NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041

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

Nuclear Medicine Department
Memorial Medical Center
1615 Maple Lane
Ashland, Wisconsin 54806

TELEPHONE NO.: AREA CODE (715) 682-4563 ext. 251

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

N/A

2. PERSON TO CONTACT REGARDING THIS APPLICATION

M.J. Fischer, M.D.

TELEPHONE NO.: AREA CODE (715) 682-4563 ext. 151

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 48-16593-01

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

M.J. Fischer, M.D.
Robert G. Lind, M.D.

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.)*

M.J. Fischer, 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	200 mCi
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

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

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE	
X — Names and Specialties Attached; and	
X — Duties as in Appendix B; or *(Check One)*	
___ Equivalent Duties Attached	
8. TRAINING AND EXPERIENCE	
X — Supplements A & B Attached for Each Individual User; and	
___ Supplement A Attached for RSO.	
9. INSTRUMENTATION *(Check One)*	
___ Appendix C Form Attached; or	
___ List by Name and Model Number	
10. CALIBRATION OF INSTRUMENTS	
X — Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	
___ Equivalent Procedures Attached; and	
___ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	
X — Equivalent Procedures Attached	
11. FACILITIES AND EQUIPMENT	
X — Description and Diagram Attached	
12. PERSONNEL TRAINING PROGRAM	
X — Description of Training Attached	
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X — Detailed Information Attached	
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X — Appendix F Procedures Followed; or	
___ Equivalent Procedures Attached	
15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X — Appendix G Rules Followed; or	
___ Equivalent Rules Attached	
16. EMERGENCY PROCEDURES *(Check One)*	
X — Appendix H Procedures Followed; or	
___ Equivalent Procedures Attached	
17. AREA SURVEY PROCEDURES *(Check One)*	
X — Appendix I Procedures Followed; or	
___ Equivalent Procedures Attached	
18. WASTE DISPOSAL *(Check One)*	
X — Appendix J Form Attached; or	
___ Equivalent Information Attached	
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X — Appendix K Procedures Followed; or	
___ Equivalent Procedures Attached	
20. THERAPEUTIC USE OF SEALED SOURCES	
N/A — Detailed Information Attached; and	
___ Appendix L Procedures Followed; or *(Check One)*	
___ Equivalent Procedures Attached	
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
N/A — Detailed Information Attached	
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
N/A — Detailed Information Attached	
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
N/A — 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. & Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, J.r & 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: 43 FR 7210
7.B Renewal

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Markham J Fischer MD

(1) NAME *(Type or Print)*

(2) TITLE
Radiation Officer

c. DATE
July 1, 1980

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FORM NRC-313M
(8-78)

VPO SHEET PROTECTOR MY-1

FORM NRC-313M-SUPPLEMENT A — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Markam J. Fischer M.D.	Michigan Minnesota, South Dakota Wisconsin

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Radiology	

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Minn. - Veteran Administration Hospital July 1969 to Dec 1972	150	100
b. RADIATION PROTECTION	University of Minn. - Veteran Administration Hospital July 1969 to December 1972	25	25
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Minn. - Veteran Administration Hospital July 1969 to Dec 1972	30	30
d. RADIATION BIOLOGY	University of Minn. - Veteran Administration Hospital July 1969 to December 1972	75	75
e. RADIOPHARMACEUTICAL CHEMISTRY	University of Minn. - Veteran Administration Hospital July 1969 to December 1972	15	15

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc 99m	150 mCi	Memorial Medical Center	5 years	practice
I 131	300 uCi	University of Minn.	2 years	training
Xe 133	10 MCi	University of Minn.	2 years	training
Co 60	External Source	University of Minn.	3 years	training

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Robert G. Lind, M.D.	Wisc., Mich., Minn.

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
American Board of Radiology	Diagnostic Radiology	June, 1976

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING (A)	LOCATION AND DATE(S) OF TRAINING (B)	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) (C)	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D)
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Minnesota Hospitals and Minneapolis Veterans Administration	150	100
b. RADIATION PROTECTION	Hospital (Diagnostic Radiology Residency - 1 July 1972 - 30 June 1975)	30	30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Merle Luken, M.D., Chief Dept. of Nuclear Medicine Thomas Payne, PhD, Radiation Physicist	30	30
d. RADIATION BIOLOGY	↓	25	20
e. RADIOPHARMACEUTICAL CHEMISTRY	↓	50	30

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc^{99m}	200 mc/week	Memorial Medical Center - Ashland, Wisc.	1000 Hours (1½ year)	Medical Diagnosis

FORM NRC-313M Supplement A (8-78)

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FORM NRC-313M-SUPPLEMENT A
78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
John O. H Peterson MD	Wisc, Mich, Minn.

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
American Board of Radiology	Diagnostic Radiology	June 1975

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING (A)	LOCATION AND DATE(S) OF TRAINING (B)	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) (C)	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D)
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Minnesota Hospitals and Minneapolis	150	100
b. RADIATION PROTECTION	Veterans Administration Hospital (Diagnostic Radiology)	30	30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Residency - July 1, 1972 - June 30, 1975)	30	30
d. RADIATION BIOLOGY	Merle Larken, M.D. Chief Dept of Nuclear Medicine	25	20
e. RADIOPHARMACEUTICAL CHEMISTRY	Thomas Kane, Ph.D Radiation Physicist	50	30

DELETED PER NRC NOTIFIED

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc^{99m}	200 mc / week.	Memorial Medical Center Ashland, Wisconsin	1,500 hrs (2 yrs)	Medical Diagnosis

Item 7: Radiation Safety Committee

A. Members

1. M.J. Fischer, M.D. - Chief Radiologist
2. R.G. Lind, M.D. - Radiologist
3. Steven Becktold, M.D. - Chief Pathologist
4. Marjorie Kacvinsky - Radiology Director
5. Lowell Miller - Hospital Administrator
6. Robert Wadzinski - Chief Nuclear Medicine Technologist
7. Barb Peikert - Director of Nursing
8. Tom Stipetich - Laboratory Technologist

B. Radiation Safety Committee, Medical Isotope Committee and Diagnostic Services Committee are all one and the same.

APPENDIX B

MEDICAL ISOTOPES* COMMITTEE

Responsibility

The committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by §19.12 of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users, and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Meeting Frequency

The medical isotopes committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

*Alternative titles are "radioisotope" or "radiation safety" committee.

APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Victoreen Instrument Company

   Manufacturer's model number: Model No 6B

   Number of instruments available: One

   Minimum range: 0 mr/hr to 0.5 mr/hr

   Maximum range: 0 mr/hr to 50.0 mr/hr

   b. Manufacturer's name: Victoreen Instrument Company

   Manufacturer's model number: Model No. 1A

   Number of instruments available: One

   Minimum range 0 mr/hr to 0.5 mr/hr

   Maximum range 0 mr/hr to 50.0 mr/hr

2. Dose calibrator

   Manufacturer's name: Chicago Nuclear

   Manufacturer's model number: Mediac - 018896

   Number of instruments available: One

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Gamma Camera	General Electric	62-123

4. Other

APPENDIX D

CALIBRATION OF INSTRUMENTS*

Section I

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.

2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points such that (a) one point is in each half of the scale and (b) the two points are separated by 35-50% 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 (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

Note:

Sources of Cs-137, Ra-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, 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 and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

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

This calibration may be done either

1. As in item A above with calibrated standards of radionuclides at or near the desired energies or

2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

D. Records of the above items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1 A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.

a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

b. The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

*See ANSI N42.1.8, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

2. Inverse Square Law

S (R$_1$) (R$_2$)

* - - P$_1$

- - - - - - - P$_2$

Exposure rate at P$_2$:

$$R_2 = \frac{(P_1)^2}{(P_2)^2} (R_1)$$

where

S is the point source

R$_1$ and R$_2$ are in the same units (mR/hr or R/hr)

P$_1$ and P$_2$ are in the same units (centimeters, meters, feet, etc.)

3. Radioactive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-\left[\frac{0.693}{T_{1/2}} \times t\right]}$$

where

R$_o$ and R$_t$ are in the units mR/hr or R/hr

R$_o$ is exposure rate on specified calibration date

R$_t$ is exposure rate t units of time later

T$_{1/2}$ and t are in the same units (years, months, days, etc.)

T$_{1/2}$ is radionuclide half-life

t is number of units of time elapsed between calibration and present time

4. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

= 100 x 0.77 = 77 mR/hr at 1 foot on March 10, 1977.

b. Output at 3 feet, 2.0 years after calibration date:

$$R_3 \text{ feet} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr}$$

$$= \frac{1}{9} \times 77 = 8.6 \text{ mR/hr at}$$

3 feet, 2.0 years after calibration.

i.e., greater than ±2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

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

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. 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.

3. 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 (CF).

   Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

   $$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x Correction Factor

   where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial and a correction factor may be calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

   An alternate to providing syringe calibration 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).

G. Test For Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Ba-133 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, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. 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.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5% after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that 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 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-131, 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.

H. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semi-log graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the ±5% limits on the graph as illustrated.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than ±5% from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	_____	_____
Ba-133	_____	_____
Cs-137	220uCi	_____
Ra 226	_____	_____ +5%
_____	_____	_____

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

or

____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

MEDI-NUCLEAR CORPORATION
6735 LANMAN ROAD DRAYTON PLAINS, MICHIGAN 48020
(313) 332-8600

January 1, 1983

NEW: CALICHECK™

DOSE CALIBRATOR ACTIVITY LINEARITY TEST KIT

Calicheck is a kit designed to perform the activity linearity test on a dose calibrator quickly and accurately. The kit consists of seven tubes, six of which are lead-lined. The seventh, an unlined tube, is used to center a source of Tc-99m, whether in a syringe or vial, in the dose calibrator chamber. Each lead lined tube is manufactured with various thicknesses of lead. This allows attenuation of gamma radiation from the radioactive source by different orders of magnitude which simulates various stages of radioactive decay. The tubes are sequentially placed over the Tc-99m source in the dose calibrator and within minutes, seven successive measurements are acquired. The displayed readings represent measurements that would have been obtained at approximately 0, 6, 12, 20, 30, 40 and 50 hours after the initial assay of Tc-99m.

The displayed readings from the tubes are then multiplied by specific correction factors, which were determined by the operator upon receipt of the kit. With only some simple calculations, the operator can then confirm whether or not the measurements are within the acceptable error for activity linearity allowed by their license.

The kit comes complete with a storage cylinder, instruction manual, work sheets, and a parts order form. Any components of the kit can be ordered separately, if needed.

In some agreement states and all NRC licensed states, the use of the kit requires that your radioactive materials license be amended. An amendment application form is included with the kit for this purpose.

SAVES TIME: Activity linearity testing can be done quickly and easily. The whole test can be completed within 4-8 minutes, including the calculations.

ANY ACTIVITY LEVEL: Linearity can be checked from the largest activity levels assayed in the dose calibrator (generator elutions) to the smallest dose that can be accurately measured by your instrument. This is done by simply generating one or two series of readings with the kit.

REDUCED TECHNITION EXPOSURE: The radioactivity is handled only once, possibly twice, and radiation exposure to personnel is maintained ALARA. Therefore, use of the Calicheck Kit is within the spirit of the ALARA philosophy.

ELIMINATES DOSE CHARGE: The same activity can be reused for kit preparation or patient dose administration. This saves the unnecessary expense of purchasing a special dose of activity just to check linearity.

NRC APPROVAL: This linearity testing has been found acceptable by the Nuclear Regulatory Commission and numerous agreement states.

CALICHECK KIT $ 375.00

order

To Order Phone (313) 332-8600
Please Specify Dose Calibrator Make and Model

ORDERED 4-15-83

Kit Calibration

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

TUBES A		DISPLAYED ACTIVITY B		CALIBRATION FACTORS C
Black Only / Black Only	=	_____ mCi / mCi	=	1.00
Black Only / Black & Red	=	_____ mCi / mCi	=	_____
Black Only / Black & Orange	=	_____ mCi / mCi	=	_____
Black Only / Black & Yellow	=	_____ mCi / mCi	=	_____
Black Only / Black & Green	=	_____ mCi / mCi	=	_____
Black Only / Black & Blue	=	_____ mCi / mCi	=	_____
Black Only / Black & Purple	=	_____ mCi / mCi	=	_____

SOURCE CONFIGURATION

_____ Syringe

_____ Vial

*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. KEEP THIS FORM FOR FUTURE REFERENCE!

Dose Calibrator Activity Linearity Check

Dose Calibrator _____ Date _____

Model _____ Technologist _____

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

All readings must be taken at 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 = $\frac{\text{SUM}}{7}$ = _____

MEAN X 1.05 = _____ = UPPER LIMIT*

MEAN X 0.95 = _____ = 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.

ITEM 12 PERSONNAL TRAINING PROGRAM

1. Personnel working with radioactive material shall be registered technologists with a minimum of 80 hours additional, of Intensive Training (formal class work and lectures).

2. Annually or when appropriate the Radiation Safety Officer shall hold inservice programs for Radiation Safety for all personnel that may come in contact with radioactive material. Participation is mandatory and is to be recorded.

3. Personnel shall be kept apprised of all pertinent NRC regulations as well as the Institution's NRC license.

4. Personnel are to be fully trained in the proper responses to any emergency or unsafe condition and report same to RSO and the Radiology Supervisor. Appropriate incident forms are completed, asin Hospital safety policies.

5. Radiation exposure records are available to all personnel and any excessive doses are to be explained to the RSO in writing.

6. A monthly inservice program is available for all personnel for Nuclear Medicine.

Appendix E.

PROCEDURES FOR ORDERING
AND
RECEIVING RADIOACTIVE MATERIALS

1. The Radiology Supervisor must place all orders for radioactive material; he must ensure that the requested materials and quanities are authorized by the license, and that possession limits are not exceeded.

2. During normal working hours, carriers must be instructed to deliver Radioactive packages directly to the Radiology Department. Those hours are 0700 until 2030 hours on weekdays, weekends and holidays are 0800 until 1630 hours.

3. During off-duty hours, and no radiology personnel are readily available, call the person on duty in Building Operations to place the package in Radiology in x-ray room #1 on the floor beside the entrance. Then re-lock the department. If the package appears to be damaged or is wet immediately contact the Radiologist on call as acting Radiation Safety Officer and the technician on call. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. 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 and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer.

3. 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 slip, and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packaging material). Check also that shipment does not exceed possession limits.

6. Wipe external surface of final source container with moistened cotton swab or filter paper held with forceps; assay and record.

7. Monitor the packing material and packages for contamination before discarding.

   a. If contaminated, treat as radioactive waste.

   b. If not contaminated, obliterate radiation labels before discarding in regular trash.

In all the above procedures, take wipe tests with a paper towel, check wipes with a thin-end-window G-M survey meter, and take precaution against the spread of contamination as necessary.

APPENDIX G

GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. 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 when their use would compromise the patient's well-being.

5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

6. 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 devices should be worn at chest or waist level.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, 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 shielding containers.

APPENDIX H

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. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

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.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

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: _____
OFFICE PHONE: _____
HOME PHONE. _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RSO:

_____
_____
_____

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with a low-range thin-window G-M survey meter and decontaminated if necessary.

2. Laboratory areas where only small quantities of radioactive material are used (less than 100 μCi) will be surveyed monthly.

3. All other laboratory areas will be surveyed weekly.

4. The weekly and monthly survey will consist of:

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

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 100 dpm per 100 cm^2 for the contaminant involved.

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

   a. Location, date, and type of equipment used.

   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 100 dpm/100 cm^2.

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.

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

___ By commercial waste disposal service (see also item 4 below).

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

___ Other (specify): _____

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

___ Returned to the manufacturer for disposal.

X Held for decay until radiation levels, as measured 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 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 item 4 below).

___ Other (specify): _____

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

Y Held for decay until radiation levels, as measured 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. _____

MPO SHEET PROTECTOR MY-11

MPO SHEET PROTECTOR MY-11

APPENDIX K

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with iodine-131 or gold-198 will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination to be expected. Particular attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate.

2. The patient's room will be properly posted in accordance with §20.203 of 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, 3 feet (or 1 meter) away, and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times on 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.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

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 designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. 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 the radioactive waste storage area. When it has reached background levels, as measured with a low-level survey meter, it may 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.

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 on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department with 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 precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet from the patient.

    d. Patients containing radioactive materials 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.

    f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers

having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should 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 Radiation Safety Officer or his designee 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 should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For iodine-131 patients:

(1) Urine from iodine-131 patients will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal 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, disposable gloves should be worn. Afterwards, hands should be washed 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 Radiation Safety Officer or his designee.

(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 18 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) All vomitus must also be kept in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).

l. 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 Radiation Safety Officer or his designee.

m. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

n. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

o. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department, and request that the room be surveyed for contamination before remaking the room.

Date: _____

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Date	Exposure Rates in mRem/hr	
	3 feet from bed	10 feet from bed

(Comply with all checked items.)

____ 1. Visiting time permitted: _____

____ 2. Visitors must remain _____ from patient.

____ 3. Patient may not leave room.

____ 4. Visitors under 18 are not permitted.

____ 5. Pregnant visitors are not permitted.

____ 6. Film badges must be worn.

____ 7. Tag the following objects and fill out the tag:

____door

____bed

____chart

____wrist

____ 8. Gloves must be worn while attending patient.

____ 9. Patient must use disposable utensils.

____10. All items must remain in room until approved by the Radiation Safety Officer or his designee.

____11. Smoking is not permitted.

____12. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

____13. Other instructions.

In case of an emergency contact:

RSO Name _____ _____/_____

On-duty/Off-duty Telephone Nos.

Condition for Molybdenum Breakthrough

1. Technetium-99 seperated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and qualify molybdenum-99 activity prior to administration to patients.

2. The licensee shall not administer to patients technetium-99m containing more than one (1) microcuire of molybdenum-99 per millicurie of technetium-99 or more than five (5) microcuries of molybdenum-99 perdose of technetium-99 at the time of administration. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

3. The licensee shall establish wri ten procedures for personnel performing tests to detect and qualify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99 in excess of the limits specified in item 2. above are detected.

4. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

5. a. The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test preformed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.
   b. Records described in a. above shall be maintained for two (2) years following the preformance of the tests and the training of the personnel.

Memorial Medical Center Ashland, WI. 035-27

DCS 03/09/81

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. & Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, J.r & 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: 43 FR 7210
7.B Renewal

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
Markham J. Fischer MD

(1) NAME *(Type or Print)*
MARKHAM J. FISCHER, MD

(2) TITLE
Radiation Officer

c. DATE
July 1, 1980

FORM NRC-313M (8-78)

O'Connor.

JAN 05 1981

Donald F. Mills
Executive Director

APPENDIX D

CALIBRATION OF INSTRUMENTS*

Section 1

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS, INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.

2. The source activities shall be traceable within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

3. The frequency shall be at least annually and after servicing.

4. Each scale of the instrument shall be calibrated at least at two points such that (a) one point is in each half of the scale and (b) the two points are separated by 35-50% 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 (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

Note:

Sources of Cs-137, Ra-226, or Co-60 are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

B. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, 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 and also after each survey to ensure that the instrument was operational during the survey.

2. After each maintenance and/or battery change.

3. At least quarterly.

If any reading with the same geometry is not within ±20% of the reading measured immediately after calibration, the instrument should be recalibrated (see item A).

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

This calibration may be done either

1. As in item A above with calibrated standards of radionuclides at or near the desired energies or

2. As a relative intercomparison with an energy-independent instrument and uncalibrated radionuclides.

D. Records of the above items A, B-2, B-3, and C must be maintained.

E. Use of Inverse Square Law and Radioactive Decay Law

1. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specified date by the manufacturer or NBS.

a. The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

b. The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

*See ANSI N42.1.3, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides." Copies may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

2. Inverse Square L[illegible]

S (R$_1$) (R$_2$)

* - - P$_1$

- - - - - - - P$_2$

Exposure rate at P$_2$:

$$R_2 = \frac{(P_1)^2}{(P_2)^2} (R_1)$$

where

S is the point source

R$_1$ and R$_2$ are in the same units (mR/hr or R/hr)

P$_1$ and P$_2$ are in the same units (centimeters, meters, feet, etc.)

3. Radio[illegible]tive Decay Law

Exposure rate t units of time after specified calibration date

$$R_t = R_o \times e^{-[\frac{0.693}{T_{1/2}} \times t]}$$

where

R$_o$ and R$_t$ are in the units mR/hr or R/hr

R$_o$ is exposure rate on specified calibration date.

R[illegible] is exposure rate [illegible] units of time later

T$_{1/2}$ and t are in the same units (years, months, days, etc.)

T$_{1/2}$ is radionuclide half-life

t is number of units of time elapsed between calibration and present time

4. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1975. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1977 (2.0 years)?

a. Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.3}}$$

= 100 x 0.77 = 77 mR/hr at 1 foot on March 10, 1977.

b. Output at 3 feet, 2.0 years after calibration date:

$$R_3 \text{ feet} = \frac{(1 \text{ foot})^2}{(3 \text{ feet})^2} \times 77 \text{ mR/hr}$$

$$= \frac{1}{9} \times 77 = 8.6 \text{ mR/hr at}$$

3 feet, 2.0 years after calibration.

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.

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% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3. Survey instruments will be calibrated

____ a. By the manufacturer

____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
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 Midwest Radiation Consultants, Inc.

(2) Location 16 Park Lane, Minneapolis, Mn 55416

(3) Procedures and sources

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

X are attached

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR

All radiopharmaceuticals must be assayed for activity to an accuracy of 10%. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument linearity (at installation and quarterly thereafter)
2. Geometrical variation (at installation)
3. Instrument accuracy (at installation and annually thereafter).

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Daily or before each use of the instrument:

1. Measure and record the activity of at least one reference source (e.g., 1-2 mCi of Co-57). This check should be repeated during the day whenever sample readings are not within 10% of the anticipated assay. Variation greater than 5% in this test will indicate the need for instrument repair, adjustment, or recalibration.
2. Measure and record the apparent activity of a long-lived standard radionuclide such as Cs-137 or Ra-226 at all the commonly used radionuclide settings (when the unit was first calibrated against NBS-traceable standards). Choose a source with activity in the 100 μCi range.

D. 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).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will utilize a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator)

1. Assay the Tc-99m vial in the dose calibrator and subtract background level to obtain net activity in millicuries.
2. 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 predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time (hr)	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

Example: If the net activity measured at 30 hours was 15.625 mCi, the predicted activity for 6 and 48 hours would be 15.625 mCi x 16 = 250 mCi and 15.625 mCi x 0.125 = 1.95 mCi, respectively.

4. Plot the measured net activity for each time interval versus the predicted activity on log-log graph paper.
5. The activities plotted should be within ±5% of the predicted curve if the instrument is linear and functioning properly. Errors greater than ±5% indicate the need for repair or adjustment of the instrument.
6. If instrument linearity cannot be corrected, it will be 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.

F. 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,

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F. 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 ±2% (even though correction factors may be provided by the manufacturer, the accuracy of these should be checked).

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

1. Assay vial at the appropriate instrument setting and subtract background level to obtain net activity.

2. 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.

3. 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 (CF).

   Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected,

   $$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

   True Activity = Measured Activity x Correction Factor

   where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial and a correction factor may be calculated.

7. It should be noted that differences of 200% in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125. Hence, adequate correction factors must be established for this type of syringe.

   An alternate to providing syringe calibration 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).

G. Test For Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides such as Cs-137, Co-57, and Ba-133 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, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. 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.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5% after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that 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 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-131, 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.

H. Test for Instrument Constancy

Assay two reference sources such as Cs-137 and Co-57 using a reproducible geometry before each daily use of the instrument.

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

2. Measure background level at same instrument setting.

3. Calculate net activity of each source subtracting out background level.

4. For each source, plot net activity versus the day of the year on semi-log graph paper.

5. Log the background levels.

6. Indicate the predicted activity of each source based on decay calculations and the ±5% limits on the graph as illustrated.

7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.

8. Variations greater than ±5% from the predicted activity indicate the need for instrument repair or adjustment.

9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

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

or

____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
Co-57	_____	_____
Ba-133	& 7uCi	± 3-5%
Cs-137	7uCi	± 3-5%
Ra 226	1.6 mCi	_____ +5%
_____	_____	_____

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

or

____ Equivalent procedures are attached.

*Must be equivalent to the highest activity used.

PROTOCOL FOR CALIBRATING RADIATION SURVEY INSTRUMENTS

Radiation survey instruments are calibrated against certified radium-226 sources. These sources are accurate to within 5% accuracy, traceable to National Bureau of Standards.

The instruments are calibrated on at least two points of each scale. One calibration point is made on the lower half of the scale and the other on the upper half of the scale. The two points are separated by 35-50% full scale.

Multiple point sources of Ra-226 are used for calibration, the maximum quantity used being 50 milligrams (mCi). The active length of these sources is about 1.5 cm; thus, they appear as point sources from distances of about 15 cm or greater. A gamma ray dose constant of 7.425 R/hr at 1 cm for 1 mgm of Ra-226 filtered with 1.0 mm of P+ is used. The quantity of Ra-226 and distance of the source to the survey meter are varied to provide the necessary exposure rates with which the instruments are calibrated. The inverse square law is used to calculate the radiation output at a specified distance.

Radiation exposure to the individual making the measurements is held to a minimum by following the principles of minimum time and increased distance. The Ra-226 is stored in a radium safe when not in use.

A report of the instruments reading and actual radiation exposure is provided with each calibration. Discrepancies greater than 10% are considered to require special attention. For readings within 20%, a calibration chart will be prepared. For discrepancies greater than 20%, the instrument must be repaired or replaced. It is the responsibility of the institution owning the survey meter to take the necessary action to correct for such a discrepancy.

Survey meters should be calibrated at least once each year, after maintenance or whenever a question of their accuracy arises.

Midwest Radiation Consultants, Inc.
December, 1979

RADIATION EXPOSURE VERSUS DISTANCE

Table for Ra-226 Tubes

Ra-226 tubes - gamma dose constant 7.425 R/hr at 1 cm for 1 mg (1.0mm Pt)

Source strength	Exposure mR/hr	Distance
1 tube - 10 mgm	0.2	6.09 meter
	0.4	4.31 meter
	2.0	1.93 meter
	4.0	1.36 meter
4 tubes - 40 mgm	20.0	1.22 meter
	40.0	0.86 meter
5 tubes - 50 mgm	200	43 centimeter
	400	30 centimeter
	1000	20 centimeter

RADIATION SURVEY METER CALIBRATION

Instrument _____ Facility _____
Serial _____ Survey performed by _____
Date _____

Source used Ra-226, 10 to 50 milligrams (mCi) with an accuracy of ± 5% (NBS traceable).

Survey instrument range _____
Scales _____
Battery _____

Scale	Meter Reading (mR/hr)	Calculated Output (mR/hr)	% Difference

Survey meter is accurate to within ± 10% Yes _____ No _____

Remarks:

J. THOMAS PAYNE Ph.D.
Medical Physicist
ABR Certified

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543 Tomlyn Ave. St. Paul, MN 55112

Item 7: Medical Isotopes Committee

A. Members

1. M.J. Fischer, M.D. - Radiologist
2. J.O.H. Peterson, M.D. - Radiologist
3. R.G. Lind, M.D. - Radiologist
4. E.H. Parker, M.D. - Pathologist
5. T.A. Stolle, M.D. - Pathologist
6. R.L. Abler, M.D. - Pathologist
7. Lowell Miller, Executive Director

B. Medical Isotope Committee and Diagnostic Services Committee Are One and The Same.