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

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved by OMB 3150-0041

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

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

Research Medical Center
2316 E. Meyer Boulevard
Kansas City, Missouri 64132

TELEPHONE NO.: AREA CODE (816) 276 4000

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

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Morton H. Levitt, M.D.
Vice President, Clinical Services

TELEPHONE NO.: AREA CODE (816) 276 4302

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. XX RENEWAL OF LICENSE NO. 24-18625-01

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

Walter G. Dukstein, M.D.
William E. White, M.D. Jorge C. Paradelo M.D.
Ben J. Throne, M.D. George A.B. Cowan 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.)*

Robert A. Morgan RSO
Walter J. Kopecky Ass't RSO

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	5
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	2000
10 CFR 35.100, SCHEDULE A, GROUP IV	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1000

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.	X	500

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
Gadolinium - 153	Sealed Source	2000	Bone Densitometer
Cesium - 137	Sealed Source	120	Instrument Calibration

RECEIVED
AUG 06 1984
REGION III

O/N 77241

NRC FORM 313M (9-81)

8506060682 850517
REG3 LIC30
24-18625-01 PDR

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: 1980

7. MEDICAL ISOTOPES COMMITTEE	
X	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and
X	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
	Appendix C Form Attached; or
X	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed, or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
X	Appendix I Procedures Followed; or
	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
	Appendix J Form Attached; or
X	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix K Procedures Followed; or
X	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
	Detailed Information Attached; and
	Appendix Procedures Followed; or *(Check One)*
X	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

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

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

(1) NAME *(Type or Print)*
Morton H. Levitt, M.D.

(2) TITLE
Vice Pres. , Clinical Services

c. DATE
August 1, 1984

C/N 7724J

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 NRC Form 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 COMMITTEE

Committee Members:

Walter G. Dukstein, M.D., Hematology, Nuclear Medicine

William E. White, M.D., Radiology, Nuclear Medicine

Ben J. Throne, M.D., Therapeutic Radiology

Morton Levitt, M.D., Vice President, Clinical Services

Walter J. Kopecky, Ph.D., Assistant Radiation Safety Officer

Robert A. Morgan, M.S., Radiation Safety Officer

Joy McKee, R.N., Supervisor, Oncology Nursing Staff

The responsibilities, duties and meeting frequency will be as described in Appendix B, of A Guide for the Preparation of Applications for Medical Programs, Regulatory Guide 10.8, Revision 1 and in 10CFR35.11.

Item No. 7

Date: August 2 1984

TRAINING AND EXPERIENCE

Name	Requested Groups	Previous License
Walter G. Dukstein	1 - 6	NRC 24-18625-01
William E. White	1 - 6	NRC 24-18625-01
Ben J. Throne	4 - 6	NRC 24-18625-01
George A.B. Cowan	4 - 6	NRC 24-18625-01
Jorge C. Paradelo	4 - 6	NRC 24-18625-01

Those physicians requesting groups 4 through 6 only will use sources for therapeutic radiology.

Robert A. Morgan		NRC 24-18625-01
Walter J. Kopecky		NRC 24-18625-01

Item No. 8

Date: August 2, 1984

INSTRUMENTATION

1. Survey Meters

a. Manufacturer's name: EBERLINE

Manufacturer's model number: E-120

Number of instruments available: 2

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

Maximum range: 0 mr/hr to 50 mr/hr

b. Manufacturer's name: VICTOREEN

Manufacturer's model number: 740-F

Number of instruments available: 1

Minimum range: 0 mr/hr to 25 mr/hr

Maximum rnage: 0 mr/hr to 25,000 mr/hr

Item No. 9

Date: August 2 1984

INSTRUMENTATION

2. Dose Calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-4

Number of instruments available: 1

3. Diagnostic Instrumentation

Type of Instrument	Manufacturer	Model No.
Gamma Camera	Picker	DynaCamera 4
Gamma Camera	Searle	Pho/Gamma
Gamma Camera	Siemens	Rota Dual Head
Xenon Delivery System	Atomic Products	130-500
Thyroid Probe	Picker	2801D
Spectroscaler	Picker	628438
Gamma Counter	Micromedics	28100

4. Other

Liquid Scintillation Counter	Searle	Isocap/300
Automatic Gamma Counter	Searle	1185 Series
Well Counter	Picker	2804E
Multichannel Analyzer	Canberra	Series 35
Personnel Monitor	Berthold	LB 1210B, 1211

Item No. 9

Date: August 2, 1984

CALIBRATION OF DOSE CALIBRATOR

A. Sources used for linearity test:

Check as appropriate

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

XX Other(specify) Calicheck

B. Sources used for instrument Accuracy and Constancy tests:

Radionuclide	Activity(mCi)	Accuracy
57 Co	5	± 5%
133 Ba	0.200	± 5%
137 Cs	0.200	± 5%

C. The procedures described in Appendix B, Section 2 of A Guide for the Preparation of Applications for Medical Programs, Regulatory Guide 10.8, Revision 1 will be used for the calibration of the dose calibrator.

Item No. 10

Date: August 2, '84

CALIBRATION OF SURVEY INSTRUMENTS

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

2) Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

3) Survey instruments will be calibrated by a consultant or outsied firm

   (i) Name SYNCOR INTERNATIONAL CORPORATION

   (ii) Location 1734 E. 63rd Street, Suite 214, Kansas City, Missouri 64110

   (iii) Procedures and sources have been approved by the NRC and are on file in NRC License No. 24-16617-01MD.

Item No. 10

Date: August 2, 1994

FACILITIES AND EQUIPMENT

The following items are provided for handling radioactive materials and will be used appropriately:

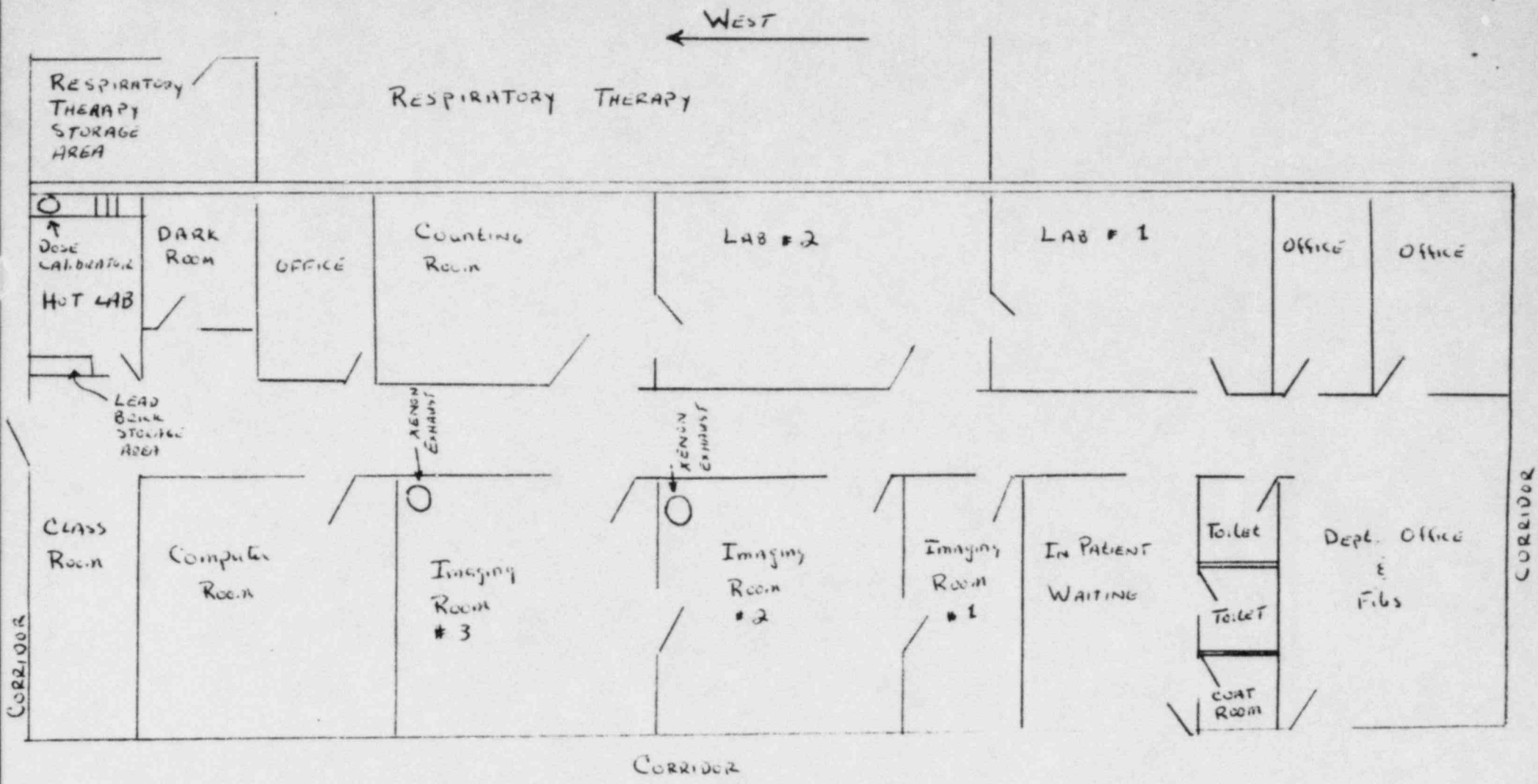
a. disposable gloves
b. syringe shields
c. lead vial shields
d. tongs and forceps
e. 2" x 4" lead bricks
f. boiling device for preparing Sulfur Colloid shield by lead bricks provided.
g. work bench area with absorbent paper

The area designated Hot Lab will be used for the receipt, storage (including waste), preparation and measurement of radioactive materials.

The waste storage bin will be located on the floor under the work bench area, and will have 1/16" of lead shielding. The Hot Lab area is a locked and labeled area with keys made available only to those people authorized as Nuclear Medicine Personnel. All radiopharmaceuticals are stored in their shipping containers or in the two-inch lead brick safe on the bench in the Hot Lab. All solid waste is stored in plastic bags in the lead storage bin provided in the Hot Lab.

Item No. 11

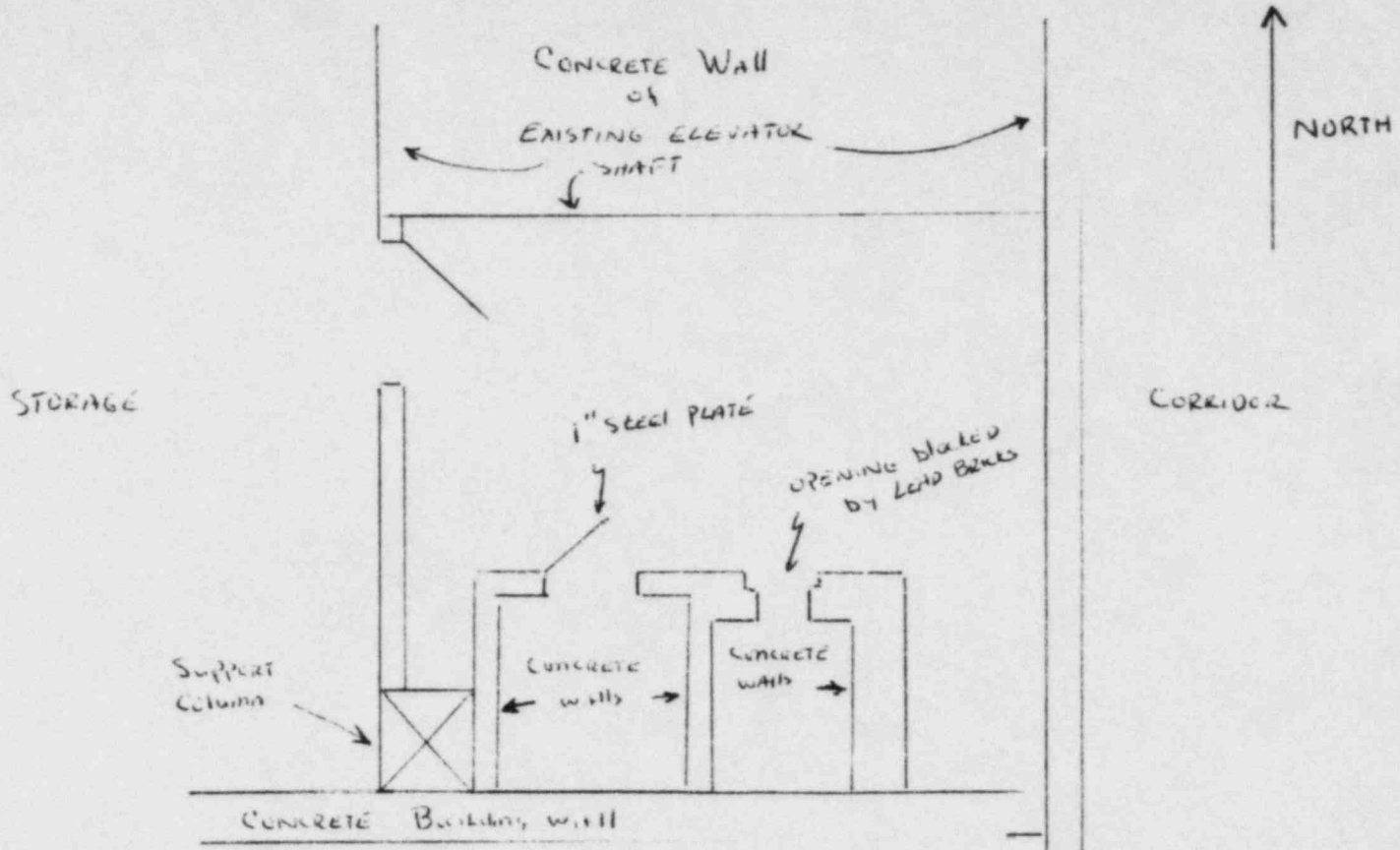
Date: August 2 1984



DEPARTMENT OF NUCLEAR MEDICINE

RESEARCH MEDICAL CENTER

LEVEL A (NOT TO SCALE)



DEPARTMENT OF NUCLEAR MEDICINE

LONG TERM STORAGE AREA

LEVEL B

PERSONNEL TRAINING PROGRAM

NUCLEAR MEDICINE TECHNOLOGIST. These individuals will be registered or registry eligible technologists by their respective registry group at this time, AART, ASCP or NMTCB, and will receive instruction initially and annually as specified in 10CFR19.12

CLINICAL, NURSING, HOUSEKEEPING AND SECURITY PERSONNEL. These individuals will be required to attend lectures before assuming their duties with or in the vicinity of radiaoactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations or terms of the license. The training will be of sufficient scope to insure that all personnel will receive proper instruction in the items specified in Section 19.12 of 10 CFR, Part 19 and will include:

A. Areas where radioactive material is used and stored
B. Potential hazards associated with radioactive materials
C. Radiological safety procedures appropiate for their respective duties
D. Pertinent NRC regulations
E. The rules and regulations of the license
F. The pertinent terms of the license
G. Their obligation to report unsafe conditions
H. Appropiate response to emergencies and unsafe conditions
I. Their right to be informed of their radiation exposure and bioassay results

Lectures will be given by the Nuclear Medicine Technologist, the Radiation safety Officer or a consulting physicist.

Item No. 12

Date: August 2 1984

Internal Communication

Date: July 27, 1984

To: Emergency Room Personnel

From: Robert A. Morgan Radiation Safety Officer, Nuclear Medicine

Subject: Receipt of packages containing radioactive materials

---

Any packages containing radioactive material that arrive between 5:00 p.m. and 7:00 a.m. shall be signed for by the emergency room nurse on duty and taken immediately to the Nuclear Medicine Department. Unlock the door to the Hot Lab, the last door on the right when entering the department through the main enterance, and place the package on the work bench. Make sure to relock the door when leaving.

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

Radiation Safety Officer: Robert A Morgan

Office Phone: (816)276-4235

Home Phone: (913)262-6232

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIALS

1. The Chief Nuclear Medicine Technologist, the Technologist In Charge or a qualified Nuclear Medicine Physician will place all orders for radioactive materials and will insure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department. Those sources used for brachytherapy will be delivered directly to the Radiation Oncology Department.

3. During off-duty hours, EMERGENCY ROOM PERSONNEL will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed memorandum. (Attached)

Item No. 13

Date: August 2 1994

PROCEDURES FOR SAFELY OPENING PACKAGES

CONTAINING RADIOACTIVE MATERIALS

Packages will be opened in accordance with procedures described in Appendix F of A Guide For The Preparation Of Applications For Medical Programs, Regulatory Guide 10.8, Revision 1.

Item No. 14

Date: August 2 1954

LABORATORY RULES FOR USE OF RADIOACTIVE MATERIALS

We will follow the laboratory rules described in Regulatory Guide 10.8, Revision 1, Appendix G, A Guide for the Preparation of Applications for Medical Programs.

Item No. 15

Date: August 2 1984

EMERGENCY PROCEDURES

Emergency procedures will be posted in all laboratory areas where radioactive materials are used. The emergency procedures outlined in Appendix H of Regulatory Guide 10.8, Revision 1, A Guide for the Preparation of Applications for Medical Programs, will be followed.

Item No. 16

Date: August 2, 1984

AREA SURVEY PROCEDURES

Area surveys will be done in accordance with Appendix I of Regulatory Guide 10.8, Revision 1, dated October 1980.

Item No. 17

Date: August 2 1984

C/N
77241

WASTE DISPOSAL PROCEDURE

1. Liquid waste will be disposed of in the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

2. Mo-99/Tc-99m generators will be held for decay until radiation levels as measured with a low level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash.

3. Other solid waste will be held for decay until the radiation level as measured with a low level survey meter and with all shielding removed have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash. Those isotopes that are extremely long lived, particularly 3-H (tritium), will be disposed of by a commercial waste disposal service.

4. The commercial waste disposal service used will be:

   Chem-Nuclear Systems, Inc.
   P.O. Box 1866
   Bellevue, WA 98009

   NRC/Agreement State License No. 46-19524-01

Item No. 18

Date: August 4 1984

RADIATION SAFETY PROCEDURES FOR THERAPUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with Iodine-131 or Gold-198 will be placed in a private room that has a toilet. Three end corridor rooms located on the oncology ward has been designated as the Hospital Radiopharmaceutical Therapy rooms. Each room has had the carpeting removed and has a negative air flow of at least 30 feet per minute into the room. The large surfaces in the rooms and toilet areas that are more likely to be contaminated will be covered with absorbant pads as appropriate to the amounts of contamination to be expected. Special attention will be given to objects likely to be touched by the patient, for example telephones, doorknobs and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable will be used on smaller items.

2. The patient's room will be properly posted or attended in accordance with Section 20.203 or 20.204 of 10 CFR part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practical after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and three feet from the patient after administration and at the entrance of the room. The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times on the patient's chart and on the door. The results of the daily surveys will be used to recalculate permitted times which will be posted on the patient's chart and on his door.

4. A form containing nursing instructions for patient's treated with radiopharmaceuticals will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

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

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

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated as appropriate.

9. All excreta from Iodine-131 therapy patients will be released to the sanitary sewer system as permitted by Section 20.303 of 10 CFR part 20.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactivity waste and waste containers will be removed.

11. Nursing Instructions: The guidelines outlined in Appendix K, Radiation Safety Procedures for Therapeutic use of Radiopharmaceutical of Regulatory Guide 10.8, A Guide of the Preparation of Applications for Medical Programs will be followed.

12. When contaminated wastes are transported to waste storage-disposable area, precautions will be taken to minimize external radiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas according to ALARA.

Item No. 19

Date August 2 1984

THERAPEUTIC USE OF I-131

1. In most cases, liquid iodine will be used for those therapy procedures requiring I-131. Liquid iodine, under most circumstances, will be delivered via a closed system. The system is a Paramedical Oral Radioisotope Administration Set (#32-27). Personnel will be instructed to wear gloves when administrating any liquid I-131 therapy. In those rare instances when an open delivery system must be used personnel will be instructed to open vials or remove liquid I-131 from the vial in a well ventillated area in order to minimize the possible intake of volatile iodine.

2. Liquid I-131 therapies requiring patient hospitalization will be administered in one of three designated therapy rooms located on the Oncology ward. Each room is designed as an isolation room and has a negative airflow of at least 30 feet per minute with an open door. The Oncology nursing staff will be instructed in proper radiation safety procedures on a yearly basis and will have their own personnel dosimetry monitor.

3. Immediately following the administration of liquid I-131 a whole body scan using a survey meter will be performed on the physician administering the therapy in an attempt to locate contamination. Should contamination be found, immediate decontamination procedures will be implemented to prevent the spread of radioactive materials.

4. Bioassays will be performed no earlier than six(6) hours but no later than seventy two(72) hours following administration of liquid I-131. Bioassays will be performed by a qualified Nuclear Medicine Technologist using a thyroid uptake probe and the rsults of the bioassay kept in a log book.

THERAPEUTIC USE OF I-131

4.(cont) The results of the bioassay will be interprelated to 24 hours which is assumed to be the time of maximal uptake(see enclosed graph which will be used to generate interprelative values).

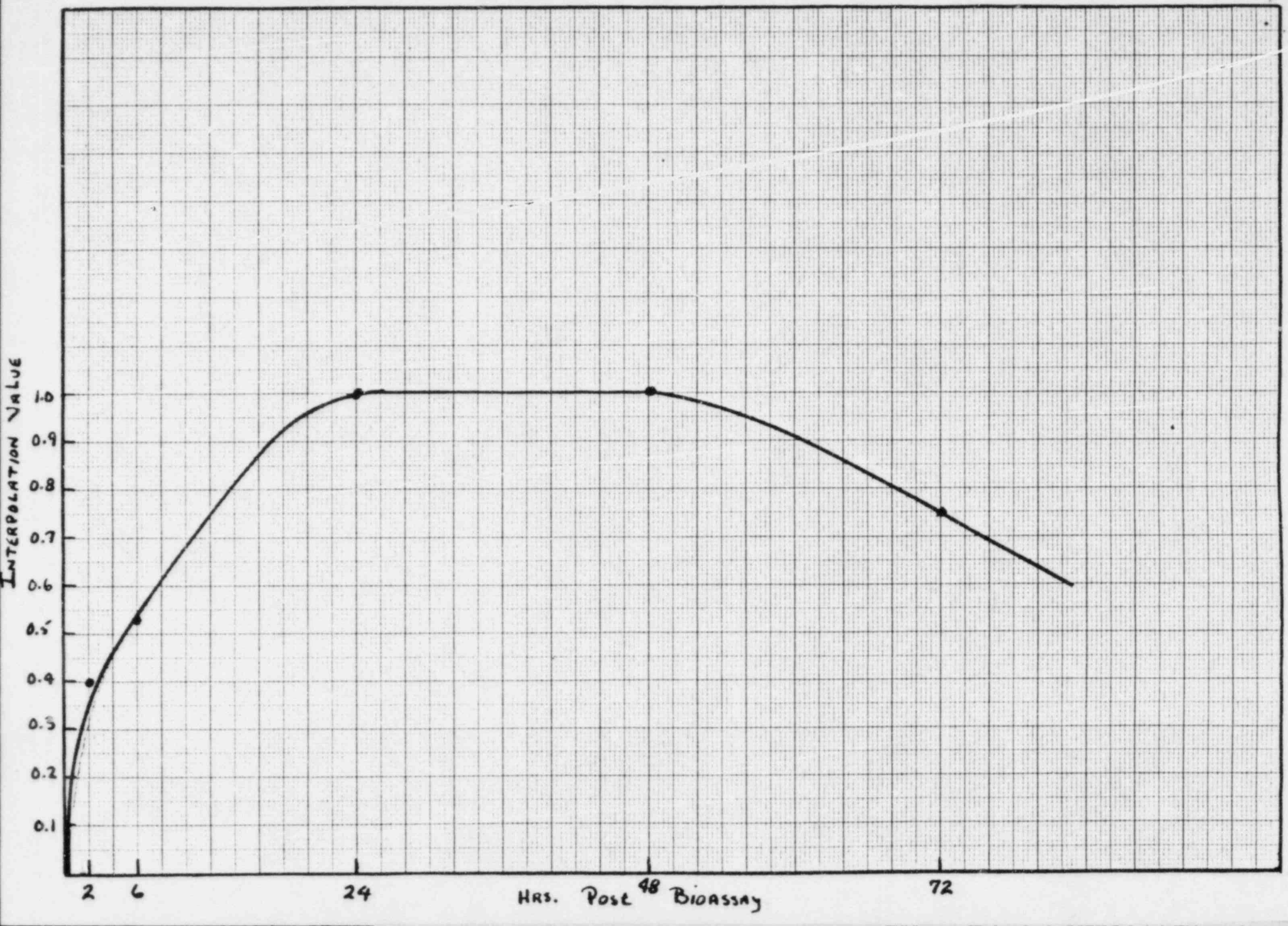
5. Should a physician approach either the 40 hour MPC of 0.1003 uCi or the 520 hour MPC of 1.300 uCi, that physician will not be allowed to administer further therapies until the beginning of the next monitioring period. A running total of I-131 accumulated in the thyroid of all personnel involved in the administering of liquid I-131 will be maintained.

6. Bioassays will be performed and records maintained on any personnel involved in the cleanup of a spill of I-131.

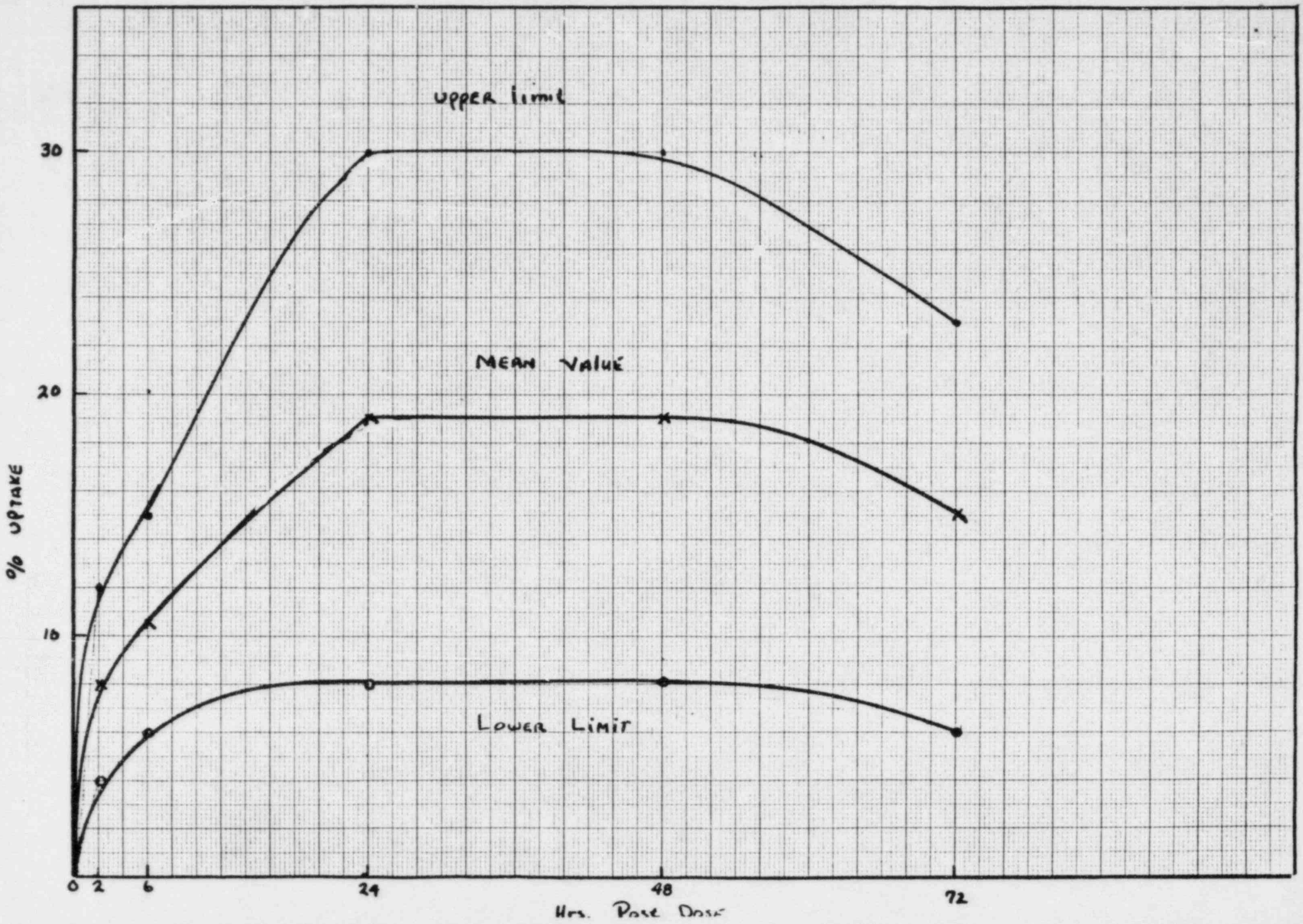
Item No. 19

Date: August 21 1984

Interpolative Value Using Mean Normal Thyroid Uptake



Normal Range of Thyroid uptake



THERAPEUTIC USE OF SEALED SOURCES

1. The sources will be stored in their shipping containers before and after use.

2. The containers will be located in a remote room of the Radiation Oncology department and in a restricted area more than 100 feet from the nearest nonrestricted area.

3. Sealed sources will be handled in such a manner as not to rupture, heat or abrade them in any manner.

4. The Geiger counter will be available at all times while handling sealed sources.

5. Sealed sources will never be left unattended or unshielded.

6. Instructions to the nursing staff will follow Appendix L of Regulatory Guide 10.8, A Guide for the Preparation of Applications for Medical Programs, Version 1, dated October 1980.

7. Personnel handling sealed sources will routinely wear finger badges.

8. Any procedure in handling sealed sources out of the routine will be monitored by a self-reading dosimeter attached to the wrist or fingers.

9. Carts with three inches of lead shielding are available for transporting sources.

10. Our source accountability procedure includes a sign-in/sign-out register kept in the storage area.

11. When sources are removed from the room the removal is recorded in the log and signed by the person removing the source.

12. When sources are returned to the room this is recorded in the sign-in column of the log.

13. Surveys are performed immediately after application of the sources to determine radiation levels in the proximity of the patient and in surrounding areas.

14. Surveys are performed at any time during the course of treatment if there is any suspicion of shifting or misplacement of sources.

15. Surveys are taken on the removal of the sources to insure that no sources are left in the patient or in the proximity of the patient.

Item No. 20

DATE August 2, 1984

ANALYSIS OF VENTILATION REQUIREMENTS

FOR XENON-133 STUDIES

Summary

1. Air concentrations of Xe-133 in restricted areas will be less than 5.65×10^{-7} uCi/ml (Estimated by calculation).

2. Air concentrations of Xe-133 in unrestricted areas will be less than 2.15×10^{-7} uCi/ml (Estimated by calculation).

3. In the event of an accidental release of Xenon-133, the area where the study is performed will need to be vacated for only 14 minutes.

4. These are conservative estimates as the assumed procedural volume is twice that currently being performed and the average amount of Xenon-133 used per study is less than that assumed in the calculations.

Briefly, the studies are performed in one of two imaging rooms. The procedures are performed using a Pulmonex Xenon System, Model #130-500, which exhausts through a 2" flexible hose into a 6" duct. This duct in turn exhausts into a a single pass ventilation system servicing the three imaging rooms. The total exhaust for the entire system is 3250 cfm.

Data for the two imaging rooms where Xenon-133 studies may be performed are given in the accompanying tables. Sample calcualtions follow.

Item No. 21

Date: August 2 1984

AIR CONCENTRATIONS OF ^{133}Xe IN RESTRICTED AREAS

Define:

A = the maximum amount of activity to be used per week = 10 patients/wk x 20 mCi/patient = 200 mCi/week.

F = the fraction of ^{133}Xe that is lost during use = 0.20.

V = the exhaust rate in the imaging room where studies are performed. For imaging room #2 V = 1100 cfm (measured with an Alnor Velometer).

C = the concentration of Xenon = (A x F)/V.

$$C = \frac{2.0\times10^{5}\ \mu Ci/wk \times 0.2}{1100\ cfm \times \frac{1.7\times10^{6}\ ml/hr}{cfm} \times \frac{40\ hrs}{wk}}$$

$C_2 = 5.35\times10^{-7}\ \mu Ci/ml$ for imaging room #2.

Similar calculation show that

$C_3 = 5.65\times10^{-7}\ \mu Ci/ml$ for imaging room #3.

These concentrations are well below the limit of $1\times10^{-5}\ \mu Ci/ml$ specified in Section 20.103 of 10 CFR 20 for restricted areas.

AIR CONCENTRATIONS OF ^{133}Xe IN UNRESTRICED AREAS

The patient exhaust is vented through a single pass ventilation system which discharges 3250 cfm. Thus:

$$V = 3.25 \times 10^{3} \text{ cfm} \times \frac{1.49 \times 10^{10} \text{ ml/yr}}{\text{cfm}} = 4.84 \times 10^{13} \text{ ml/yr}$$

$$C = \frac{2 \times 10^{5} \text{ uCi/wk} \times 52 \text{ wks/yr}}{4.84 \times 10^{13} \text{ ml/yr}} = 2.15 \times 10^{-7} \text{ } \mu\text{Ci/ml}.$$

This value will be the same for both imaging rooms since they both exhaust into the smae ventilation system. This concentration is below the limit of 3×10^{-7} μCi/ml specified in Section 20.106 of 10 CFR 20 for unrestricted areas.

ACCIDENTAL RELEASE OF XENON-133

1. The maximum amount of Xenon-133 that can be accidentally released is equal to 1 patient dose. On the average this will not exceed 20 mCi.

2. The volume of imaging room # 2 is 4817 cu.ft. or 1.36×10^8 ml. The volume of imaging room # 3 is 5522 cu.ft. or 1.56×10^8 ml.

3. The room exhaust rate is 1100 cfm and 1040 cfm for imaging rooms #2 and #3 respectively (measured with an Alnor Velometer).

4. The air pressure in the imaging rooms is negative with respect to adjoining hallways.

5. The maximum allowable concentration is 1×10^{-5} μCi/ml in a restricted area.

Thus, an accidental release of Xenon-133 in imaging room #2 will result in an initial air concentration, $C_{(0)}$, of

$$C_{(0)} = \frac{20 \text{ mCi} \times 10^3 \ \mu\text{Ci/mCi}}{1.36 \times 10^8 \text{ ml}} = 1.47 \times 10^{-4} \frac{\mu\text{Ci}}{\text{ml}}$$

The concentration C(t), at time t will be given approximately by:

$$C(t) = C(o)e^{-kt}$$

The elimination rate, k, can be estimated as

$$k = \frac{1100 \text{ cfm}}{4817 \text{ cu.ft.}} = 0.228 \text{ min.}^{-1}$$

or

$$C(t) = 1.47 \times 10^{-4} \ \mu\text{Ci/ml} \times e^{-0.228t}$$

when t is in minutes.

The time, t, required for the average air concentration to be reduced to 1×10^{-5} μCi/ml is given be:

$$1 \times 10^{-5} \ \mu\text{Ci/ml} = 1.47 \times 10^{-4} \ \mu\text{Ci/ml} \times e^{-0.228t}$$

$$t = 11.8 \text{ min. for imaging room \#2.}$$

Similar calculations yield

$$t = 13.6 \text{ min. for imaging room \#3.}$$

If an accidental release of Xenon-133 does accur, the patient and all staff shall immediately vacate the imaging room, the door shall be closed and no re-entry will occur for at least 14 minutes. The Radiation Safety Officer or his designate shall be immediately notified for further instructions. Prior to re-entry a survey of the room where accidenatal release occurred shall be carried out to insure that the levels of radioactive Xenon-133 are acceptable.

VENTILATION CHARACTERISTICS OF IMAGING ROOMS

	IMAGING ROOM NO. 2	IMAGING ROOM NO. 3
VOLUME	4817 ft^3	5522 ft^3
	1.36×10^8 ml	1.56×10^8 ml
SUPPLY	950 cfm	560 cfm
	1.41×10^{13} ml/yr	8.34×10^{12} ml/yr
EXHAUST	1100 cfm	1040 cfm
	1.64×10^{13} ml/yr	1.55×10^{13} ml/yr

XENON CONCENTRATIONS

IN RESTRICTED AND UNRESTRICED AREAS*

	IMAGING ROOM NO. 2	IMAGING ROOM NO. 3
RESTRICTED AREA	5.35×10^{-7} μCi/ml	5.65×10^{-7} μCi/ml
UNRESTRICTED AREA	2.15×10^{-7} μCi/ml	2.15×10^{-7} μCi/ml

* This assumes that the Xenon-133 is vented into the room exhaust system via the Pulmonex Xenon System through a specially designed exhaust

RADIOACTIVE MATERIALS NOT LISTED IN ITEM 6A

Gadolinium - 153

Manufacturer	Model Number
Gulf Nuclear, Inc. 202 Medical Center Boulevard Webster, Texas 77598 (713)332-3581	GD - 1

See attached Nuclear Data specification sheet for intended use.

Cesium - 137

Manufacturer	Model Number
Nuclear Associates, Inc 35 Urban Avenue Westbury, New York 11590 (516)333-9344	64 - 764

See attached Nuclear Associates specification sheet for intended use. This source is no longer used for in house instrument calibration and has been placed in storage.

Item No. 23

Date: August 2 1984

DESCRIPTION

The Gamma Survey Instrument Calibrator is a device for making calibrations in radiation fields from 2 to 800 mR/hr. It contains a non-removable Cs-137 sealed source. The unit radiation output of a Cs-137 source is 3100 R/hr per curie at a distance of 1 centimeter. The calibrator meets the requirements of the A. E. C. and Agreement States.

It consists of heavy-duty brass housing that holds 100 mc of Cs-137 encapsulated at one end of a control rod. The brass housing is filled with approximately 48 lbs. of lead to provide the radioactive shielding required. Since Cs-137 has a long half-life of 29 years, there is no need to calculate a correction factor for at least 1 or 2 years after the instrument has been received in the laboratory, or after the date on the nameplate, whichever is later.

WARNING

This unit contains a 100mc Cs-137 source, and all applicable precautions of the A. E. C. and Agreement States must be observed. Do not remove the radioactive source or tamper with it in any way except as described under "Operation". Do not use the Calibrator except with the authorization of the Radiation Safety Officer. Any calibrator malfunction, loss, theft, or other emergency must be reported to the Radiation Safety Officer immediately.

If any questions arise, please call the manufacturers: Nuclear Associates, Inc., 35 Urban Ave., Westbury, N. Y. -- phone (516) 333-9344 .... or call Eon Corp., 175 Pearl St., Brooklyn, N. Y. -- phone (212) 858-0250.

The outside surfaces of the calibrator should be wipe tested every 6 months in accordance with the regulations of the A. E. C. and Agreement States.

INSTALLATION

The Gamma Calibrator is a portable instrument and requires a minimum of set-up. The location for use should be selected carefully to prevent accidental radiation exposure. An area 15 feet in front of the cone should be clear at all times; this will also eliminate any appreciable scatter radiation. After the calibrator has been examined to determine if any damage has occurred during shipping, and the area has been cleared, open the padlock and follow the operating instructions.

OPERATION

The source is kept in either of 2 positions: stored or exposed. In the fully-shielded "stored" position, radiation at the container's surface is less than 60 mR/hr; at 6 inches away it is less than 15 mR/hr. In the "exposed" position the source faces a 45^{o} port at the side of the shield, and the field can vary from 2 to 800 mR/hr. The source is moved from "stored" to "exposed" merely by raising the control rod. For safety, the Cs-137 source cannot be removed from its shield except by the manufacturer.

Included is a built-in tape measure which helps accurately determine the distance from the Cs-137 source to the instrument being calibrated. A key-lock prevents any unauthorized use of the equipment. To activate the source, remove the padlock and swing the grip-handle on its pin hinge. The source cannot be raised unless the handle is swung away.

The timer on the gamma calibrator is a safety device and can also be used to set the length of time that the source remains in the exposed position. When the source is raised, the timer must be set to a time between one and 60 minutes (in one minute intervals) or the source will automatically drop back to the safe position. If the timer is set with the source raised, the source will remain in the exposed position for the time period selected and then drop to the safe position. To return the source to the safe storage position before the end of a pre-set time cycle, turn the timer knob to "zero". The source automatically drops into safe storage.

For momentary exposures of less than one minute, keep the timer at zero and lift the source handle. In this mode the source will automatically drop into the safe position when the handle is released. This feature offers two advantages:

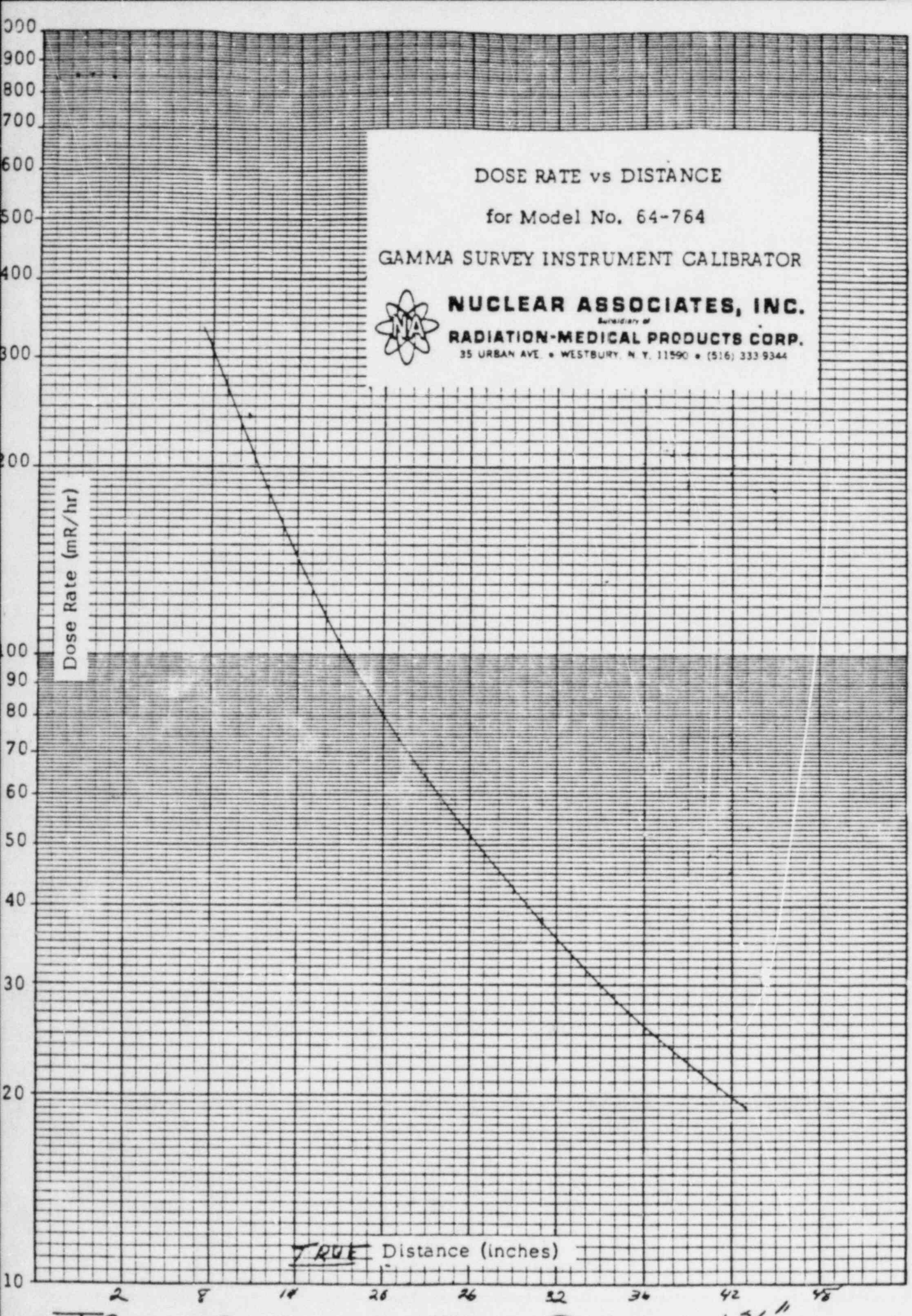
1) The source cannot be left accidentally in the exposed position for a period longer than the time selected when it is raised.

2) The timer can be used for the automatic control of exposure time -- a convenient preset time feature for calibrating dosimetry equipment.

Instruction Manual

GAMMA SURVEY INSTRUMENT CALIBRATOR

NUCLEAR ASSOCIATES, INC.
35 URBAN AVENUE, WESTBURY, N.Y. 11590
PHONE (516) 333-9344 • TWX 510-222-8958



TRUE DISTANCE = TAPE RULE + 1 3/8"

ND Medical Products

ND2100 DUAL PHOTON BONE DENSITOMETER

Features

- Microprocessor control
- High resolution video display for exceptional imaging
- Large scanning area (60 cm by 80 cm)
- Scanning area can be repositioned without moving patient
- Patient positioning system

Application

This method eliminates the need for a soft tissue equivalent and is thus applicable to regions containing extensive soft tissue such as the spine. Direct evaluation of trabecular bone such as in the spine can be used effectively in monitoring and managing the treatment of patients with osteoporosis

PRELIMINARY SPECIFICATIONS

SCAN TABLE:

Dimensions: 600 x 760 x 1900 mm (HXWXL)
Weight: 100 kg
Mobile with lockable wheels
Translucent fiber table top

SCANNING MECHANISM:

Scanning area: 600 x 800 mm (WXL)
Oblique scanning: 0-360° with 5° steps
Scanning speed: 1-10 mm/sec.
Manual positioning: 2.5 mm/sec. or 10 mm/sec.
Stepping motors: 1.8°/step
Synchronized source/detector travel
Pivoting detector arm for patient access
Automatic source shutter
Exchangeable collimators for source and detector: 2, 4 and 6 mm

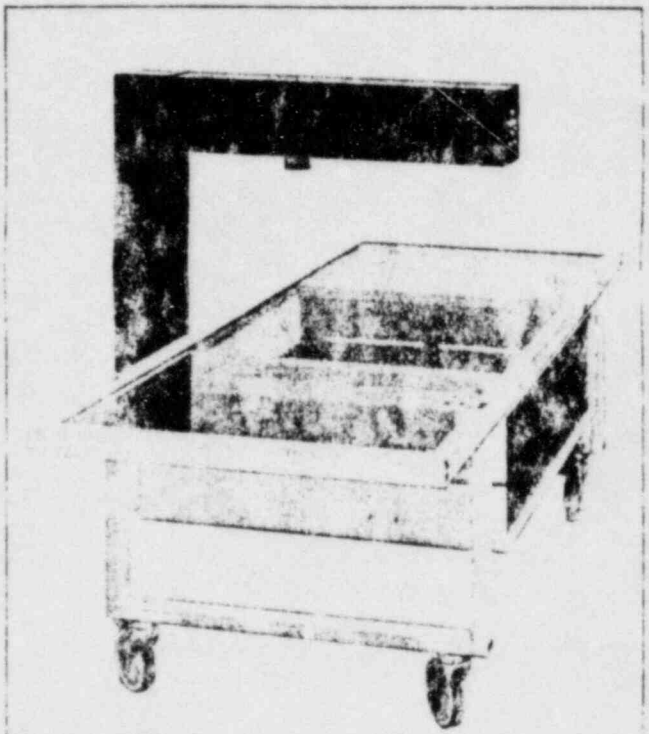
ELECTRONICS

Microprocessor controlled
Automatic gain control
Unipolar amplifiers, low deadtime
High resolution dual analyzers

Benefits

Dual photon absorptiometry using the ND 2100 provides a number of benefits for the patient as well as the physician including:

- Direct and precise measurement of bone mass (bone mineral content)
- Highly reproducible measurements
- Excellent edge detection program
- Cost effective
- Convenient patient access and positioning



Description

The ND 2100 provides essential information on total body bone mineral content as well as a clear, high resolution image of the area of interest for investigation of trabecular bone in the axial skeleton.

This system utilizes dual photon absorptiometry to measure net bone mass by differential absorption of two gamma ray photons from an isotope (^{153}Gd) having two different energies. The dual photon technique provides a precise, cost-effective means of obtaining bone mineral content for an assessment of osteoporotic patients.

The ND 2100 includes the scanner unit in which the radioactive source is located, patient table, sodium iodide detector, computer for operational control, data processing, storage and software.

ND
Nuclear Data Inc
ND Medical Products
Golf and Meacham Roads
Schaumburg, Illinois 60195
Telephone: 312/884-3630

C/N 77241

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Research Medical Center

(Licensee's Name)

July 31, 1984

(Date)

1. **Management Commitment**

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

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

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

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

2. **Radiation Safety Committee (RSC)[2]**

a. Review of Proposed Users and Uses

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

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

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

b. Delegation of Authority

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

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

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

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

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

c. Review of ALARA Program

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

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).[3]

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

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

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

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

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

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

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

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

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

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

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

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

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

(2) The authorized user will ensure that persons under his/her supervision who are

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

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

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

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

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

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

Table 0-1

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

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

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by §20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

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

   Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 0-1 values for the Investigational Level I.

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

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

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

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

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

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

   The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official[4]

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

Morton H Levitt MD

Signature

Morton H. Levitt, M.D.

Name (print or type)

Vice President, Clinical Services

Title

Institution (or Private Practice) Name and Address:

[4]The person who is authorized to make commitments for the dministration of the institution (e.g., hospital administrator) or, n the case of a private practice, the licensed physician.

C/N
77241