FORM NRC-313M (8-78) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved GAO R0557

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

Pana Community Hospital
South Locust Street
Pana, Illinois 62557

TELEPHONE NO. AREA CODE (217) 562 -2131

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

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Ashwin Patel

TELEPHONE NO. AREA CODE (312) 564 - 3330

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 12-18890-01

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

George A. Collodi, 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.*)

George A. Collodi, 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	x	2.0
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	2,500
10 CFR 35.100, SCHEDULE A, GROUP IV	N/A	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	N/A	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	N/	A
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	N/	A
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	N/	A
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.	N/	A
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	N/	A
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	N/	A

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
	N/A		

Applicant: MA023
Check No. 3923783580
Amount/Fee Category 7C
Type of Fee: anal
Date Check Rec'd 3/25/83
Received By: CG

8506040093 850515
REG3 LIC30
12-18890-01 PDR

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CONTROL NO. 78490

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

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

CONTROL NO. 78496

24. PERSONNEL MONITORING DEVICES

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

N/A

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

(2) LICENSE FEE ENCLOSED $ 580.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
John F. Mauldin Jr.

(2) TITLE
Administrator

c. DATE
3/11/85

RECEIVED
MAR 13 1985
REGION III

FORM NRC-313M (8-78)

CONTROL NO. 73496

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.

CONTROL NO. 78496

RADIATION SAFETY COMMITTEE

7(a) 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 in accordance with NRC regulations and 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, the information submitted in support of the request for the license and its amendments.

2. Review the training and experience of any individual who uses readioactive material (including physicians, technologists, physicians, 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 Section 19.12 or 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 reveiw shall include an examination of all records, reports from the Radiation Safety Officer, results of NRC inspection, written safety procedures and management control systems.

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.

10. Review dosimetry reports with reference to the ALARA Program.

RADIATION SAFETY OFFICER -

Among the specific responsibilities of the Radiation Safety Officer, or his deputy, are the following:

(1) To assure that the institution is in compliance with all pertinent Federal, State and Local Regulations.

(2) To establish and supervise operating procedures and to review them periodically to assure their conformity with the recommendations.

(3) To instruct personnel in proper radiation protection practices.

(4) To conduct, or have conducted, radiation surveys and source leak tests where indicated and to keep records of such surveys and tests, including summaries of corrective measures recommended and/or instituted.

(5) To assure that personnel monitoring devices are used where indicated and that records are kept of the results of such monitoring.

(6) To investigate each known or suspected case of excessive or abnormal exposure to determine the cause and to take steps to prevent its recurrence.

The Radiation Safety Officer or his deputy will be available at the hospital during working hours and by phone for all emergency situations after normal working hours.

ITEM 7(a)&(b) (3/85)

7(b) MEETING FREQUENCY

The Radiation Safety Committee shall meet as often as necessary to conduct its business, but not less than once in every calendar quarter.

RADIATION SAFETY COMMITTEE

George A. Collodi, M.D.	Chairman & Radiation Safety Officer
Mr. John Mauldin	Administrator
Mrs. M. Horsthemke RN, B.S.	Director of Nursing
Mr. Charles Sherman, R.T.	Radiology Supervisor
IML Representative	

ITEM 7(c) (3/85)

CONTROL NO. 78496

INSTRUMENTATION

1. **SURVEY METER**
   - A. Manufacturer: Elscint *
   - B. Model Number: GSM-1
   - C. Number of Instruments Available: one
   - D. Minimum Range: 0 to 0.5 mR/hr
   - E. Maximum Range: 0 to 2,000 mR/hr

2. **DOSE CALIBRATOR**
   - A. Manufacturer: Capintec
   - B. Model Number: CRC-70
   - C. Number of Instruments Available: one

3. **DIAGNOSTIC INSTRUMENTS**
   - A. Type of Instrument: Scintillation Camera
   - B. Manufacturer: General Electric
   - C. Model Number: Porta IIC

* In the event that we acquire our radiopharmaceuticals in unit doses from a local radiopharmacy, we may have a substitute survey meter such as the Victoreen CDV-700 with a minimum range of 0 to 0.5 mR/hr and a maximum range of 0 to 50 mR/hr.

CALIBRATION OF INSTRUMENTS
Methods, Frequency, Standards

SURVEY INSTRUMENTS:

Calibration and repair of survey instruments will be done annually by Health Physics Associates, Ltd., 3304 Commercial Avenue, Northbrook, Illinois 60062.

The procedure used to calibrate survey meters is on file with the Nuclear Regulatory Commission, under Health Physics Associates Ltd.'s license No. 12-09160-01. When a survey meter is sent for repair or calibration, a "loaner" survey meter will be supplied by Health Physics Associates, Ltd.

Cs-137 reference standard will be used to check the constancy of the GM survey meter prior to use. If a reading with the same geometry is not within ±20% of the reading measured after calibration, the instrument will be recalibrated.

DOSE CALIBRATOR:

The following checks will be performed on the dose calibrator:

A. Constancy - Daily
B. Linearity - Quarterly
C. Accuracy - Annually
D. Geometrical Variation - At installation and after chamber replacement

A. Constancy

A Cs-137 standard, consisting approximately 200 µCi of activity will be assayed in the dose calibrator daily in the Cs-137 setting on the instrument. The standard used will be traceable to the National Bureau of Standards. The dose calibrator initial assay of the standard should not differ by more than ±5% from the anticipated range of activity of the standard.

The Cs-137 source will be assayed daily in other radionuclide settings routinely used in the department. The assay of the sources will not vary by more than ±5% from week to week. Once a week, the Cs-137 source will be assayed in other radionuclide settings occasionally used in the department and the readings should not vary by more than ±5% from week to week.

B. Linearity will be performed using one of the following two methods

1] The linearity of the instrument will be established quarterly. The procedure employed will be such that it will cover the entire range of activity that the department may use. The maximum quantity of radioactivity that we may have on hand in a single container would be elution from Mo99/Tc99m generator (Tc99m pertechnetate).

Knowing the volume in the vial, the concentration of the activity can be calculated. One milliliter of eluent is drawn precisely into a syringe and it is assayed in the dose calibrator. The reading should be within ±5% to be acceptable.

Further linearity will be determined as follows: The same syringe is then further assayed at approximately 6 hours, 24 hours, 30 hours and 48 hours after the activity was drawn into the syringe. For acceptable linearity, all the assay results must be within ±5% of the calculated values.

2] We may use a linearity check kit approved by the NRC (such as "Calicheck Kit" from Calcorp, Inc.). The initial linearity of the dose calibrator will be confirmed using the decay method as indicated above. The linearity check kit will be used according to the instructions from the supplier of the kit.

C. Accuracy

The accuracy of the dose calibrator at various energy levels will be confirmed at installation, after repairs, and once a year thereafter, using three reference standards whose activity is traceable to the National Bureau of Standards. These standards are obtained from New England Nuclear.

RADIONUCLIDE	CATALOG No.	APPROXIMATE ACTIVITY	SOURCE TYPE
Cs-137	NES-356	200 µCi	Vial E
Ba-133	NES-358	250 µCi	Vial E
Co-57	NES-206	5.0 mCi	Vial E

Each standard will be assayed in the appropriate settings three times and the average of the three settings will be calculated. After subtracting the room backgrounds, the average source assay should be within ±5% of the anticipated range of activity of each source. The sources are possessed by IML Imaging Inc., for the specific purpose of annual calibration of the dose calibrator. The sources will not be stored on site at the hospital.

D. Geometrical Variation - At Installation and After Chamber Replacement

As explained in paragraph "B" above, the geometrical independence between the vial and the syringe is first established. The activity in the syringe is then further diluted 0.5 ml at a time, mixed properly, and the syringe assayed after every step. In this manner, a series of readings of the same activity in different volumes are obtained. If the assay result in any volume is above ±2% of the mean value, a corrective value will be determined.

Similarily, a 20 mCi activity in a vial is assayed in different volumes and correction factors computed when necessary.

E. Acceptable Performance

If a dose calibrator does not meet the specifications in sub-items A-D above, replacement dose calibrator will be obtained while the instrument is shipped for repairs.

Patient Doses

All patient doses will be assayed prior to administration to ensure that they are within ±10% of the prescribed dose.

DOSE CALIBRATOR CHECKS

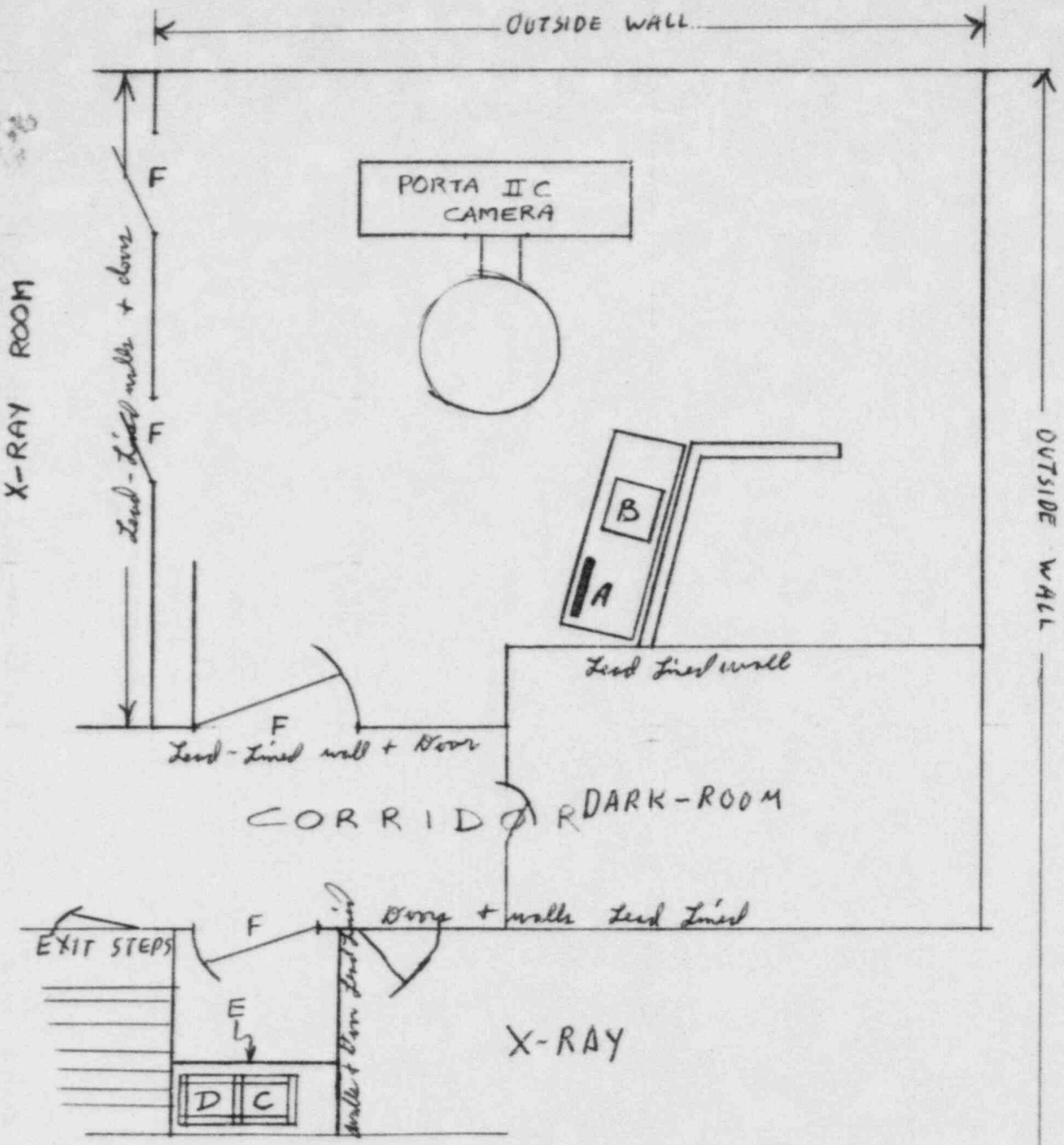
HOSPITAL ______________________________

DOSE CALIBRATOR MAKE & MODEL # ______________________________

CALIBRATOR SOURCE ____________ ACTIVITY ________ DATE ________ S/N ______

DATE	Cs-137	Tc-99m	Mo99	I-131	I-123	Ga-67	Xe-133	Tl-201		
									(3/85)	

PANA COMMUNITY HOSP.
NUCLEAR MEDICINE



A : L-BLOCK : DOSE PREP AREA
B : DOSE CALIBRATOR
C : RADIONUCLIDE STORAGE SHIELDED BY 1/2" LEAD.
D : Mo 99/Tc 99m GENERATOR SHIELDED BY 2" THICK LEAD BRICKS.
E : RADIOACTIVE WASTE STORAGE SHIELDED BY 1/16" LEAD.
F : SECURED DOORS.

SCALE: 1" ≈ 4 ft.

ITEM # 11 (2100)

PERSONNEL TRAINING PROGRAM

In accordance with NRC Regulations, instructions to workers will be carried out in the following manner:

1. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer or use of radioactive materials or of radiation in such portions of the restricted area.

2. All individuals working in or frequenting any portion of a restricted area shall be instructed in the health protection problems associated with exposure to such radioactive materials, in precautions or procedures to minimize exposure, and in the proceses and functions of protective devises employed.

3. All individuals working in or frequenting any portion of a restricted area shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of the Commission to radiation or radioactive materials occuring in such areas.

4. All individuals working in or frequenting any portion of a restricted area shall be instructed of their responsibility to report promptly to the licensee, any conditions which may lead to or cause a violation of Commission Regulations and Licensee of unnecessary exposure to radiation or to radioactive material.

5. All individuals working in or frequenting any portion of a restricted area shall be instructed in the appropriate response to warnings made in the event of any unusual occurence or malfunction that may involve exposure to radiation or radioactive material.

The Nuclear Medicine Technologist will be classified as occupational employees. These individuals perform their duties from the radiation safety viewpoint under the direction of the physician at the hospital named on the license application.

Every effort will be made to find technologists educated in Nuclear Medicine Technology in an institution approved by the American Medical Association. Such employees will be certified or eligible for certification in Nuclear Medicine Technology and for licensure by IDNS. Orientation of radiation safety and techniques of such personnel, for one or two days by the Radiation Safety Officer, will be considered sufficient.

All Nuclear Medicine Technologists will be instructed before assuming duties and annually thereafter by the Radiation Safety Officer or the Chief Technologist in the following areas:

(a) New procedures and radiopharmaceuticals in Nuclear Medicine

(b) Radiation Safety Techniques

(c) NRC and State Rules and Regulations for the use of radioactive materials.

(d) Location of regulations, license, license applications, regulatory notices and dosimetry and bioassay reports. All of these documents and reports are available for employee inspection upon request to the R.S.O.

With regard to non-occupational personnel at hospitals and their contact with the Nuclear Medicine Department, the Staff Technologist will be instructed to restrict access to the department to those people having business there.

NON-OCCUPATIONAL PERSONNEL WHEN REQUIRED TO ASSIST THE TECHNOLOGIST WITH A PATIENT, WILL NEVER BE ALLOWED TO HANDLE ANY RADIOACTIVE MATERIAL.

CONTROL NO. 18496

continued

Any person requested to assist with a patient will do so under the direction of the Nuclear Medicine Technologist who will ensure that the exposure to these persons is held to a minimum (through time, distance and shielding) during the performance of the Nuclear Medicine procedure.

A short "orientation" program will be conducted annually for the non-occupational personnel such as security, clerical, housekeeping, etc., who may be involved in Nuclear Medicine Department functions where radioactive materials are stored or used. The orientation will include:

(a) Tour of the Department to indicate the radioactive material storage space(s), location of the 10 CFR Parts 19, 20, 30, 31 and 35, location of the survey meter, etc.

(b) Concepts of radiation safety - distance, time, shielding.

(c) Names and phone numbers of person(s) to contact in case of a radiation emergency.

If a new, non-occupational employee is involved in Nuclear Medicine Department functions, the employee will be given a short orientation program before the employee begins duties in the Nuclear Medicine Department.

(d) The radioactive material, if used (injected) in our Cardiac Stress Lab for Tl-101 stress studies, the access to the stress unit will be limited to the physician, the stress lab technologist(s) and the patient during the use of Tl-201. The stress lab technologists will be given a copy of "Emergency Procedures for Minor Spills" for posting in the stress unit room.

PROCEDURES FOR ORDERING AND RECEIPT OF RADIOACTIVE MATERIAL

ORDERING

Radiopharmaceuticals will be ordered from suppliers licensed by the NRC or State according to 10 CFR 32 or Agreement State Regulations. Ordering will be initiated by the Nuclear Medicine Technologist who will ensure the inventory is adequate for planned and anticipated procedures, but not in excess of possession limits where applicable.

RECEIVING

Instructions will be issued to the carrier delivering radiopharmaceuticals to effect delivery directly to the Nuclear Medicine Department. Radiopharmaceutical packages are not to be left unattended in the unrestricted areas.

In the event that the radiopharmaceuticals arrive during off duty hours, the security staff member on duty will escort the carrier to the Nuclear Medicine section, unlock the door, direct the carrier to place the shipment on the designated counter and resecure the area against unauthorized removal of the shipment.

If the radioactive package appears damaged or damp, the carrier will be requested to remain on the premises until the Radiation Safety Officer can determine that neither he nor the delivery vehicle is contaminated.

Telephone 217/562-2131

Pana Community Hospital

South Locust Street Pana, Illinois 62557

TO: DEPARTMENT HEAD OF:

Security
Purchasing
Receiving
Switchboard
Emergency Room
Radiology
Nuclear Medicine

FROM: ADMINISTRATOR

SUBJECT: RECIEPT OF PACKAGES CONTAINING RADIOACTIVE MATERIALS BEARING WHITE 1, YELLOW II OR III, HAZARDOUS MATERIAL.

1. During hours in which the Nuclear Medicine Department is open, all couriers or common carriers requesting assistance in delivering packages containing radioactive materials are to be directed to the Nuclear Medicine Department. Personnel, except for those in the Nuclear Medicine Department, are not to accept the package personally.

2. If couriers or common carriers attempt delivery of packages containing radioactive materials during those hours in which the Nuclear Medicine Department id closed, the package must be transported immediately to the Nuclear Medicine Department and placed in the hot-lab- the doors to the department are to be relocked and the package signed for.

3. If the package is wet or appears to be damaged, immediately contact the hospital's Radiation Safety Officer. Have the carrier place the potentially damaged radioactive package on absorbent pads on a clean surface in a secure area. Then 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: Gary A. Collai M.D.

ROUTINE WORK HOURS: CALL RADIOLOGY DEPARTMENT

AFTER WORK HOURS: CALL TECHNICIAN ON CALL

ITEM #13 (3/85)

CONTROL NO. 18486

PROCEDURE FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Wear gloves during package inspection and opening to prevent contamination.

2. Inspect and open all packages **IMMEDIATELY** upon receipt. Should package arrive when the Nuclear Medicine Department is closed, this procedure will receive top priority as soon as the Nuclear Medicine personnel returns. If visual inspection shows any signs of damage (if wet or crushed, etc.) stop procedure and notify the Radiation Safety Officer.

3. All radioactive packages will be surveyed at surface and at three feet to verify that the radiation levels on the surface of the package are not in excess of 200 millirems per hour, or at three feet from the external surface of the package in excess of 10 millirems per hour. If the levels are in excess of the ones indicated above, the NRC Region III will be notified by telephone.

4. Open package, remove packing slip and verify that the contents agree in name and quantity with the packing slip. Check also that shipment does not exceed possession limits.

5. If a wipe test of the package is required to be done as specified in 10CFR20.205, the wipe will be performed and analyzed as instructed in "Wipe Test Procedure" which follows.

6. Check the possible breakage of seals or container's loss of liquid or change in color of absorbing material. Wipe test the final source container to rule out contamination. (For wipe test procedure, refer to next page.)

7. Place the radioactive source in its shield and store in the Isotope Storage Area.

8. Monitor the shipment packing material for contamination after removal of the sources. Deface labels and discard.

9. Record type of activity, quantity present, date of receipt and invoice number on the radiopharmaceutical inventory form (attached).

10. If the material was packaged in dry ice, refrigerate immediately.

11. If excessive radiation levels, contamination, leakage or shortages are observed, notify the final delivering carrier and by telephone or telegraph contact the Regional Office of the Nuclear Regulatory Commission. Also notify the Radiation Safety Officer of any damage or leakage resulting in contamination.

WIPE TEST PROCEDURE

1. To be performed on all shipments, specified in Part 10CFR20.205, and on final containers of all radioactive sources.

2. To be performed as soon as practicable after receipt. If recieved during working hours, wipe test must be performed within three (3) hours; if received at some other time, within eighteen (18) hours after receipt.

3. PROCEDURE -

   a] Wipe the surface of the container over its entirety with an alcohol swab.

   b] Check the wipe using a low level GM survey meter probe with window open. The wipe should be placed in a small plastic or paper cup and the base of the cup should be centered on the open window of the probe and held in place, in contact with the probe, for approximately 10 to 15 seconds. Record the reading in mR/hr.

   If the radiation level is higher than the natural background levels in an unrestricted area, a scintillation camera detector without collimator will be used to determine the level of contamination.

RADIOPHARMACEUTICAL INVENTORY

DATE RECEIVED __/__/__ RADIATION LEVELS (mR/hr): SURFACE_____ 3 FT_____ EMPTY_____ INITIALS____

WIPE: mR/hr

PLACE LABEL HERE ACT. ADM_____mCi TIME _____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME _____ INITIALS_____	PLACE LAPEL HERE ACT. ADM._____mCi TIME _____ INITIALS_____
PLACE LABEL HERE ACT. ADM._____mCi TIME_____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME_____ INITIALS_____	PLACE LABEL HERE ACT. ADM._____mCi TIME_____ INITIALS_____

All used syringes, needles, & unused doses above, returned to supplier. DATE _____ INITIALS _____

RADIOPHARMACEUTICAL INVENTORY

HOSPITAL:

DATE RECEIVED:	RADIATION LEVEL mR/hr: Surface	3 Ft.	Empty	Wipe	Date or Time	Patient Name	Patient #	Concentration mCi/ml	Activity administered mCi	Volume administered ml	Volume remaining ml	Activity remaining mCi
RADIOPHARM												
MANUFACTURER:												
LOT #												
DATE RECEIVED:	RADIATION LEVEL mR/hr: Surface	3Ft.	Empty	Wipe								
RADIOPHARM:												
MANUFACTURER:												
LOT #:												
DATE RECEIVED:	RADIATION LEVEL mR/hr: Surface	3Ft.	Empty	Wipe.								
RADIOPHARM:												
MANUFACTURER:												
LOT #:												

HOSPIT

IML INVENTORY FORM
Mo99/Tc99m Generator

Mo99 concentration limits:
1. No more than 1 uCi Mo99/ 1 mCi Tc99m, or
2. No more than 5 uCi per dose

ATE RECEIVED: / ADIOPHARM: / ANUFACTURER: / OT #:	RADIATION LEVEL mR/hr: Wipe	Empty	3 Ft.	Surface	DATE	TIME	Tc99m Pertechnetate QUANTITY (mCi)	Volume (ml)	Concentration mCi/ml	Net Mo99 Activity	uCi Mo99 / mCi Tc99m	Date Generator Disposed	GM reading mR/Hr	ini ia
ATE RECEIVED: / ADIOPHARM: / ANUFACTURER: / OT #:	RADIATION LEVEL mR/hr: Wipe	Empty	3Ft.	Surface										
ATE RECEIVED: / ADIOPHARM: / ANUFACTURER: / OT #:	RADIATION LEVEL mR/hr: Wipe	Empty	3Ft.	Surface										

USE OF Mo99/Tc99m GENERATOR

The Mo99/Tc99m generator will be eluted according to the instructions described in the package insert from the radiopharmaceutical company. This will provide an eluent of pharmaceutical quality.

99mTc and 99Mo assay of the eluted material from the generator will be performed after each elution according to the instructions described in the package insert from the radiopharmaceutical company. The assay, along with the assay of compounds synthesized from technetium eluates, will be accomplished through the use of a dose calibrator device. When the dose calibrator is sent away for repairs, a "loaner" will be obtained.

The purity of the eluted material will be determined by the above assay. The eluted sources containing more than 1.0 uCi of 99Mo per millicurie of 99mTc or final patient dose containing more than 5.0 uCi of 99Mo, will not be used directly or in compounding.

Compounds formulated using kits and technetium from the above generator will be prepared by following the kit manufacturer's directions, exactly as outlined in the package insert. No alterations or substitutions will be permitted. In this way a product or pharmaceutical quality will be insured. Syringe shields and lead containers for vials will be used during formulation of these compounds.

All patient doses will be assayed with a dose calibrator to assure that the dose is within ±10% of the prescribed dose.

GENERAL RULES AND SAFE USE OF RADIOACTIVE MATERIAL

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

2. Wear disposable gloves while handling radioactive materials.

3. Monitor hands and clothing if contamination is suspected after handling radioactivity.

4. Always use syringe shields for routine 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. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g. through use of a butterfly valve).

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

   Do not store food, drink or personal effects with radioactive material.

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%.

   For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

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. Personnel monitoring devices, when not being worn to monitor occupational exposures, should be stored in a designated, low background area.

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 and properly sheilded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination at the end of the day. Decontaminate if necessary.

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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.

14. Mo99/Tc99m generator eluent will be assayed to determine Mo99 concentration and the eluent will not be used if Mo99 concentration is equal to or exceeds 1 uCi Mo99 per 1 mCi of Tc99m; or if a dose contains more than 5 uCi of Mo99.

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EMERGENCY PROCEDURES FOR RADIOACTIVE SPILLS

Unsealed radioactive liquids are handled routinely in the Nuclear Medicine Department. The potential for spillage is always present. It is imperative that individuals handling radioactive materials respond properly to these spills so as to limit their radiation exposure and prevent the spread of contamination.

MINOR SPILLS: (tracer activities)

1. Notify persons in the immediate area that a spill has occurred.
2. Cover the spill with absorbent paper.
3. Limit access to area to only those persons dealing with the spill.
4. Survey (GM survey meter) potentially contaminated personnel before they disperse; and decontaminate as necessary.
5. Notify the Radiation Safety Officer of the incident.

MAJOR SPILLS: (therapy activities)

1. Notify all persons not involved in the spill to vacate the room at once. Limit the movement of displaced persons to confine the spread of contamination.
2. Cover spill with absorbent paper.
3. Switch off all fans. Close windows.
4. Vacate room.
5. Close the door to the room. Prevent entry into the room.
6. If the spill is on the skin, flush thoroughly.
7. If the spill is on the clothing, discard outer or protective clothing at once.
8. Notify the Radiation Safety Officer immediately.
9. Survey (GM survey meter) personnel involved. Immediately initiate decontamination of personnel as necessary, using mild soap and luke warm water.

FIRE AND / OR EXPLOSIONS

1. In the event of fire, explosion or similar catastrophy, the emergency within the hospital must be given attention first. Patients must be immediately cared for.

2. Should the catastrophe occur within the Department of Nuclear Medicine, vacate the area and all surrounding areas immediately.

   HOWEVER, DO NOT LET THE LOCATION OF OCCURRANCE PREVENT ADEQUATE AND IMMEDIATE PATIENT PROTECTION.

3. Block off the area with ropes, chairs or whatever is available until such time as fire or other emergency personnel arrive.

4. Notify the Radiation Safety Officer immediately.

5. Monitor area to determine extent of contamination.

6. Take necessary steps to decontaminate the area according to instructions of the Radiation Safety Officer.

LOSS OR THEFT OF RADIOACTIVE MATERIALS

OR

DAMAGE TO A RADIOACTIVE SOURCE

If the radioactive source is damaged, the precaution to prevent the spread of the contamination will be taken. The area concerned will be decontaminated and the damaged source will be stored in adequate shielding.

If a source is lost or stolen, the Radiation Safety Officer and the U.S. Nuclear Regulatory Commission or the appropriate State authorities will be notified.

If a source is involved in a fire and/or explosion and if a source is damaged, the appropriate State authorities will be notified.

PLEASE CONTACT IML FIRST FOR FURTHER INFORMATION

IML IMAGING INC.	**(312) 564 - 3330 (24 hours)**
U.S. Nuclear Regulatory Commission	**(312) 790 - 5500**
Illinois Department of Nuclear Safety	**(217) 782 - 7860**

AREA SURVEY PROCEDURES

1. All elution, preparation and injection areas will be surveyed daily with a GM survey meter and decontaminated if necessary. Results will be recorded on the form attached: "DAILY RADIATION SAFETY RECORD".

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

3. All the areas in the Nuclear Medicine Department will be surveyed once a week using a low-level GM survey meter. Results will be recorded. The areas surveyed are:

   A. Dose Preparation Area
   B. Generator
   C. Radioactive Material Storage
   D. Radioactive Material Waste Storage
   E. Floor Near the Dose Prep Area
   F. Tl-201 Stress Unit (if Tl-201 is used during the week)
   G. Injection Area

4. Wipe tests of areas (listed above) A-E, and F if used during the week, and injection areas will be taken once a week. The wipe will be checked in an unrestricted area (natural background radiation levels) using a low level GM survey meter with the window on the probe open. The wipe will be held for approximately 20 seconds as close to the probe as possible, without actually touching the probe.

   If the wipe indicates radiation levels above those of natural background in unrestricted areas (0.1 mR/hr or less), the area will either be secured and/or decontaminated until a wipe indicates natural background radiation levels.

   We have found in our experience that a wipe test of an area is essential when attempting to detect contamination near a radioactive container such as near an Mo99/Tc99m generator. If a GM survey is done, it would be impossible to differentiate between the radiation levels from the source and the radiation levels from contamination in the proximity of the source. But a wipe of the area can be analyzed in an unrestricted area, away from any source of radiation (other than natural background). Hence, the generator area and the dose preparation area (where sources emitting radiation, easily detectable by a GM survey meter, may be stored) would be wipe tested once a week. Any contamination in the other areas in the department would be easily detected by a low level GM survey meter and hence, a wipe test would not be necessary.

DAILY RADIATION SAFETY RECORD

YEAR_____ HOSPITAL_____

Monitor your clothing and shoes, dose preparation, injection and elution areas prior to leaving the department for the day. Use a low level GM survey meter and record and initial the survey meter readings below. If radiation contamination is detected in any of the surveys, remonitor after decontamination. Record levels in mR/hr.

NATURAL BACKGROUND RADIATION LEVELS ARE: _____mR/hr

DATE	CLOTHING & SHOES	DOSE PREP AREA	INJ. AREA	ELUTION AREA	INITIAL	DATE	CLOTHING & SHOES	DOSE PREP AREA	INJ. AREA	ELUTION AREA	INITIAL

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(3)85

WEEKLY AREA SURVEYS & WIPE TESTS - [To Be Used At Generator Locations]

All Levels in mR/hr Unless Stated Otherwise

LOCATION _____ YEAR _____

SURVEY INSTRUMENT: Mfg _____ Model _____ Due for Calibr _____ Natural Background _____ mR/hr

Checks Source Used: _____ ;Nuclide _____ ;Activity _____ µCi; Date _____

Probe Window Open, Centered Over The Top Of The Source And In Contact With The Source

	AREA SURVEYS										WIPES								
	DOSE	PREP									DOSE	PREP							
DATE	L BLOCK	FLOOR	Mo99/ Tc99m GENERATR	RADIO PHARM STORAGE	RADIO ACTIVE WASTE	SPENT GENERATR	WORK AREA	MAIN ENTRANCE DOOR	EXTERIOR OF THE OUTSIDE WALL		L BLOCK	FLOOR	GENERATR ELUTION	RADIO PHARM STORAGE	RADIO ACTIVE WASTE	WORK AREA		SURVEY INSTR. CHECK	INITIALS

N - NOT APPLICABLE

WEEKLY AREA SURVEYS & WIPE TESTS - [For Hospital Use]

All Levels in mR/hr Unless Stated Otherwise

HOSPITAL _____ YEAR _____

SURVEY INSTRUMENT: Mfg _____ Model _____ Due for Calibr _____ Natural Background _____ mR/hr

Checks Source Used: _____ ;Nuclide _____ ;Activity _____ µCi; Date _____

Probe Window Open, Centered Over The Top Of The Source And In Contact With The Source

	AREA SURVEYS										WIPES									
	DOSE PREP		RADIO PHARM STORAGE	RADIO ACTIVE WASTE STORAGE	WORK AREA	SINK AND TRAP	INJ. AREAS	CAMERA ROOMS	STRESS LAB		DOSE PREP		RADIO PHARM STORAGE	RADIO ACTIVE WASTE STORAGE	WORK AREA	INJ. AREAS	STRESS LAB		SURVEY. INSTR. CHECK	INITIA
DATE	L BLOCK	FLOOR									L BLOCK	FLOOR								
	A	B	C	D	E	F	G	H	I		A	B	C	D	E	G	I			

(3/85)

Mo99/Tc99m GENERATOR

RADIOACTIVE WASTE, STORAGE AND DISPOSAL

Radioactive waste storage and disposal can be broken down into three categories:

1. Molybdenum-99 Technetium-99m generators
2. Technetium 99m residues
3. "Long-lived" radionuclides: radionuclides with relatively longer (greater than six hours) half-life such as Selenium-75, I-131, etc.

1. Mo99m/Tc99m GENERATOR DISPOSAL

A. The current Mo/Tc99m generator used for daily elution will be stored behind the lead bricks in the hot lab. Generator systems, one week old and older, can be safely stored in their original lead shipping containers for the balance of the decay necessary to reduce levels from the generator core to those of background.

It is estimated that Mo99/Tc99m generators will be decayed for approximately two months from the date of assay; that is, about 25 half-lives. The generator core will be monitored with a low level GM survey meter and, upon reaching background level, will either be incinerated or the labels defaced and discarded.

B. In the event a return program is initiated, the generator may be sent to the supplier intact according to directions received with shipment. The date of the disposal will be recorded on the "RADIOPHARMACEUTICAL INVENTORY FORM". If returned to the supplier, the date will be recorded.

2. Tc99m COMPOUNDS

Ninety percent or more of the radioactivity used in this hospital will be associated with the use of Tc99m in its various chemical forms.

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Tc99m sources and residues, i.e. contaminated syringes, needles, vials of unused Tc99m preparation and Tc99m eluents, will be stored in a plastic bag behind the lead bricks. At the beginning of the following week, the plastic bag containaing the Tc99m contaminated sources will be sealed and held in the Nuclear Medicine Department behind lead shielding. At the end of the week, the contents of the plastic bag containing the decayed compounds (every item in the bag now has been decayed for a minimum of seven days, 24 half-lives) will be brought out from their lead shielding.

The low level survey meter probe will be brought into contact with the unshielded vials and/or syringes. If the meter needle does not deflect above background levels, these formerly contaminated items will be discarded, after defacing or removing the "radioactive" labels . The date of disposal and the survey meter reading indicating background levels will be recorded on the isotope disposition form.

3. UNIT DOSE FROM A RADIOPHARMACY

All used syringes, needles and unused doses will either be stored for decay or will be returned to the radiopharmacy in containers in which the doses were received. A representative from the radiopharmacy will pick up the containers from the hospital. Records of such disposal will be maintained. Applicable Department of Transportation Regulations will be followed.

4. "LONGER HALF-LIFE RADIONUCLIDES

Radionuclides having half-lives up to and including I-131:

Such nuclides and their residues will be stored behind lead bricks. A survey will be conducted with the probe held against the unshielded source. After a period of decay of from one to three months, depending upon the nuclide's half-life, levels as measured with the lowest range on the GM survey meter in excess of background will indicate the need for a continuing period of decay. Finding levels the same as that of background will result in discarding these sources.

Radionuclides having half-lives in excess of I-131 will be diluted via the sewer as early as convenient (in compliance with 10 CFR 20.303).

A measurement of the quantity of radioactivity will be made using the dose calibrator prior to disposing of the radioactivity down the drain. Syringes, needles and vials contaminated with such radionuclides will then be rinsed three or four times and then they will be surveyed unshielded in contact with a low level GM survey meter prior to disposal.

If levels in excess of background are noted, the contaminated articles will be further rinsed until background levels are achieved. In-vitro test wastes in the laboratory will be recorded as 100% sewer-deluted, based on receipt quantity. No measurement with the dose calibrator will be made. The date and quantity of radioactivity sewer-diluterd, will be entered on the isotope disposition form. To comply with 10 CFR 20.303(b), a sample calculation for Se-75 is attached. Similar procedures will be followed for other radionuclides.

To comply with 10 CFR 20.203(d), a separate record of all types of activity sewer-diluted by this institution will also be maintained to ensure that the gross quantity of licensed and other radioactive material released into the sewer system does not exceed one curie per year.

Calculation for the quantity of Se-75 which can be sewer-diluted daily:

As specified in 10 CFR 20.303(b)(1), the average concentration for Se-75 as give in Appendix B, Table 1, Column 2, is 9×10^{-3} uCi/ml.

Quantity of Se-75 which can be sewer-diluted:

= number of beds occupied X 10^6 X Appendix B, Table 1, Column 2, limits for Se-75

= $100 \times 10^6 \times 9 \times 10^{-3}$ uCi/day

= 900×10^3 uCi/day

= 900 mCi/day

The total quantity of all types of radioactivity sewer-diluted is not to exceed 1000 mCi/year.

RADIOACTIVE WASTE DISPOSAL RECORDS

DATE DISPOSED	RADIONUCLIDES IN WASTE (Includes Gloves Needles, Syringes Swabs, etc.)	DATES DURING WHICH THE WASTE WAS PUT IN THIS CONTAINER		GM READING (mR/hr) At time of Disposal	NATURAL BACKGROUND (mR/hr)	COMMENTS	INITIALS
		FROM	TO				

CONTROL NO. 78496

ITEM 18

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(12/84)