NRC FORM 313M (9-81) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Dickinson County Memorial Hospital
400 Woodward Avenue
Iron Mountain, Michigan 49801

TELEPHONE NO.: AREA CODE (906) 774-1313

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

Same as 1a

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Stan A. Huber
200 North Cedar Road
New Lenox, Il
TELEPHONE NO.: AREA CODE (815) 485-6161

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO 21-18889-01

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

See attached Item 8

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.)*

Mervin Specht, 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	3000
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 each 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
8505090165 850423 REG3 LIC30 21-18889-01 PDR			
NOT APPLICABLE			

RECEIVED BY LFMB
Date 3/29/85
Log Apr - 1 ...
By ...
Orig. To ...
Action Compl. 4/1/85

MAR 18 1985

FEE EXEMPT 170.11(a)(4)

CONTROL NO. 78526

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

NOTE: All appendices referenced on this page are based on Regulatory Guide 10.8, Rev. 1, and are attached to this application. Some appendices have been slightly modified to reduce the regulatory burden.

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
Names and Specialties Attached; and	X Appendix G Rules Followed; or
X Duties as in Appendix B; or *(Check One)*	Equivalent Rules Attached
Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	X Appendix H Procedures Followed; ~~or~~
X ~~Supplements A & B Attached for Each Individual User~~; and see attached Item 8	Equivalent Procedures Attached
Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	X Appendix I Procedures Followed; ~~or~~ and
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
X Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X Equivalent Information Attached
Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
X Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	N/A Appendix K Procedures Followed; or
Equivalent Procedures Attached	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
X Description and Diagram Attached	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
X Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
Equivalent Procedures Attached	N/A Detailed Information Attached

FORM NRC-313M
(8-78)

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. and Company	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. and Company	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

This institution is committed to the ALARA program set forth in Appendix O, attached to this application.

Based on the radionuclides and procedures to be used, the use of pocket dosimeters and bioassay services are considered not applicable for Groups I, II, and III.

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: 7C

(2) LICENSE FEE ENCLOSED: $ Fee Exempt

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)* Marvin Dehne

(2) TITLE Administrator

c. DATE February 20, 1985

RECEIVED
MAR 18 1985
REGION III

FORM NRC-313M (8-78)

CONTROL NO. 78526

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.

RADIATION SAFETY/MEDICAL ISOTOPES COMMITTEE

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;

2. the hospital administrator or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;

3. a physician specialist* from each department where radioactive materials are used; and

4. a representative of the hospital's nursing staff.

*Some departments, such as the nuclear pharmacy, may not be under the supervision of a physician. In these cases, the supervisory paramedical professional will be a member of the committee.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

APPENDIX B

RADIATION SAFETY/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 all individuals who use radioactive materials (including physicians, technologists, physicists, and pharmacists) and determine that their 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 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 the adequacy of the institution's 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, as specified in the license.

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.

Ref: NRC 31 3M Item 8

TRAINING AND EXPERIENCE

Radiation Safety Officer

Radiation Safety Officer; Training, Duties & Availability:

a). Training:

The training and experience descriptions of the Radiation Safety Officer (R.S.O.) are appended to this application.

b). Duties:

The R.S.O. is responsible for the overall radiation protection program within the institution. The R.S.O. has authority to implement and enforce all NRC license stipulations and regulations pertaining to the institution on a daily basis and has authority immediately terminate any hazardous operation The R.S.O. responsibilities involve not only routine applications and occupational personnel within the restricted areas using radioactive materials in the institution but also all non-occupational personnel and visitors in non-restricted areas, as well as security and handling procedures from the time radioactive shipments arrive in the hospital, day or night, through the time all such sources are properly used or disposed. The R.S.O. must provide and document extensive education (initialy, as needed and at least annually) of all personnel and public who may come within the vicinity of radioactive materials.

c). Availability:

The R.S.O. must provide back-up 24 hours per day coverage during illness, vacations or emergency by providing Administration and the occupational personnel with the phone numbers of consulting physical scientists and the Regional NRC Division of Compliance.

NAME OF AUTHORIZED USER	AUTHORIZATION
Dale R. Shampo, M.D.	Groups I, II, and III
Mervin J. Specht, M.D.	Groups I, II, and III

Ref: NRC 31 3M - Item 9

INSTRUMENTATION

a) Survey Meter(s)

One (1) Bicron Corp Model Surveyor 2000 AHS S/N A314B survey meter
0-.2; 0-2; 0-20; 0-200; 0-2000

One (1) Victoreeen Model CDV-700 low level survey meter
Beta Gamma Detection
Ranges: 0-0.5, 0-5, 0-50, mR/hr

B) Dose Calibrator(s)

One (1) Picker Model #632-220 Dose Calibrator

d) Other

One (1) Dyna Camera 4/15
22-002-C-2

One (1) ADC Medical Model 300 Nuclear Spectrometer Well Counter

e) Add one (1) Victoreen Model 740F "Cutie Pie" survey meter

f) Add one (1) Capintec CRC-5 Dose Calibrator, Product ID CR16106, Set #51338, Chamber #42736, Meter # 0341144

g) Add one (1) G.E. Maxi-Camera II with MED IV Computer

Model #OMH2503A - Camera

Model # 14378B - MED IV

Add one (1) Thyroid uptake system from Atomic Products Corp.
Model # 187-290

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Ref: NRC 31 3M - Item 10

CALIBRATION OF INSTRUMENTS

a). Survey Meter:

The survey meters will be calibrated at least annually, and after repairs, by any firm that is approved by the NRC for such calibrations. Instruments will be calibrated on at least two points on each scale range. Currently, our calibration service firm is Stan A. Huber Consultants, Inc., of New Lenox, Illinois, whose radiation sources and procedures are on file with the NRC under license #12-17503-01.

The licensee shall perform operational constancy checks on survey instruments before each day's use to ensure proper functioning of the devices. For any infrequently used meters, these reference source operational checks shall be taken at least quarterly, per NRC Regulatory Guide 10.8 (October 1980) Appendix D, Section 1, Item B.

b). Dose Calibrators:

We shall follow the calibration methods and frequencies for dose calibrators as defined in NRC Regulatory Guide 10.8, dated October 1980, Appendix D, Section 2, "Methods for Calibration of Dose Calibrator".

For the linearity test, we will use a vial of Tc99m whose activity is equivalent to the maximum anticipated activity to be assayed. For the accuracy test, Stan A. Huber Consultants, Inc., of New Lenox, Illinois, or other licensed calibration firms, will use the following sources under the authority of their NRC license:

Model NES-356, 200 microcuries of Cs-137 (high energy)

Model NES-352, 1 millicurie of CO-57 (low energy)

Model NES-358, 250 microcuries of Ba-133 (medium energy)

We use a NEN Model NES-356 Cs-137 standard, 200 microcuries, for our day-of-use dose calibrator constancy checks. Records of all tests and checks will be maintained.

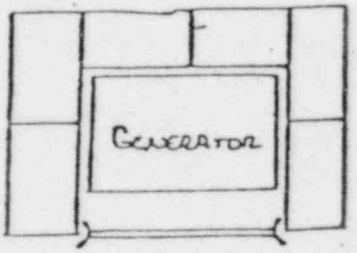
We request use of the "Calicheck" (CaliCorp) system or "Lineator" system (Atomic Products) as an alternate method of performing dose calibrator quarterly linearity checks. The product certifications for those devices are on file with the NRC.

FACILITIES AND EQUIPMENT

Shielding Around Generator:

The generator is shielded on the rear by a wall of standard size lead bricks (each 2" thick X 4" wide X 8" long). This wall is three (3) bricks (12") high and two (2) bricks (16") long. Immediately adjoining both sides of this rear wall are side walls of lead bricks of the same dimensions as the rear wall. The front of the generator area is shielded by an upright Protective Lead Barrier 15" high X 15" wide X 1/2" thick, to prevent direct exposure to personnel eluting the generator. The generator area location on the hot lab work bench is shown on the facility sketch. A top view of this arrangement is shown below.

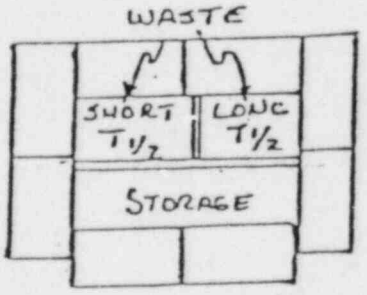
See (A) on attached sketch.



Storage and Waste Area Shielding:

The active storage/waste area is sheilded on all four (4) sides by standard size lead bricks as described above for the generator area shielding, except that a front lead brick wall is substituted for the protective lead barrier. This storage area is located on the hot lab area work bench as shown on the facility sketch. This lead brick storage area will be divided by plywood or similar material into three (3) compartments as shown on the diagram below. We do not anticipate the use of many long-lived radionuclides and the short-lived waste compartment contents can be more frequently surveyed for disposal to avoid waste accumulation or the need for any other radioactive storage or waste areas. A top view of the storage area shielding is shown below:

See (B) on attached sketch.



Dose Preparation Area:

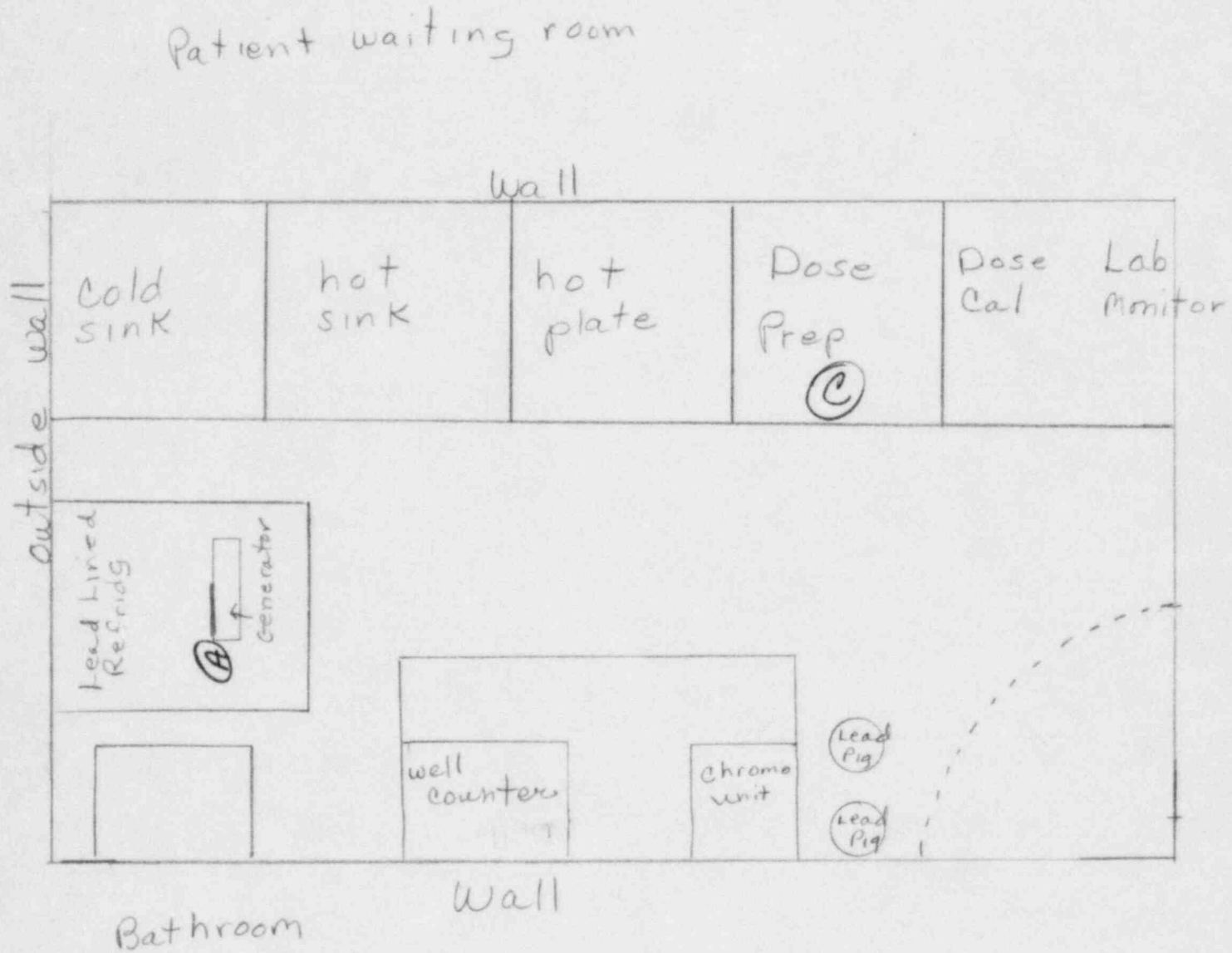
The dose preparation area on the hot lab area work bench as shown on the facility sketch, is shielded in the front by an upright Protective Lead Barrier (15" X 15" X 1/2" thick). Disposable gloves, remote handling tongs (4" to 8" long), survey meters, plastic backed absorbent pads and all other ancillary supplies mentioned in NRC Regulatory Guide 10.8, dated October 1980, will also be on hand in this hot lab area.

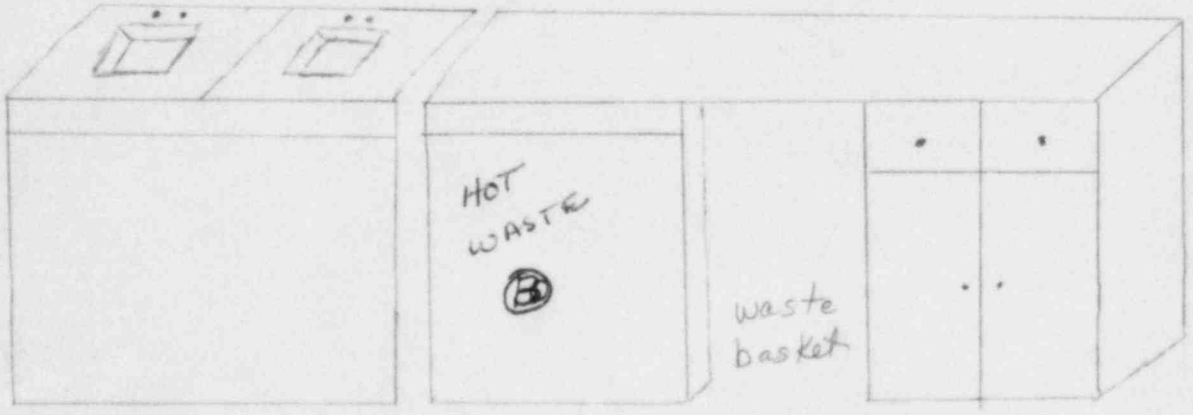
Equivalent shielding to maintain minimal exposure levels may be used.

See (C) on attached sketch

Dickenson County Memorial Hosp
Iron Mountain, MI

Not-to-scale





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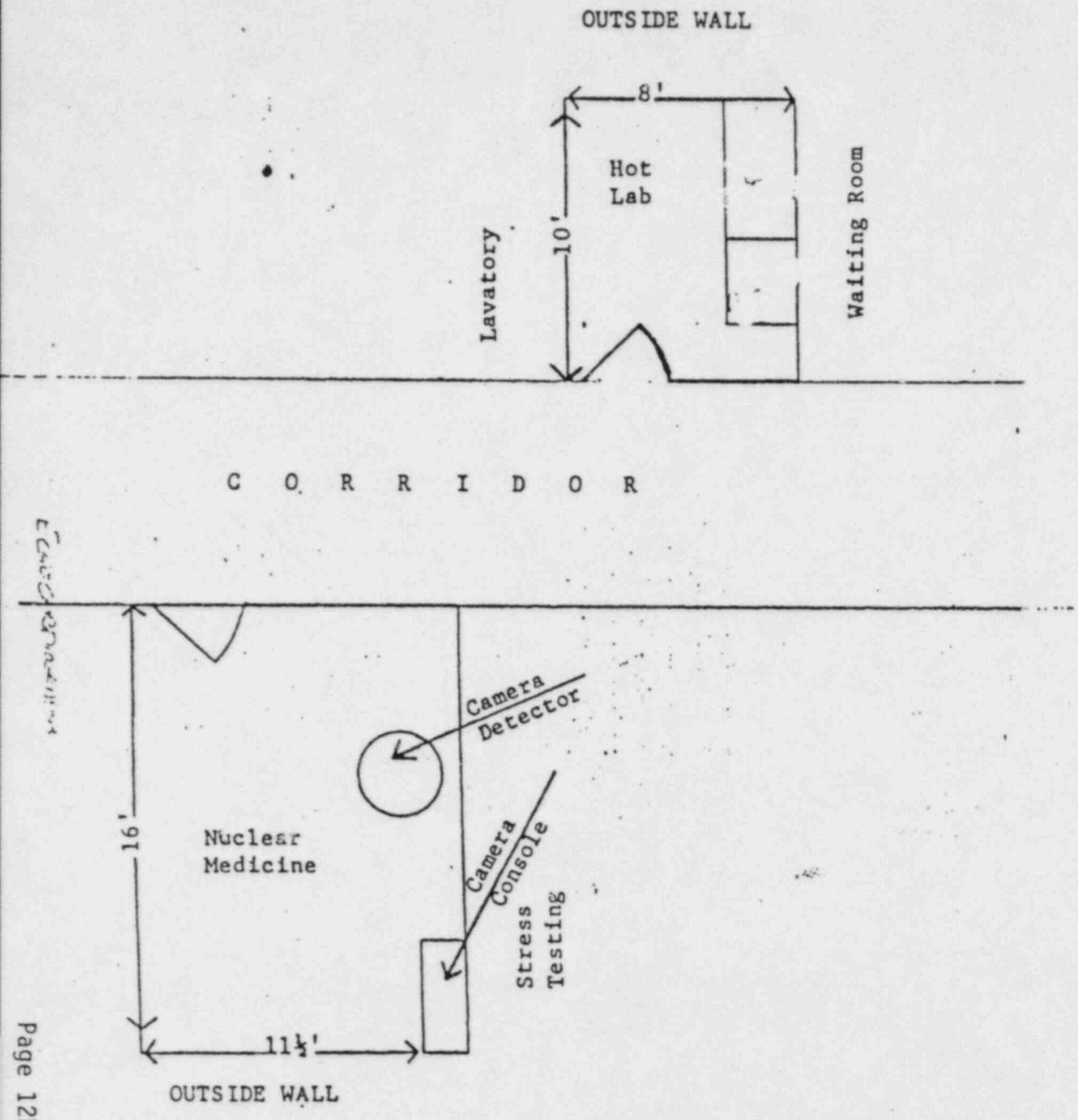
Dickinson County Memorial Hospital
Iron Mountain, MI

FACILITIES SKETCH



PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence, as required y 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

APPENDIX E

PROCEDURES FOR ORDERING AND ACCEPTING DELIVERY
RADIOACTIVE MATERIAL

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

2. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following.

   a. Ordering of routinely used materials

      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc, will be used.

      (2) The written records will be referenced when opening or storing radioactive shipment.

   b. Ordering of specially used materials (e.g., therapeutic uses)

      (1) A written request will be obtained from the physician who will perform the procedure.

      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.

      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.

   c. It is essential that written records* be maintained for all ordering and receipt procedures.

3. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

4. During off-duty-hours, security personnel or other designated individuals will accept delivery of radioactive packages in accordance with the procedures outlined in the sample memorandum below.

*In the case of special orders, the physician's written request and appropriate shipping/receipt records will be referenced and the dose assayed prior to its administration.

SAMPLE**MEMORANDUM

MEMORANDUM FOR: Security

FROM: Hospital Administrator

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

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

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

**RADIATION SAFETY OFFICER_____

**OFFICE PHONE_____

**HOME PHONE_____

**On the actual memo that is used, this information will be filled in and updated as necessary.

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Only trained Nuclear Medicine personnel are to open radioactive material shipments. These personnel have been instructed in the "Radioactive Shipment Receipt and Notification Procedures" which the Radiation Safety Officer has distributed to personnel who could possibly have contact with a radioactive shipment delivery.

The radioactive material shipments are to be opened in accordance with the NRC Regulatory Guide 10.8 dated October, 1980, Appendix F, "Procedures for Opening Packages Containing Radioactive Material".

The basic steps are:

a. Monitor the outside of the package and record the survey reading. The exterior reading limits and notification procedures are in the Appendix F guide. (200 mr/hr at surface and 10 mr/hr at 3 feet from the package surface.)

b. Wear gloves while opening the package behind the lead shield on the hot lab work bench.

c. Check packing material in accordance with the Appendix F guide referenced above. Record the inside packing material survey reading.

d. Report any leakage immediately to the Radiation Safety Officer who in turn will notify the supplier and/or NRC Division of Compliance.

e. Detain the driver or courier of the radioactive shipment if any package is apparently damaged or suspected as leaking, until the shipment is pronounced safe by the Radiation Safety Officer or the proper authorities have been notified. If the driver insists on leaving prior to this time, obtain the driver's name, company name, and phone numbers for any follow-up that may be needed.

APPENDIX G

GENERAL RULES FOR 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. 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. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

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

6. a. 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 percent.

   b. 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 shielded 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 shielded 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 radiactive 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 Radiaton 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 RADIATION SAFETY OFFICER:

_____
_____
_____

*On the actual copy that is posted in the nuclear medicine department, this information will be filled in and updated as necessary.

APPENDIX I

AREA SURVEY PROCEDURES

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

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

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

4. The weekly and monthly surveys will consist of:

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

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

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

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

   b. Name of person conducting the survey.

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

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

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

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

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

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

APPENDIX I

ALTERNATE WIPE TEST METHOD

Alternate method of assaying wipe test (smear test) samples for detecting surface contamination. Because of the relatively small quantities of radioactive materials used at our hospital, we feel the following procedure is sufficient to detect surface contamination levels:

a. Wipe test samples will be assayed by holding the smear immediately adjacent to the open window of our low level g.m. survey meter. Care will be taken to avoid contamination of the probe.

b. The smear will be held adjacent to the probe for approximately 30 seconds to ensure that any contamination over normal background levels will be detectable.

c. Normal background levels at our hospital are approximately 0.05 mr/hr. Any wipe test reading over that level will indicate the need to decontaminate the tested area.

Ref: NRC 313M - Item 18

WASTE DISPOSAL PROCEDURES

G. Unused sources and/or residues are decayed in the lead shielded hot lab storage area for a period of at least (10) half lives (fifteen (15) half lives in the case of Mo-99 and Tc-99m) and/or until radiation levels, as determined with a low level survey meter are found to be that of normal background readings (usually $\leq$0.05 mR/hr) before disposal as regular trash. In certain cases when the initial calibrated activity of a radionuclide is already low, the Radiation Safety Officer may authorize specific disposals before the ten half-lives have elapsed, as long as the surveyed source shows no detectable activity above background on the low level survey meter. Radiation labels are obliterated before such disposal. Surveys are performed with source shielding removed.

We may use any NRC licensed waste disposal service as a back-up method of disposal, especially if an accumulation of long lived waste would develop. We may also transfer radioactive materials to any appropriately licensed recipient.

H. At this time the Radiation Safety Program was developed, this institution does not apply for treatment of patients with by-product material or with brachytherapy sources. The Radiation Safety Officer is to be consulted if any questions arise about changes in licensure, special precautions, or any matters related to radioactive material usage and radiation safety.

*RADIATION SAFETY OFFICER:
ON DUTY PHONE:
HOME PHONE:

*On the actual copy that is posted in the nuclear medicine department, this information will be filled in and updated as necessary.

REF: NRC 313M - Item 23
Leak Testing of Sealed Sources

Leak testing of sealed sources will be performed on a semi-annual frequency. We will use the leak test services of Stan A. Huber Consultants, Inc., New Lenox, Illinois (NRC License #12-17503-01), using their Model LT-2 Leak Test Kit for Sealed Sources, or other firm specifically authorized by the U.S. Nuclear Regulatory Commission to perform these tests.

We confirm that sealed sources will be stored in their original lead shielded containers. Any readings above background would indicate the need for additional shielding.

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Dickinson County Memorial Hospital
(Licensee's Name)

February, 1985
(Date)

1. Management Commitment

a. We, the managment of this (medical facility, hospital, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)* and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program, icluding ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

* Private practice physician licenses do not include an RSC.

2. Radiation Safety Committee (RSC)*

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA concept.

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necesary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).**

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

** The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific proedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program.

(3) Quarterly review of records of radiation level surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision.

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures.

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initial review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed on Table O-1 below. These levels apply to the exposure of individual workers.

Table O-1

Investigational Levels
(mrems per calendar quarter)

	Level I	Level II
1. Whole body, head and trunk;active blood-forming organs;lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by 10.401 of 10 CFR part 20. The following actions will be taken at the Investigational Levels as stated in Table O-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table O-1 values for Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

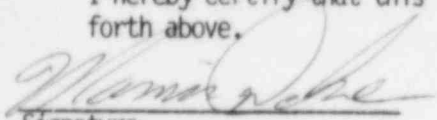
d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table O-1.

In cases where a worker's or a group of workers' exposures need to exceed Investigation Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for and will approve all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official*

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.



Signature

Marvin Dehne
Name (print or type)

Administrator
Title

Institution (or Private Practice) Name and Address:

Dickinson County Memorial Hospital
400 Woodward Avenue
Iron Mountain, MI

* The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

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