOULD REVIEW 10 CFR PART 35 TO DETER-MINE THE EFFECT OF CHANGES IN THIS REGULATION ON YOUR PROGRAM.
- 4. AFTER YOU HAVE COMPLETED YOUR REVIEW, YOU SHOULD SUBMIT A LETTER IN DUPLICATE WITH PROPER FEE, REQUESTING RENEWAL OF YOUR LICENSE. IF YOUR CURRENT LICENSE AND SUPPORTING DOCUMENTS ACCURATELY REFLECT YOUR FROGRAM, YOU SHOULD STATE THAT YOU WISH TO CONTINUE TO OPERATE UNDER YOUR CURRENT LICENSE, LIST THE DOCUMENTS BY DATE WHICK YOU HAVE PRE-VIDUSLY SUBMITTED THAT REFLECT YOUR CURRENT PROGRAM, AND STATE THAT YOU WILL CONTINUE TO OPERATE IN ACCORDANCE WITH THOSE DOCUMENTS AND APPLICABLE NRC REGULATIONS AND LICENSE CONDITIONS. ANY OBSOLETE OR SUPERSEDED DOCUMENTS SHOULD BE DELETED.
- 5. IF YOUR CURRENT LICENSE AND/OR SUPPORTING DOCUMENTS DO NOT REFLECT YOUR CURRENT PROGRAM, YOU SHOULD IDENTIFY AND DESCRIBE CHANGES AS APPROPRIATE. IF YOU REQUEST ADDITIONAL AUTHORI-ZATION AND CHANGES IN YOUR PROGRAM, YOU SHOULD INCLUDE APPROPRIATE SUPPORTING DOCUMENTS IN DUPLICATE.
- 6. PLEASE INCLUDE THE NAME AND TELEPHONE NUMBER OF THE PERSON WHO MAY BE CONTACTED CONCERNING YOUR RENEWAL APPLICATION, AND INCLUDE YOUR CORRECT MAILING ADDRESS IF IT IS NOT INDI-CATED CORRECTLY ON YOUR LICENSE.

IT IS IMPORTANT THAT THE INFORMATION YOU PROVIDE IN YOUR APPLICATION FOR LICENSE RENEWAL, AND WHICH WILL BECOME PART OF YOUR LICENSE BY REFERENCE, ACCURATELY REFIECTS YOUR PROGRAM. YOU WILL BE EXPECTED TO FULFILL THE COMMITMENTS YOU MAKE. YOU WILL BE INSPECTED AGAINST THOSE COMMITMENTS AS WELL AS NRC REGULA-TIONS AND THE TERMS AND CONDITIONS OF YOUR LICENSE.

AFTER OUR REVIEW OF YOUR APPLICATION FOR LICENSE RENEWAL, WE RESERVE THE RIGHT TO REQUEST ANY ADDITIONAL INFORMATION, INCLUDING A COMPLETE UP-TO-DATE APPLI-CATION, WHICH WE DEEM NECESSARY PRIOR TO ISSUANCE OF A RENEWAL LICENSE. IN PARTICULAR, UP-TO-DATE INFORMATION MAY BE REQUESTED FOR LICENSES WHICH HAVE SEEM AMENDED FREQUENTLY OR ARE SUPPORTED BY A LARGE NUMBER OF FRAGMENTED CR DISJOINTED DOCUMENTS.

IF YOUR APPLICATION FOR LICENSE RENEWAL IS FILED AT LEAST THIRTY (30) DAYS BEFORE THE EXPIRATION DATE OF YOUR LICENSE <u>AND THE APPLICATION IS ACCOMPANIED</u> <u>BY THE APPROPRIATE FEE FOR LICENSE RENEWAL</u>, YOUR LICENSE WILL AUTOMATICALLY REMAIN IN EFFECT UNTIL FINAL ACTION IS TAKEN ON YOUR APPLICATION. HOWEVER, IF YOUR APPLICATION IS FILED LESS THAN THIRTY (30) DAYS BEFORE THE EXPIRATION DATE AND IT CANNOT BE PROCESSED BEFORE THAT DATE, YOU COULD BE WITHOUT A VALID LICENSE WHEN THE LICENSE EXPIRES.

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LICENSE NO: 21-03194-01

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- 5. IF YOUR CURRENT LICENSE AND/OR SUPPORTING DOCUMENTS DO NOT REFLECT YOUR CURRENT PROGRAM, YOU SHOULD IDENTIFY AND DESCRIBE CHANGES AS APPROPRIATE. IF YOU REQUEST ADDITIONAL AUTHORI-ZATION AND CHANGES IN YOUR PROGRAM, YOU SHOULD INCLUDE APPROPRIATE SUPPORTING DOCUMENTS IN DUPLICATE.
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IT IS IMPORTANT THAT THE APPROPRIATE FEE FOR LICENSE RENEWAL ACCOMPANY YOUR APPLICATION FOR LICENSE RENEWAL. IN ACCORDANCE WITH SECTION 170.12 OF 10 CFR PART 170, NO APPLICATION WILL BE ACCEPTED FOR FILING OR WILL BE PROCESSED BEFORE THE PROPER FEE IS PAID.

AN IMPORTANT ELEMENT OF THE REGULATORY PROCESS IS THE MAINTENANCE OF AN UP-TO-DATE LICENSE. IT IS YOUR RESPONSIBILITY TO REQUEST A LICENSE AMENDMENT FOR CHANGES YOU WISH TO MAKE IN YOUR PROGRAM. CHANGES IN YOUR PROGRAM MAY NOT BE IMPLEMENTED UNTIL YOU RECEIVE THE LICENSE AMENDMENT. IF YOUR LICENSE IS KEPT UP-TO-DATE, FUTURE LICENSE RENEWALS SHOULD BE SIMPLE AND STRAIGHTFORWARD.

IF YOU DO NOT WISH TO RENEW YOUR LICENSE, YOU MUST DISPOSE OF ALL LICENSED RADIDACTIVE MATERIAL IN YOUR POSSESSION IN A MANNER AUTHORIZED IN 10 CFR PART 20, COMPLETE THE ENCLOSED FORM NRC-314, "CERTIFICATE OF DISPOSITION OF MATE-RIALS," AND RETURN IT BEFORE THE EXPIRATION DATE OF YOUR LICENSE WITH A REQUEST THAT YOUR LICENSE BE TERMINATED. IF YOU CANNOT DISPOSE OF ALL LICENSED RADIO-ACTIVE MATERIAL IN YOUR POSSESSION BEFORE THE EXPIRATION DATE, YOU MUST REQUEST A LICENSE RENEWAL FOR STORAGE ONLY OF THE RADIOACTIVE MATERIAL TO AVOID VIOLA-TIONS OF POSSESSING LICENSEABLE MATERIAL WITHOUT A VALID LICENSE.

> MATERIAL LICENSING BRANCH DIVISION OF FUEL CYCLE AND MATERIAL SAFETY

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ENCLOSURES: NRC-313M NRC-314 REG. GUIDE 10.8 10 CFR PARTS 20, 30, 35, 170

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10 CFR 35.100, SCHEDU	LE A, GROUP II	X	AS NEEDED	PHOSPHORUS-32 AS CO PHOSPHATE FOR INTR MENT OF MALIGNANT	LLOIDAL CHROMIC ACAVITARY TREAT		
10 CFR 35. 100, SCHEDUL	LE A, GROUP IV	x	AS NEEDED	GOLD-198 AS COLLOID CAVITARY TREATMEN EFFUSIONS.	FOR INTRA-		
10 CFR 35.100. SCHEDU	LE A, GROUP V	x	ASNEEDED	ODINE-131 AS IODIDE	FOR TREATMENT	X	250
10 CFR 35.100, SCHEDU	LE A. GROUP VI			XENON-133 AS GAS OR BLOOD FLOW STUDIES FUNCTION STUDIES	GAS IN SALINE FOR		
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INFORMATION REQUIRED FOR ITEMS 7 THE OUGH 23

Submit a detailed description of all the information requested in Items 7 through 23. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right hand corner of each page. Two copies of each appended sheat should be submitted with the application.

7. MEDICAL ISOTOPES COMMITTEE	14. PROCEDURES FOR SAFELY OPENING PACKAGES
a Committee's Duties and Responsibilities	CONTAINING RADIDACTIVE MATERIAL
b. Maeting Frequency.	15. GENERAL LABORATORY RULES FOR THE . SAFE USE OF RADIOACTIVE MATERIALS
c. Name and Specialty of Each Committee Member.	16. EMERGENCY PROCEDURES, INCLUDING - NAMES AND TE LEPHONE NUMBERS OF
B. TRAINING AND EXPERIENCE.	PERSONNEL TO BE NOTIFIED.
 Authorized User(s). (Each physician must complete Supplements A and B.) 	17. AREA SURVEY PROCEDURES.
h Beninsion Safaty Officer	18. WASTE DISPOSAL PROCEDURES.
(Complete Supplement A, if other than a physician already listed.)	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS.
	A Procedures
9. INSTRUMENTATION. (List by manufacturer s name and model number.)	a Precoutions
a. Survey instruments.	c. Personnel Instructions.
b. Dose Calibrator.	20. THERAPEUTIC USE OF SEALED SOURCES.
c. Diagnostic Instruments.	a. Procedures.
d. Other (e.g. liquid scintillation counter, ense manitor.)	b. Precoutions.
10 CALIBRATION OF INSTRUMENTS	c. Personnel Instructions.
a Methods.	21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES. (e.g., xenon- 133)
b. Frequency.	22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS
c. Standards (Redionuclide and Activity).	
11. FACILITIES AND EQUIPMENT. (Complete description and diagram.)	0F RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.8.
12. PERSONNEL TRAINING PROGRAM AND FREQUENCY.	
13. PROCEDURES FOR ORDERING AND RECEIPT OF	
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- a. Medical Isotopes Committee's Duties and Responsibilities for a medical isotopes committee will be as described in Appendix B to this guide.
- b. The Medical Isotopes Committee will meet quarterly.
- c. Marinus Van Ooyen, M.D., Radiology Ronald Isley, M. D., Internal Medicine Gordon Hammersley, M.D., Pathology Waldron Stewart, M.D., Assistant Administrator D. Jerry Wolcott, R.T., Radiology Department Manager Richard L. Taylor, M.D., Radiology Consultant: Joe Windham, PhD., Physicist

Item #7 September 17, 1978

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TRAINING AND EXPERIENCE

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See.

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a. Richard L. Taylor, M.D.

Marinus Van Ooyen, M.D. see previous license # 21-03194-01 expiration date: October 31, 1978, amendment # 18 condition 12.
b. Richard L.Taylor, M.D.

> Item #8 September 17, 1978

INSTRUMENTATION

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a. Survey Instruments:

G.M. Nuclear Chicago Model 2612
 .1 - 20 mR/hr monitoring

Victoreen Model 492
 1 - B+ Gamma to 1000 mR/hr survey meter

b. Dose Calibrator

General Electric Model CRC - 8 dose calibrator
 Diagnostic Instruments:

1. B-Gamma dual probe maxiscanner - scanning

Item #9 September 17, 1978

CALIBRATION OF INSTRUMENTS

- . a. General Electric Dose Calibrator measured daily using Cs. 137-standard and quarterly by physicist . See attached.
 - Calibration of survey meters provided by Dr. Joe Windham, physicist, at least annually.
 - c. Standards (Radionuclide and Activity) see attached.

Item # 10 September 17, 1978

DOSE CALIBRATOR CALBRATION PROCEDURES

The calibration procedures contained in the Nuclear Regulatory Commission's "A Guide for Preparation of Applications for Medical Programs," dated February 1976, will be followed. A copy of the procedures are attached.

The following type and activity of radioactive sources will be used:

- Daily consistency check
 Cs-137 ~- 200 microcuries
- Quarterly linearity check
 The first eluate from a new generator or the highest activity of use.

c. Annual accuracy check.

Cs-137	200	microcuries
Co-57	300	microcuries
Co-60	50	microcuries

Item # 10 September 17, 1978

METHODS FOR CALIERATION OF DOSE CALIERATOR.

All radiopharmaceuticals are required to be assayed for activity with a dose calibrator to an accuracy of 10%. In order to accomplish this, it is necessary to ascertain that the instrument is operating properly and accurately upon installation and periodically thereafter.

A. Test for the following:

1. Instrument linearity (at installation and ensually)

2. Geometrical variation (at installation)

3. Instrument accuracy (at installation and annually).

- B. After repair or adjustment of the dose calibrator, repeat all of the appropriate tests listed above (dependent upon the nature of the repairs).
- C. Before each daily use of the instrument, test for constancy of operation. Variations greater than 5% in this test will indicate the need for instrument repair, adjustment, and/or recalibration.
- D. On a quarterly basis, measure the apparent activity of a long-lived standard radionuclide such as Cs-137 or Radium-226 at all of the commonly used radionuclide settings and compare to the initial readings recorded with

this source at these settings (when the unit was first calibrated egainst NBS-traceable standards). Choose a source with "apparent" activity in the 2 - 10 mCi range.

- E. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
- F. Test of Instrument Linearity

The linearity of the dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vital of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (perhaps up to several hundred millicuries).

- Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
- Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- 3. Using the 30 hour activity measurement as a starting point calculate the decay predicted activities at 0, 6, 24, and 48 hours using the following table:

Ansay Time (hrs.)	Correction Factor
0	32
6	16
24	2
30	1
10	0.125

Example: if the net activity measured at 30 hrs. was 15.625 millicuries, then the predicted activity for 6 and 48 hours would be 15.625 mC x 16 - 250 mC and 15.625 mC x 0.125 - 1.95 mC respectively.

- Plot the measured net activity for each time interval versus 4. the decay predicted activity on log-log graph paper as illustrated.
- The activities plotted should be within + 5% of the decay 5. predicted curve if the instrument is linear and functioning properly. Errors greater than + 5% indicate the need for repair or adjustment of the instrument.
- If the instrument linearity cannot be corrected, it will be 6. necessary in routine assays to either assay an aliquot of the eluate that can be accurately measured, or to use the graph constructed in step 4 to relate measured activities to true activities (decay predicted activities).

G. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e. greater than $\pm 2\%$ (even though correction factors may be provided by the manufacturer, the accuracy of these should be . checked).

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

- Assay the vial at the appropriate instrument setting and subtract background level to obtain net activity.
- Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20 and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1.
- Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy) and

calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor.

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

4 ml Volume CF = 2.04 = 1.02 2.00

- 4. Plot the correction factors against the volume on linear graph paper as illustrated. Use this graph to select the proper volume correction factors for routine essay of that radionuclide.
- 5. The true activity of a sample is calculated as follows: True Activity = Measured Activity x CF Where the CF used is for the same volume and geometrical configuration as the sample measured.
- Similarly the same activity of Co-57 in a syringe may be compared with that in 10 ml in a 30 cc vial and a correction factor calculated.
- It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed

for lower energy redionuclides such as I-125. Hence adequate correction factors must be established for this type of syringe.

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

H. Test For Instrumant Accuracy

The accuracy of the dose calibrator should be checked for several radionuclides such as Cs-137, Co-57, and I-131 using appropriate reference standards whose activity is traceable to NBS. The activity levels of the reference sources used should approximate those levels normally encountered, giving adequate attention to source configuration. The lower energy reference standards (Tc-99m, Xa-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

 Assay the reference standard in the dose calibrator at the appropriate setting and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations and average results.

- The average activity determined in step 2 should agree with the certified activity of the reference source within ± 5% after decay corrections.
- Repeat the above steps for other composity used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

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- 6. Calibration checks which do not agree within ± 5% indicate that the instrument should be repaired or adjusted. If this is not possible a calibration factor should be calculated for use during routine assays of the radionuclides.
- 7. At the same time the instrument is being initially calibrated with the NBS traceable standards, place a long lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-231, Tc-99m, I-125, etc.) and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long lived source), without requiring more NBS traceable standards. Keep a log of these initial and subsequent readings.

Test for Instrument Constancy

1.

A long-lived standard radionuclide such as Cs-137 or Ra-226 (these are commercially available from most of the manufacturers of dose calibrators) should be assayed using a reproducible geometry before each daily use of the instrument.

 Assay the reference source using the appropriate instrument cetting (i.e. Cs-137 setting for Cs-137, etc.).

2. Measure background level at same instrument setting.

- 3. Calculate net activity by subtracting out background level.
- Plot net activity versus the day of the year on semi-lc. graph paper.

5. Log the background levels.

6. Repeat the same procedure using the To-99m instrument setting.

 Indicate the predicted activity based upon decay calculations and the ± 5% limits on the graph as illustrated.

SURVEY METER CALIBRATION PROCEDURE

The survey meter calibrations are to be performed at the Medical College of Ohio, Radiation Safety Office, C. S. 10008, Toledo, Ohio 43699. The calibration source is 96 millicuries of Cs-137 as of October 4, 1976. Meters are calibrated every six months. The calibration procedures and certificate of calibration for the Cs-137 source is enclosed.

> Item # 10 September 17, 1978

Calibration of Survey Meters

- A. Calibration of survey meters shall be performed with radionuclide sources.
 - 1. The source shall be approximate point source.
 - The source activity shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.
 - 3. The frequency shall be every six months.
 - 4. Each scale of the instrument shall be calibrated at approximately 1/3 and 2/3 of full scale.
 - 5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% of full scale. Readings with + 20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument

Cs-137 is used as the calibration.

- B. Check sources of long life shall also be read at the time of the above calibration. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken
 - 1. Before each use.
 - 2. After each maintenance and/or battery change.
 - 3. At least quarterly.

If any reading with the same geometry is not within \pm 20% of the reading measured immediately after calibration, the instrument should be recalibrated.

C. The instrument shall be calibrated at lower energies if its response is energy dependent and it is to be used to measure in the I-125, Xe-133, or Tc-99m energy ranges.

This calibration will be done either by calibrated standards (traceable to NBS) at or near the desired energies or as a relative intercomposition with an energy independent instrument and uncalibrated radionuclides.

All records will be kept on file in the Radiation Safety Office.

SURVEY METER CALIBRATION CERTIFICATE

ype	window G.M.)		Owner	
ifg				
lax, Reading			Meter Model #	
atteries			Meter Serial /	,
			Probe Model #	•
			Probe Serial	ß
heck Source			Speaker Model	0
			Speaker Seria	1 #
			Speaker Batt.	
Time Constan	t 🗌 Ear	Plugs	Head Set	🗌 Integrate
Calibration Sour	rce: 96 m	illicuries	137 _{Cs} See 0	ther Side
Full-Scale Range (mR)	Meter Value (mR)	Known Value (n	n Correct nR) (Mult	ion Factor iplier)
	, 	· · · · · · · · · · · · · · · · · · ·	••••	
· Constant and the second se				
Real and the second				
An an a second second second second				
Geometry Condit	ions			
••••				
Comments	· · · · · · · · · · · · · · · · · · ·			
Recalibration I	Due By:			
	Physicist			Date

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THIS REPORT MUST BE SAVED -- SEE OTHER SIDE

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SOME TIPS ABOUT SURVEYING

- 1. Always use a "check source" to verify meter is working.
- 2. Always check background before entering radiation area.
- For G.M., if needle is not moving either the meter is broken or it can be saturated from high radiation levels.
- A speaker will respond to radiation more quickly than the needle, so use the speaker to locate "hot" areas.
- 5. When counting beta radiation, record values from the CPM scale.
- Be aware of energy dependence. Obtain energy response curves from the manufacturer or calibrate the meter for the radionuclide in use.
- 7. Be aware of geometry conditions.
- 8. Always allow the needle to stabilize before recording value.
- Most reliable readings will be obtained if needle is approximately mid-scale.
- 10. A survey meter should be calibrated semi-annually.

CALIBRATION FACILITY

The survey meter calibration source used for this calibration was 96 mCi of Cs-137 at 10-4-76. The output of this source was determined by measurement with a Victoreen "R" chamber under those scatter conditions used during actual calibration. The accuracy of the roentgen output is believed to be known within + 3%.

THIS SOURCE WAS TESTED FOR EXTERNAL CONTAMINATION OR LEAKAGE GAMMA RAY SOURCE CALIBRATION PR ATE 2-28-77 MICHOCURIES - POSEY 1K. Date Measured Isotope Test No. Technical Operations, incorporated OPERATIONS INC. C.137 98033 10-4-76 **Radiation Products Division Burlington, Massachusetts 01803** Roentgens/Hr. Source

Identification

S-207

Source decay correction factors							
	Cotal	lt-60	Iridium-192		Ceslum-137		
Age in:	years	mos	weeks	days	years		
0	1.000	1.000	1.000	1.000	1.000		
1	. 877	. 989	. 937	. 991	.977		
2	.768	.978	.877	. 981	. 955		
3	. 674	. 967	. 821	. 972	.933		
4	. 590	. 957	.769	. 963	. 912		
5	. 513	.946	.721	. 954	. 892		
G	.451	. 936	.675	.945	.871		
7	. 393	. 926	. 632	. 937	.852		
8	. 343	. 916	. 592		.832		
9	. 366	. 905	. 554		.813		
10	.268	. 895	. 519		. 795		
11	. 225	. 886	.486		.777		
12	.2(6	.877	.455		. 759		
Tj	5.	. 26y	7	4.0d	30.2y		
Rhm/ci	1	. 30		0.55	0.32		

Standards

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Laboratory Report

> The gamma-ray emission of the sealed source herein described was intercompared with the radiation from a reference standard cobalt-60 source whose intensity had been established relative to a National Bureau of Standards calibrated cobalt-60 source. Comparison was made either with an uncollimated plastic-lined ionization chamber encased in a 3-mm thick aluminum container sealed against atmospheric pressure, or with an NBS-calibrated Victoreen R-meter whose readings were compensated for atmospheric pressure and temperature. All readings were corrected for air scattering and absorption. The source was measured with its axis of symmetry parallel with/perpendicular to the line joining source and detector. The reported output is believed to be accurate within ± 3 percent, the stated uncertainty of the reference NBS sources. Precision is believed to be better than ± 1 percent.

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Signed Calibration performed for:

FACILITIES AND EQUIPMENT

Note: Change from previous license

New facility: 16' x 27'. Lead lined ith utilization of the same Kewanee Manufacturing stainless table and sink, with isotope work station (has lined drawers for storage.)

Corridor

Scale = 1/8" - 1'

#1 Kewanee Isotope Work Station

#2 Picker MagnaScanner V

#3 G.E. Maxixan Whole Body Scanner

Generator (at present diagnostic isotopes are being purchased pre-calibrated and in unit dose form) if used will be stored in basement as per previous license and description.

Item #11 September 17, 1978

PERSONNEL TRAINING PROGRAM AND FREQUENCY

QUALIFICATIONS FOR NUCLEAR MEDICINE PERSONNEL:

- 1. High school graduate, or equivalent, and
- Certified by the American Registry of Radiologic Technologists or equivalent registry.
- 3. At least three years of experience at combination of staff nuclear medicine technologist's level and gained experience and possesses capabilities determined to be adequate by the Radiology Medical Director and Department Manager.

NUCLEAR MEDICINE PERSONNEL:

- 1. Supervisor, Nuclear Medicine Technologist:
 - Colleen Stover, R.T.R., trained at Nuclear Medicine Institute, Cleveland, Ohio, under the direction of Dr.D. Bruce Sodee, M.D.,
 - b. Nuclear Medicine Registry Eligible, 1978.
- 2. Back-up Nuclear Medicine Technologist:
 - D. Alice Ford, R.T.R, Senior Technologist, trained at General Electric Nuclear Medicine Institute, Milwaukee, Wis.
 - Post-graduate programs in Nuclear Medicine, sponsored by the Michigan Society of Radiologic Technologists.
 - c. Three years experience in Nuclear Medicine.
- 3. Back-up Nuclear Medicine Technologist:
 - a. D. Jerry Wolcott, R.T.R., Radiology Department Manager, Post-graduate programs in Nuclear Medicine, sponsored by the American and Michigan Societies of Technologists.
 - Nuclear Medicine refresher courses, sponsored by the various Radiopharmaceutical companies and equipment manufacturers.
 - c. Twenty years experience in Nuclear Medicine under the supervision of Certified Radiologists.

All Nuclear Medicine Technologists perform the various Nuclear Medicine functions under the direction and supervision of Board Certified Radiologists.

> Item #12 September 17, 1978

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STAFF EDUCATIONAL PROGRAMS :

- Complete policy and procedures for the Nuclear Medicine area are published in the Department Policy & Procedures Manual. All Radiology Personnel are requested to read these regulations and rules.
- 2. All policy and procedures are reviewed annually.
- 3. Student Radiology Technologists: each student is required to spend forty hours of clinical experience and lectures in this area under the supervision of the Nuclear Medicine Supervisor.

MEMORANDUM FOR:

Security Personnel

FROM: Paul Nelson, Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 P.M. and 7 A.M., or on Sundays shall be signed by the Security guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door, place the package on top of the counter immediately to the right of the door, and relock the door.

If the package is wet or appears to be damaged, <u>immediately</u> contact the hospital Radiation Safety Officer. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER:	Rich	ard	L.Taylor, M.D.
OFFICE PHONE:	517 -	263	- 0711
HOME PHONE :	517 -	263	- 4417

Item # 13 September 17, 1878 S. 10

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

 The Chief Nuclear Medicine Technologist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

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- During normal working hours carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
- 3. During off-duty hours security personnel will accept delivery of radioactive packages in accordance with the procedures outline in Mr. Nelson's memorandum (attached.)

Item #13 eptember 17, 1978 ٠.

RADIOACTIVE SHIPMENT RECEIPT REPORT

1.	P.O.#	SURVEY DATE	TIME	
2.	CONDITION OF PACKAGE:			
	0.K.	PUNCTURED	STATUS	WET
	CRUSHED	OTHER		
3.	RADIATION UNITS OF LA	BEL:	UNITS (n	nR/hr)
4.	MEMEASURED RADIATION	LEVELS: a. Package	surface	mR/hr
		b. 3' from	surface	mR/hr
5.	DO PACKING SLIP AND V	IAL CONTENTS AGREE:		
	a. Radionuclide	no di	ifference	
	b. Amount	yesno di	ifference	
	c. Chem Form	yesno di	ifference	
6.	WIPE RESULTS FROM: a	. Outer $eff = ($	CPM =	DPM
	b	. Final source cor	ntainerCP 	M=DPM
8.	SURVEY RESULTS OF PACE	KING MATERIAL AND CA	ARTONS	_mR/hr, CPM
9.	DISPOSITION OF PACKAGE	E AFTER INSPECTION		
10.	IF NRC/CARRIER NOTIFIC	CATION REQUIRED, GIV	VE TIME, DATE	AND PERSONS

NOTIFIED.

Item #13 September 17, 1978 PROCEDURES FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

- Visually inspect package for any sign of damage (e.g., wetness. crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
- 2. Measure exposure rate at 3 feet from package surface --record. If >10 mR/hr -- stop procedure and notify Radiation Safety Officer.
- Measure surface exposure rate and record. If > 200 mR/hr -stop procedure and notify Radiation Safety Officer.
- 4. Put on gloves.
- 5. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare requisition, packing slips, and label on bottle) check integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.

Item # 14 September 17, 1978

- Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps, assay and record.
- Monitor the packing material and packages for contamination before discarding.
 - a. if contaminated, treat as radioactive waste.
 - b. if not, obliterate radiation labels before discarding in regular trash.

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GENERAL LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIAL

- Wear laboratory coats, or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.

- Monitor hands and clothing for contamination after each procedure or before leaving the area.
- 4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.
- Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
- Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.
- 7. Wear personnel monitoring devices (Film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.
- Wear TLD finger badges during elution of generator or preparation, assay, and injection of radiopharmaceuticals.
- 9. Dispose of radioactive waste only in specially designated receptacles.

Item #15 September 17, 1978 10. Never pipette by mouth.

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- Survey generator, kit perparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.
- 12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level if applicable.
- 13. Always transport radioactive material in shielded containers.

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Item #15 September 17, 1978 .

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EMERGENCY PROCEDURES

Minor Spills:

- 1. NOTIFY: Notify persons in the area that a spill has occurred.
- 2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
- 3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Include all other contaminated materials such as disposable gloves.
- SURVEY: With a G.M. Survey Meter, check the area around the spill, your hand and clothing for contamination.
- 5. REPORT: Report incident to the Radiation Safety Officer.

Major spills:

- CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
- PREVENT THE SPREAD: Cover the spill with absorbent pads, but do attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

Item # 16 September 17, 1978

- 3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
- CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
- 5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

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6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

 RADIATION SAFETY OFFICER:
 Richard L.Taylor, M.D.

 OFFICE PHONE:
 517-263-0711

 HOME PHONE:
 517- 263-4417

Item # 16 September 17, 1978

AREA SURVEY PROCEDURES

- A. All elution, preparation and 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 100uCi) will be surveyed monthly.
- C. All other laboratory areas will be surveyed weekly.
- D. The weekly and monthly survey will consist of:
 - A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.
 - A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm.
- E. A permanent record will be kept of all survey results, including negative results. The record will include:
 - 1. Location, date, and type of equipment used.
 - 2. Name of person conducting the survey.
 - Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas., etc.
 - Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

Item # 17 September 17, 1978 - 2 -

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- ive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.
- F. Area will be cleaned if contamination level exceeds 100 dmp/ 100 cm².
- NOTE: For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey reports will be recorded.

WASTE DISPOSAL PROCEDURES

Liquid Waste will be disposed of: 1.

Check as appropriate:

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By commercial waste disposal service (see also No 4 below)

In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

Other (Specify):

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

Check as appropriate:

Returned to the manufacturer for disposal and/or

Held for decay until radiation levels as measured with a low-level survey meter and will all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants)

Disposed of by commercial waste disposal service (See also No 4 below)

Other (Specify):

3. Other Solid Waste will be:

Check as appropriate:

Held for decay until radiation levels as measured with a lowlevel 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 servie (See also No 4 below:

Other (Specify:

The commercial waste disposal service used will be:

(Name) (City, State)

NRC/Agreement State License NO.

Item #18 September 17, 1978 PROCEDURES FOR USE OF GROUPS IV AND V RADIOPHARMACEUTICALS FOR TREATMENT OF PATIENTS

- All patients treated with iodine-131 will be placed in a private room with a toilet.
- The patient's room will be properly postes in accordance with Section 20.203, 10 CFR Part 20.
 - 3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside, three feet away and the entrance to the room. The Radiation Safety Officer or his designate will then determine how long a person may remains at these positions and will post these times in the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times which will be posted on the patient's chart and on his door.
 - The form, Nursing Instructions for Patients Treated with Phosphous-32, or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.
 - Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR part 20.

Item #19 September 17, 1978 All linens will be surveyed for contamination before being removed from the patient's room and will, if necessary, be held for decay.

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- 7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer (or his designate), checked for contamination, and disposed of as normal or radioactive waste, as appropriate.
- 8. Non-disposable items used for these patients will be held in plastic bags in the patient's room, and checked for contamination by the Radiation Safety Office or his designate. Items may be returned for normal use, held for decay or decontaminated, as appropriate.
- 9. Urine and vomitus, from Iodine-131 therapy patients will be stored for decay in our radioactive waste storage area. When it has reached background levels as measured with a low-level survey meter, it will be released to the sanitary sewer system.
- 10. Before a therapy patient's room is reassigned to another patient. the room will be surveyed for contamination (and decontaminated if necessary) and all radioactive waste and waste containers will be removed.

Item #19 September 17, 1978



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IMAGE EVALUATION TEST TARGET (MT-3)



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IMAGE EVALUATION TEST TARGET (MT-3)



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- 11. Nursing Instructions
 - a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet in the patient's chart. Nurses should read these instructions before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients.
 - b. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precautions sheet in the patient's chart.
 - c. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.
 - d. Radioactive patients are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
 - e. No nurse, visitor or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

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- f. Attending personnel must wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basin or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The. gloves must be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Nuclear Medicine Department for proper disposal of the contents of the designated waste container.
- h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and left in the patient's room to be checked by a member of the Nuclear Medicine Department.
- All non-disposable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.
- j. For Iodine-131 patients:
 - (1) Urine from iodine-131 patients will be collected in special containers provided by the Nuclear Medicine Department. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal

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- 4 -

or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

- (2) If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards shw should wash her hands with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Nuclear Medicine Department.
- (3) Disposable plates, cups, and eating utensils will be used by patients who are treated with iodine-131.
- (4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Nuclear Medicine Department, Ext. 271. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.
- (5) All vomitus must be also kept in the patient's room for disposal by the Nuclear Medicine Department. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and

Item # 19 September 17, 1978 it should be well flushed (3 times).

- 6 -

- k. Utmost precautions must be taken to see that no urine or vomitus, is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Nuclear Medicine Department.
- 1. If a nurse, attendant or anyone else knows or suspects that his skin, or clothing, including shoes, is contaminated, notify the Nuclear Medicine Department immediately. This person should remain the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.
- m. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately.
- n. When the patient is discharged, call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

Item #19 September 17, 1978

NURSING	INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPOUS-32 or IODINE -131
Patient'	s Name:
Room No.	: Physician's Name:
Radioisc	tope Administered:
Date and	Time of Administration:
Dose Rec	eived: Method of Adminstration:
	Exposure Rates in MR/hr
Date	3 feet from bed 10 feet from bed
	(Comply with all Check Items)
1.	Visiting time permitted:
2.	Visitors must remain from patient.
3.	Patient may not leave the room.
4.	Visitors under 18 not permitted.
5.	Pregnant visitors not permitted.
6.	Film badges must be worn.
7.	Use and complete the following tags:
	door
	bed
	chart
	wrist

Item #19 September 17, 1978

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DATE ____

- 8. Gloves must be worn while attending patient.
- 9. Patient must use disposable utensils.
- 10. All items must remain in room until OK'd by Radiation Safety.
- ____11. Smoking is not permitted.
- 12. Do not release room to admitting until OK'd by Radiation Safety.
- ____13. Other instruction

In case of an emergency contact:

RSO / / name on/off duty telephone no.

Item #19 September 17, 1978

THERAPEUTIC USE OF SEALED SOURCES

Not applicable to this license request.

Item #20 September 17, 1978 Not applicable to this license request.

Item # 21 September 17, 1978 PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS

Not applicable for this license request.

Item # 22 September 17, 1978 PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIALS SPECIFIED IN ITEM 6B.

Not applicable for this license request.

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Item # 23 September 17, 1978

NRC Form 374 (8-82)	U.S. NUCLEAR REGI	ULATORY COMMISSION	PAGE _	1	OF	3	PAGES
	MATERIA	LS LICENSE	Amenda	ment	No. 2	1	
Pursuant to the Atomic Energy Act of 1954, Code of Federal Regulations, Chapter I, Patheretofore made by the licensee, a license is source, and special nuclear material designant deliver or transfer such material to persons import such byproduct and source materia Atomic Energy Act of 1954, as amended, Commission now or hereafter in effect and to	, as amended, the Ene rts 30, 31, 32, 33, 34 hereby issued authori ted below; to use such authorized to receive I. This license shall be and is subject to all o any conditions speci	rgy Reorganization Act of 19 4, 35, 40 and 70, and in reli- izing the licensee to receive, a h material for the purpose(s) it in accordance with the reg e deemed to contain the cor applicable rules, regulation ified below.	974 (Public ance on s acquire, po and at the ulations o nditions sp s and ord	c Law tateme ossess, e place of the a pecifie ters of	93-43 ents and and tran (s) desig pplicabl d in Sec the Nuc	8), and repre- nsfer b gnated e Part(tion 1 clear R	i Title 10, sentations yproduct, below; to (s); and to 83 of the tegulatory
Licensee 1. Emma L. Bixby Hospital Department of Radiology		In accordance wi January 30, 1984 3. License number 21-0 in its entirety	th let , 3194-0 to read	ter d l is d as	amend follo	ed ws:	
2. 818 Riverside Avenue Adrian, MI 49221		4. Expiration date	March	h 31,	1989		
		5. Docket or Reference No.					
 Byproduct, source, and/or special nuclear material 	 Chemical and form 	d/or physical	8. M m u	laximu lay pos nder th	m amou sess at a his licens	int tha iny on ie	t licensee e time
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. Any rad listed and II Section 10 CFR	iopharmaceutical in Groups I of Schedule A, 35.100 of 35	Α.	As n uses in S	auth auth aubite	ary oriz m 9.	for ed A
B. Any byproduct material listed in Group III of of Schedule A, Section 35.100 of 10 CFR 35	B. Any for Group I Section 10 CFR	m listed in II of Schedule A, 35.100 of 35	В.	2 cu bypr auth Subi	oduct orize tem 6	of e mat d in .B	ach erial
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any rad listed Schedul 35.100	iopharmaceutical in Group IV of e A, Section of 10 CFR 35	c.	As n uses in S	auth auth	ary oriz m 9.	for ed C
D. Iodine-131	D. Iodide		D.	250	milli	curi	es
E. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	E. Prepack	aged kits	Е.	3 mi each mate in S	llicu bypr rial ubite	ries oduc auth m 6.	of t orized E
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CONTROL NO. 8672 1

NRC	Form 374A U.S.	NUCLEAR REGULATORY CO	MMISSION	PAGE	OF	PAGES
(8-82	2)		License number	. 21-0319	94-01	
•	MATERIALS	LICENSE ARY SHEET	Docket or Refe	rence number		
			Amendmer	nt No. 21		
. Aı	uthorized Use					
. Ai of	ny diagnostic procedure f Title 10, Code of Fede	listed in Groups I eral Regulations.	and II of Schedu	le A, Sect	tion 35.100)
. Pr Gr	reparation and use of range roup III of Schedule A,	adiopharmaceuticals Section 35.100 of	for any diagnost Title 10, Code of	ic procedu Federal H	ure listed Regulations	in
. Ar Ti	ny therapeutic procedure itle 10, Code of Federal	e listed in Group I l Regulations.	V of Srae ule A,	Section 35	5.100 of	
. Fo	or treatment of thyroid	carcinoma.				
. <u>I</u>	n <u>vitro</u> studies.					
		CONDITION	<u>s</u>			
0.	Licensed material shall 818 Riverside Avenue, A	l be used only at t Adrian, Michigan.	he licensee's fac	ilities lo	ocated at	
1.	The licensee shall comp Regulations, Part 19, Part 20, "Standards for	oly with the provis 'Notices, Instruction Protection Agains	ions of Title 10, ons and Reports t t Radiation."	Chapter 1 o Workers;	l, Code of Inspectio	Federal ns" and
2.	Licensed material lists supervision of, the fol	ad in Item 6 above : llowing individual(is authorized for s) for the materi	use by, c als and us	or under th ses indicat	e ed:
	Richard L. Taylor, M.D.		A11			
	Marinus Van Ooyen, M.D.	•	Groups I, II <u>In vitro</u> stud	and III ies		
13.	For a period not to exc physician is authorized of this license, provid	eed sixty (60) days to use licensed ma led the visiting phy	s in any calendar aterial for human ysician:	year, a v use under	visiting the terms	
	 (a) Has the prior writ Medical Isotopes (ten permission of t Committee, and	the hospital's Ad	ministrato	or and its	
	(b) Is specifically na license authorizin	amed as a user on a ng human use, and	U.S. Nuclear Reg	ulatory Co	ommission	
	(c) Performs only thos by a U.S. Nuclear	e procedures for wi Regulatory Commiss:	hich he is specif ion license.	ically aut	horized :	
	The licensee shall main written permission spec specified in Subitems (for five (5) years from Subitem (a) above.	tain for inspection ified in Subitem (a (b) and (c) above. the time the licen	n by the Commissi a) above and of t These records sh nsee grants its p	on, copies he license all be mai ermission	s of the e(s) intained under	

NRC Form 374A	U.S. NUCLEAR REGULATORY COMMISSION		PAGE	OF	PAGES
. (8-82)		License number	21-03194	-01	
•	MATERIALS LICENSE SUPPLEMENTARY SHEET	Docket or Referen	ce number		
		Amendment	No. 21		

- Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.
- 15. Patients containing Iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.
- 16. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated October 18, 1978 (received October 3, 1978); supplement dated October 17, 1978; letter dated January 30, 1983; and Model ALARA Program as contained in Appendix 0 of Regulatory Guide 10.8, dated October, 1980. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Afcensing Section, Region Ill Materials

CONTROL NO 8672 1

MAR 1 5 1984

Date

	<u>,</u>
(8-82)	License number 01 00104 01
MATERIALS LICENSE	Docket or Reference number
SUPPLEMENTARY SHEET	030-02027
	Amendment No. 22
Emma L. Bixby Hospital Department of Radiology 818 Riverside Avenue Adrian, MI 49221	
In accordance with letter dated November 15, 1985, L as follows:	icense Number 21-03194-01 is amended
Condition 12. is amended to read:	
 Licensed material listed in Item 6 above is aut supervision of, the following individual(s) for 	morized for use by, or under the the materials and uses indicated:
Richard L. Taylor, M.D. Marinus Van Ooyen, M.D. Donald C. Parker, M.D.	Groups I, II, III and IV Iodine-131 for treatment of thyroid carcinoma In vitro studies Groups I, II and III In vitro studies Groups I, II and III In vitro studies
For the U.	S. Nuclear Regulatory Commission

By Mate

JAN 2 2 1986

Date

Jaterials Licensing Section, Region III

ADDENDUM 1

Equipment change - the new thyroid uptake system was purchased October 14, 1988 to replace the uptake mode of the Picker MagaScanner-V, which was purchased in 1965.

Newer equipment is Nuclear Data, Inc. Thyroid Uptake System; ND62T; Model No. 880708.

The system utilizes are controlled module consisting of a multichannel analyzer and video display with a printer for hard copy. It measures the entire energy spectrum.

Old equipment: The Picker Magascanner-V was removed from the Nuclear Medicine area and is being stored prior to disposal.

ADDENDEUM II

Current membership of radiation safety committee 1989

R.L. Taylor, M.D. - Radiologist-Radiation Safety Officer S. Donald Zaentz - Internist - Oncologist Mohinder Chadha, M.D. - Pathologist Bruce Jones, M.D. - Internal medicine

Radall Kelley, Vice President Human Resources Diana Mason-Brown, Quality Assurance Coordinator Diane Morris, Director, Respiratory Therapy Jeanne Bope, Director, Social Services Sharon Dettling, Director, Environmental/Dietary Services Wanda Fick, Director, Ambulatory Services Jerry Wolcott, Radiology Department Manager Additional information, Nuclear Regulatory Condission Application Changes: per your letter of 10-12-78 Refer: Control No. 00836

#4 PERSONNEL TRAINING PROGRAM

At the present time we are using pre-packaged unit dose diagnostic radio-isotopes and only radioactive iodine 131 therapeutic radioisotope - rarely are we using P 32. We do have a therapeutic radium program and safety procedures are discussed with nursing personnel in regard to radium procedures.

a. In the new employee orientation program which is well developed at Bixby Hospital, we will include information in regards radiation safety, radium safety, and safety in the Nuclear medicine program. This orientation includes all incoming hospital personnel, including volunteers. The program will be designed to be informative as to where the radioactive materials are to be kept and stored, the potential hazards associated with radioactive materials and the radiologic safety procedures appropriate to any of the employee duties which would be applicable. They will be advised of the pertinent regulations and rules of the licensing and of their obligation to report unsafe conditions. We will inform them of their rights , data of radiation exposure and biologic results as applicable.

b. This orientation is relatively simple to implement with new employees, as it is in existance, and we can easily utilize the structure to provide this information.

In service programs are conducted at least bi-annually or more often in the department of Radiology which would include most of those employees of risk.

c. Annual refresher courses are in existance in regards radium and radium handling procedures for the involved nursing and housekeeping services on the floors and will be expanded to include Nuclear Medicine safety as applicable.

Memos have been circulated to the housekeeping departments and to the security men and other shipping and receiving personnel who may be transitorily involved in handling radionuclides and will be updated annually.

Item #12 October 17, 1978

OCT 201978

00836

Additional Information, Nuclear Regulatory Conclusion Application Changes: per your letter of 10-12-78 Refer: Control No. 00836

FACILITIES AND EQUIPMENT

Note: Change from previous license

New facility: 16' x 27'. Lead lined room with utilization of the same Kewanee Manufacturing Isotope Work Station, stainless steel table and sink and lead lined drawers for isotope storage. (Isotope work station and storage drawers, with 1/4 inch lead equivalent.)



Scale = 1/8" - 1' #1 Kewanee Isotope Work Station #2 Picker MagnaScanner V #3 G.E. Maxixan Whole Body Scanner Exhaust vent O Supply vents

Radiopharmaceuticals:

At present all diagnostic isotopes are being purchased in pre-calibrated unit dose form. The enclosed departmental procedure No.DM 4.2 and DM 4.7 will outline the radiopharmaceutical program and the handling of radiopharmaceuticals, plus the procedure for radiation safety survey in the isotope area.

Generator:

If a generator was to be used again, it would be stored in the basement under the Cobalt therapy room. This area is locked and controled by Radiology as outlined in the previous license and description.

> Item #11 October 17, 1978

ADRIAN, MICHICAN	SCOPE: out 1	ADIOPHARMACEUT	ODGS, Inc.	PROCEDURE NoDM Page of3 Ref. Policy:	4.2
	program and the handling of radiopharmaceuticals.			Authority: J. Wolcott	
RADIOLOGY DEPARTMENT POLICY/PROCEDURE	Effective: 3-16-76	Reviewed: 11-1-76	Revised:	Approved by: R. Taylor, M.D.	A

- The Nuclear Medicine Department at Bixby Hospital receive their radiopharmaceuticals in unit doses from Pharmatopes, Inc., 1944 W. Central Avenue, Toledo, Ohio 43605, (except for the T-3 & T-4 Kits which is ordered from E.R. Squibb & Sons)
- Pharmatopes, Inc. is licensed by the Nuclear Regulatory Commission, licensed number 34-16654-01MD, and the Ohio State Board of Pharmacy, license number 02-05-4313. Pharmatopes, Inc., also has an office in Detroit, Michigan, license number unknown at this time.
- Pharmatopes, Inc. assumes full reponsibility and liability for the radiopharmaceuticals compounded and dispensed in the nuclear pharmacy.
- Radiopharmaceuticals are dispensed on a legal prescription in unit dose syringe contained in individual lead shields, designed specifically for this purpose.
- 5. All lead shields, unused isotopes and radioactived waste materials is returned to Pharmatopes, Inc. and stored for decay as required by the . Nuclear Regulatory Commission.
- 6. All incoming and outgoing radiopharmaceuticals packages must be check for defects and survey with G.M. meter for radioactive. Any packages that check higher than background level must be reported at onces and recorded.
- Radioactive material is stored in the Isotope cabinet until Monday. The lead shields and waste materials will be picked up the Pharmatopes.
- 8. Prescription labels for isotopes used must be recorded in the log book in the Nuclear Medicine Lab, with the patient information.
- 9. Monthly records of all radiopharmaceuticals received and returned must be kept on file in the Nuclear Medicine Lab.
- 10. All radiopharmaceuticals must be recalibrated in Emma L. Bixby Hospital's dose calibrater prior to patient injection. This information must be recorded in the log book with patient information & prescription label.

DMA L. BIXBY HOSPITAL ADRIAN, MICHIGAN	SECT: NUCLEAR MEDICINE RADIATION SURVEY SCOPE: procedure for radiation safety survey in the Isotope Lab.			PROCEDURE No. <u>/DM h.7</u> Page <u>1</u> of <u>2</u> Ref. Policy:	
				Authority: J. Wolcott	
RADIOLOGY DEPARIMENT POLICY/PROCEDURE	Effective: 11-1-76	Reviewed:	Revised: 10-29-76	Approved by: R. Taylor, M.D. MG	

- All incoming & outgoing radiopharmaceuticals packages must be check for defects and radioactivity.
- 2. Daily survey of the Isotope Lab with a #492 Victoreen Survey meter or Nuclear/Chicago Survey meter, Model 2612.
- 3. Any reading on the survey meter, than that area must have a wipe test, in addition to the regular wipe test procedure.
- 4. Routine wipe testing should be done monthly or if there is a reading on the daily survey.
- 5. Report any usual reading or test to the department manager and radiologist.
- Records must be kept of all survey and wipe tests on the "Radiation Testing" form.
- 7. Wipe tests results: Max. allowed = 11,000disintegration/minute or .005 uCi (NRC) using the Picker Well with G.E. Spectrometer.

ENNA L. BIXBY HOSPITAL RADIOLOGY NUCLLAR MEDICE DEPARTMENT



Proc. No. UN 4.7 Page 2 of 2

RADIATION TESTING

- Daily survey of the Isotope Lab. with #492 Victoreen Survey meter. Any reading on the meter, that area must be wipe tested plus a routine check of whole lab..
- 2. Routine wipe testing should be done monthly or if there is a reading on the survey meter.
- 3. Report any unusual readings or tests to the Department Manager & Radiologist.



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		24. PERSONNEL	MONITOR	ING DEVICES	
10	TYPE wet copropriet box)	SU	PPLIER		EXCHANGE FREQUENCY
	X FILM	Sanala Diagon			Hoathlu
WHOLE	TLD	Searre Dragnos	SLICS II	<u></u>	HONCKITY
	OTHER (Specify)	and the second second			
	X FILM	Searle Diagnos	stics Ir	nc.	Monthly
FINGER	TLD				
	OTHER (Specify)				
	3.	FOR PRIVATE PRACTICI	E APPLICA	NTS ONLY	
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