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

Research Medical Center
2316 East Meyer Boulevard
Kansas City, MO 64132

TELEPHONE NO.: AREA CODE ( )

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 4235

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

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

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

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.*)

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)	ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	5	IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP III			GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED	IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		
10 CFR 35.100, SCHEDULE A, GROUP VI	X	1500			

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	GdO_4 (Sealed Source)	2000	Bone Mineral Densitometer

Applicant Feb 9th
Check No. 295530
Amount Fee Category $120
Type of Fee Amend
Date Check Rec'd 2/7/85
Received By

RECEIVED JAN 28 1985 REGION III
JAN 28 1985
'85 FEB -7

NRC FORM 313M
(9-81)

8506060693 850517
REG3 LIC30
24-18625-01 PDR

CONTROL NO. 78208

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

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

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
	Names and Specialties Attached; and		Appendix G Rules Followed; or
	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE			Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and		Equivalent Procedures Attached
	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*			Appendix I Procedures Followed; or
	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS			Appendix J Form Attached; or
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	X	Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*		Appendix K Procedures Followed; or
	Equivalent Procedures Attached	X	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
	Description and Diagram Attached		Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
	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)	
	Detailed Information Attached		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	
			Detailed Information Attached
	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached	X	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		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: 7C

(2) LICENSE FEE ENCLOSED: $ 120.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

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

(2) TITLE: Vice President, Clinical Services

c. DATE: 1-24-85

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RADIOACTIVE MATERIALS NOT LISTED IN ITEM 6A

Gadolinium-153

Manufacturer:	Model:
Gulf Nuclear, Inc. 202 Medical Center Blvd. Webster, Texas (713) 332-3581	Gd-1

See attached lunar data specification sheet for intended use.

The sealed source listed above will be used in a spine/femur bone mineral analyzer.

Source	Device	NRC Device Registration Number
Gd-153	Lunar DP3	NR-430-D-101-S

We will also be using the lunar forearm scanner and have requested Group VI possession limits.

Source	Device	NRC Device Number
I-125	Lunar SF2	NR-430-D-102-S

Each lunar bone mineral analyzer is installed by a qualified expert who provides two days of installation and training. This training covers source installation, wipe testing, scan operations and data analysis and interpretation. The institution's radiation safety officer will be present for instruction on source replacement and wipe testing.

LUNAR RADIATION CORP.

916 Williamson Street
Madison, Wisconsin 53703
(608) 258-8545

At Lunar Radiation our entire business is dedicated to the support of our customers' studies on bone. Lunar offers an unmatched line of systems for all research and clinical applications. Supporting these systems is a highly recognized staff dedicated to the advancement of this field. It is these systems and their support that have made Lunar the leader in bone assessment techniques. *Let us help you choose the most effective system for your needs.*

DUAL-PHOTON ABSORPTIOMETRY (^{153}Gd)

DP3 Spine/Femur Scanner: The most sensitive tool for diagnosis and monitoring of bone disease. Features fast-scan for screening or slow-scan for precision measurements. Enables critical evaluation of trabecular bone in order to monitor therapy in serial studies. (Spine measurements have a 2-3% precision in an area that changes 15% annually rather than ± 1% annually as in the radius.)

DP4 Total Body Scanner: A rectilinear scanner for measuring the total skeleton as well as spine and femoral neck. Offers compiete skeletal coverage for clinical research.

SINGLE-PHOTON ABSORPTIOMETRY (^{125}I)

SP2 Forearm Scanner: A rectilinear scanner for high precision (1%) measurements on the limbs. For diagnosis and monitoring of all bone diseases, adult and infant studies, evaluation of the new ADFR treatment modality, and small animal studies. Capable of scanning irregular anatomical areas such as the distal radius and featuring a variety of scan speeds and step intervals.

BENEFITS OF LUNAR SYSTEMS

—Automatic Bone Location by Intelligent Scanner
—Automatic Edge and Baseline Detection
—Data Base of Normals
—Standards for System Calibration
—Sophisticated Correction Factors
—Extensive Application Support
—24-Hour Replacement Service Program

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

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 perso.nel in restricted and unrestricted areas according to ALARA.

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 results of the bioassay kept in a log book.

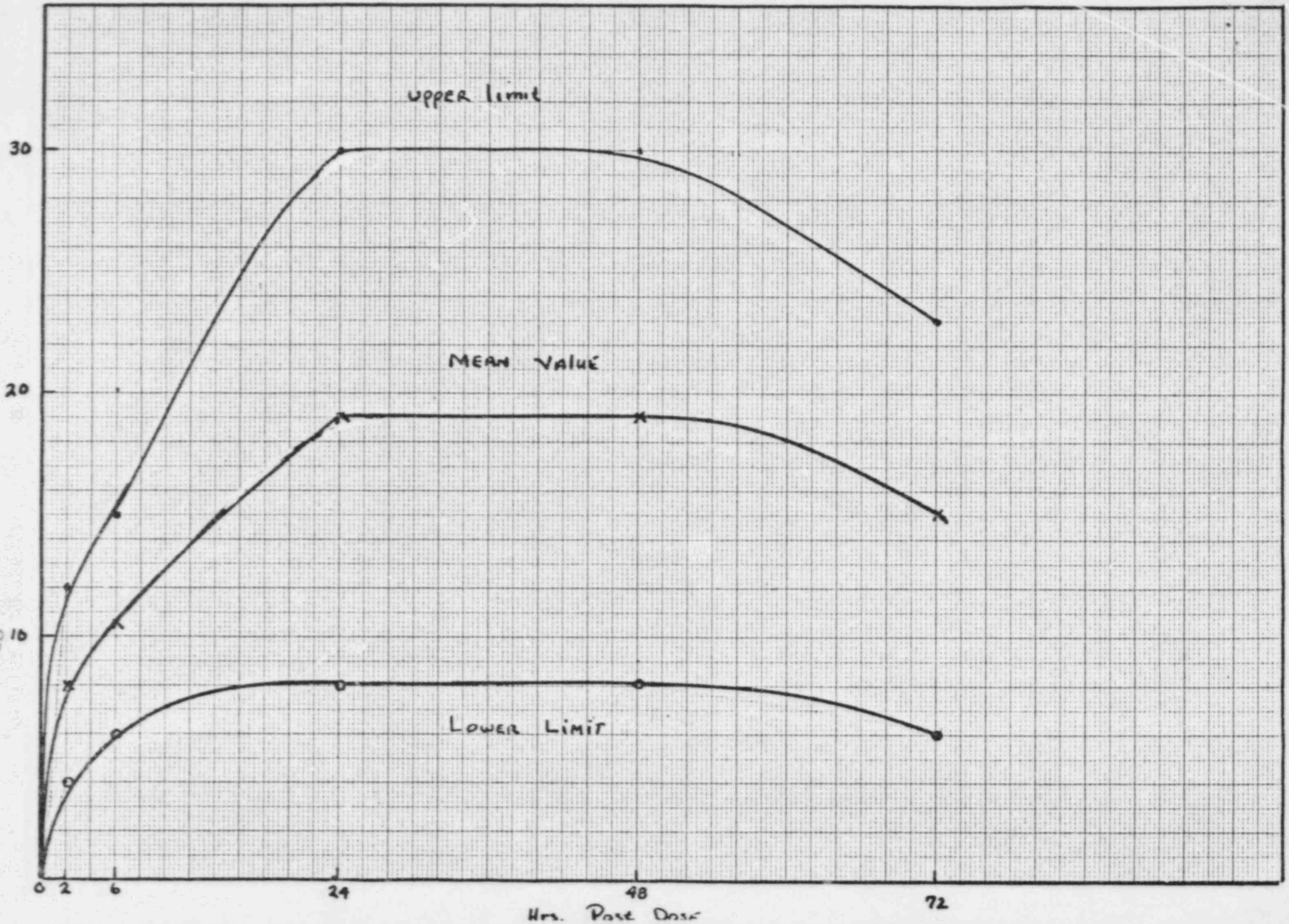
THERAPEUTIC USE OF I-131

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.

Normal Range of Thyroid uptake



Interpolative Value Using Mean Normal Thyroid Uptake