DEPARTMENT OF THE NAVY
NAVAL HOSPITAL
OAKLAND, CALIFORNIA 94627-5000

IN REPLY REFER TO
6470
755
28 MAR 1986

From: Commanding Officer, Naval Hospital, Oakland, California 94627-5000
To: United States Nuclear Regulatory Commission, License Management Branch, Division of Fuel Cycle and Material Safety, Washington, D.C. 20555
Via: (1) Commander, Naval Medical Command, Northwest Region, Oakland, California 94627-5025
(2) Commander, Naval Medical Command, MEDCOM-21, Washington, D.C. 20372-5120

Subj: REQUEST FOR AMENDMENT OF NAVAL HOSPITAL OAKLAND'S NRC LICENSE

Ref: (a) NRC License #04-00716-02
(b) CO, NHO ltr 710:LP:blb 6470 of 21 September 1984
(c) CO, NHO ltr 614:LP:lp 6470 of 16 September 1982

Encl: (1) Radioactive Material Requirements (LUNAR)
(2) Gadolinium-153 Source Information (LUNAR)
(3) LUNAR DP3-XT/AT Brochure
(4) LUNAR Assembly Diagrams

1. It is requested that the subject license be amended as follows:

a. Increase the limit of section 8.Q. of reference (a) to 150 millicuries for iodine-125. This increase is necessitated by the continuing increase in the number of tests to be performed by the Naval Drug Screening Laboratory (NDSL), Oakland that is located near this facility and is included under the provisions of reference (a). This increased limit is needed to ensure that the 100 millicurie limit requested in reference (b), our license renewal application, is not exceeded when NDSL goes to three shift operations (24 hours per day) from its present two shift program (16 hours per day).

b. The increased limit of section 8.Q. to 150 millicuries will allow for limited storage of LSA radioactive waste prior to shipment for disposal and some on site decay to background. Storage will be in one building, Building 85, located away from the main and high traffic areas. Building 85 was described in reference (c).

2. It is further requested that the subject license be amended as follows:

a. A license limit be approved for gadolinium-153 radionuclide sealed sources to be used in a commercially available bone mineral scanner. Enclosure (1) provides the activities of radioactive material required in the device and the recommended possession limits. In order to facilitate source exchanges, the enclosure (1) limits should be modified as follows:

Radionuclide	mCi per Source	mCi Possession Limit
Gd-153	1500	2000
I-125	300	500

for Acc number address
Cont'd to

The iodine-125 sealed sources required fall within our current Group VI limit, section 8.E. of reference (a). The limits indicated will allow new sources to be received, changed out and some delay in disposing of the old sources. Primary disposal of old sources will be exchanged with the new source's vendor. Enclosure (2) provides information on the gadolinium-153 sources presently available for use. Enclosure (3) describes the bone densitometry apparatus. Enclosure (4) contains representative assembly diagrams used in the system.

b. The following additional information relates to expected source characteristics:

(1) I-125 Source

(a) Manufacturer: Atomic Energy of Canada, Limited (AECL capsule C324)

(b) Dose to patient: under 10 millirem

(c) NRC registration number: NR-430-D-102-S

(d) FDA 510 K approval *K801281A)

(2) Gd-153 Source

(a) Manufacturer: Lunar Radiation Corporation

(b) Dose to patient: under 13 millirem

(c) NRC registration number: NR-430-D-191-S

(d) FDA 510 K approval *K802180A)

The system will be located on the ninth floor, Building 500, near the mobile gamma camera in the Nuclear Medicine room.

3. Questions concerning this license amendment application may be directed to the Naval Hospital, Oakland Radiation Safety Officer, LCDR M. P. Grissom, at (415) 633-5754.

J. P. SMYTH

Copy to:
RSO, NHO
Head, Radiology, NHO
Chairman, Radiation Safety Committee, NHO

Item 6a RADIOACTIVE MATERIAL FOR MEDICAL USE

The use of I-125 as a sealed source in a bone mineral analyzer is listed under 10 CFR 35.100, Schedule A, Group VI. Submitthe following information to apply for the use of I-125 in the LUNAR SP2 bone mineral analyzer:

Element and Mass Number	Chemical and/or Physical Form	Maximum Possession Limit	Describe Purpose of Use
125-Iodine	ion exchange	AECL model C234* 300 mCi each 400 mCi Total Possession	Bone mineral Analysis

* or any other equivalent NRC registered sealed source.

Item 6b RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6A

The use of Gd-153 as a sealed source in a bone mineral analyzer is covered under this section. Submit the following information to apply for the use of Gd-153 in the LUNAR DP3 bone mineral analyzer:

Element and Mass#	Chemical and/or Physical Form	Maximum# of millicuries of each form	Describe Purpose of use
153-Gadolinium	GdO_2 sealed	1. Gulf Nuclear-Model GD-1	Bone Mineral Analysis
		2. Amersham-Model GDC.CY1	
		3. New England Nuclear-Model NER-430*	
		4. LUNAR Model GD	
		5. * - 1500mCi per source - 1800mCi max possession limit	

* or any other equivalent NRC registered sealed source

LUNAR RADIATION CORPORATION

HDMORE

Gadolinium-153 Source Information:

Amersham
Direct Customer Service: (800) 323-8895

Order #: GDC 10410 in Lunar holder
NRC #: GDC.DY1

Price: $7500.00

NEN Medical Products
Marketing Department: Judy Walker
(617) 871-8472

NRC#: NEN-430

Price: $7800.00

Lunar Radiation Corporation
Contact: Donna Biddle
(6[illegible] 258-8545

NRC#: G[illegible]ies

Price: [illegible].00

Gulf Nuclear
Contact: Rusty

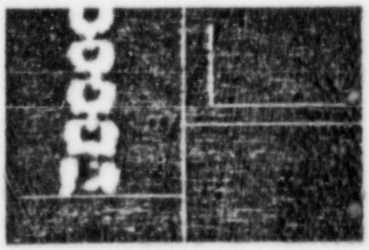
NRC#: GD-1

Price: $7200.00

Tidmore Company
6/15/85

Enclosure (2)

LUNAR DP3-XT/AT, The Unique Clinical Solution For Bone Densitometry



Over a decade of research and clinical testing has gone into the LUNAR DP3 dual-photon spine femur scanners. LUNAR scientists pioneered both single and dual-photon absorptiometry and helped LUNAR become the world's largest manufacturer of bone measurement instrumentation.

LUNAR now offers the IBM-XT and AT as options to our acclaimed DP3 scanner. Advanced features of the DP3-XT AT include:

-Multi-tasking
-Automated peaking
-High-resolution color graphics
-Hard-disk storage

LUNAR continues to set the standard for bone measurement. These new features, plus a light-localizer and a belly-band, add to the DP3's proven capability.

Contact us to see why the clinical leaders have turned to LUNAR with confidence.

Ask A User!

Our customers comprise over 85% of all clinical facilities using dual-photon absorptiometry. They selected the DP3 because LUNAR's exclusive know-how ensures trouble-free, question-free operation and because of distinct advantages such as:

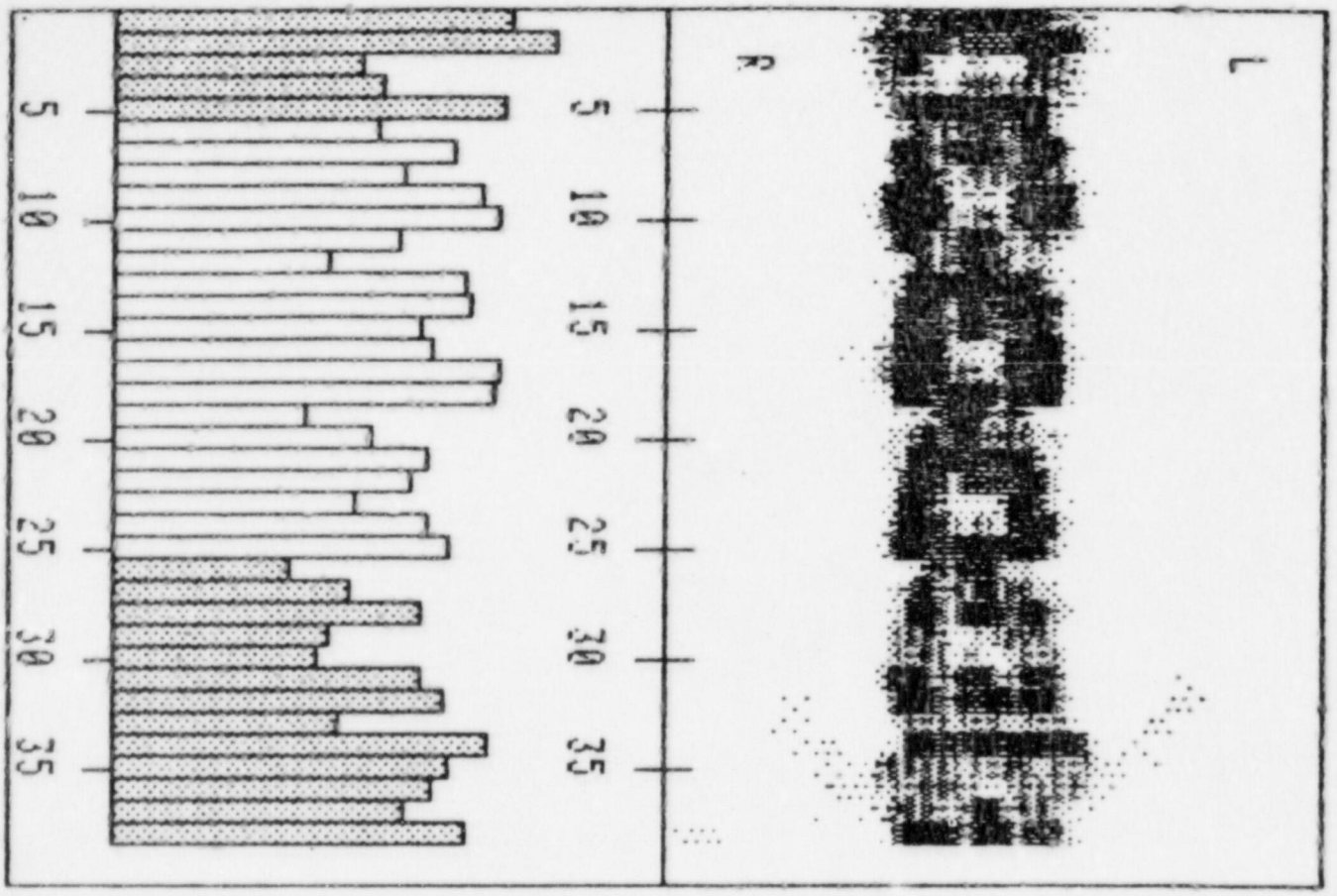
-**Intelligent scans** that reduce scan area, scan time, and patient exposure.
-**Multiple sites**—lumbar spine, proximal femur, tibia, proximal humerus and other areas
-**Graphics displays**—ultrafast, high-resolution images
-**Normal database** of US subjects
-**Accuracy precision** based on physically correct algorithms
-**High patient throughput** with 15-minute scans
-**Sophisticated software** that takes the guesswork out of scanning
-**Medical physics support** from our in-house staff
-**Software updates**—free-of-charge
-**Service**—1-year warranty with 24-hour response
-**Lower cost**—extended source life
-**Operational ease**—menu-driven automated software

LUNAR
RADIATION
CORPORATION

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

Enclosure (3)

ID#: MAZESS FILENAME: MAZESS DATE: 04/03/85



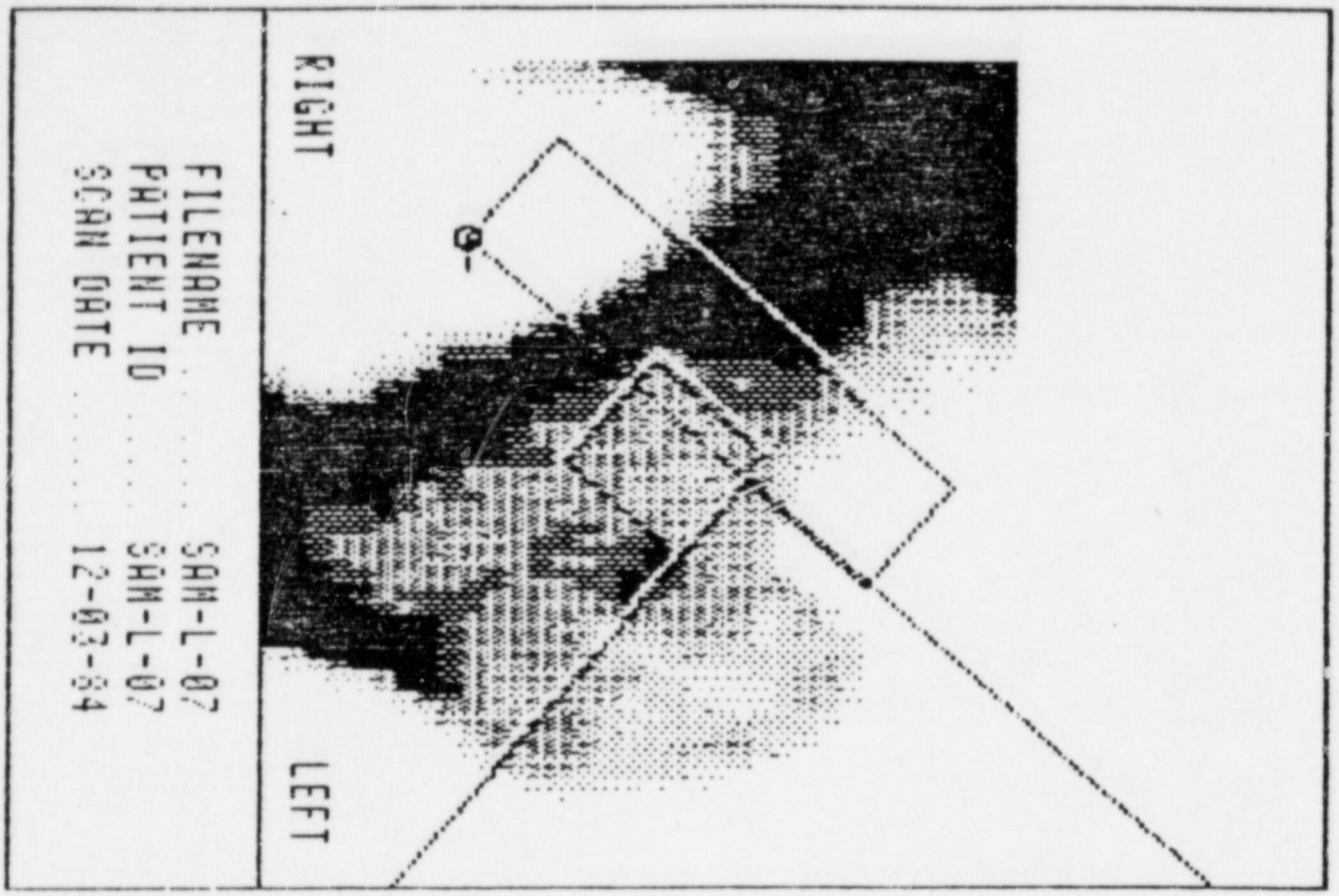
VERSION·07G CALIBRATED RESULTS LINES 6 TO 25 (L2·L4)

Large Standard	10.33	Calibrated BMC (grams)	49.2
Medium Standard	6.56	Calibrated Area (cm^2)	38.5
Small Standard	2.58	Average Width (mm)	40.8
Corrected R Value	1.39	Calibrated BMC/W (g/cm)	12.05
44 KeV Air Value	89199	Central Dens (g/cm^2)	1.214
100 KeV Air Value	64205	Trabecular Dens (mg/cm^3)	210.0
Scan Speed (mm/s)	2.5	Age Matched (% of exp)	110.5
Step Distance (mm)	4.5	Age Matched (z-score)	.9
Collimation (mm)	13		

CALIBRATED BMD	=	1.277 g/cm^2
YOUNG NORMAL	=	96.6% of expected
FRACTURE RISK	=	NORMAL

LUNAR RADIATION CORPORATION
The Leader in Bone Measurement
916 Williamson Street
Madison, Wisconsin 53703-3550
(608) 256-6744

ID# : SAM-L-07 FILENAME : SAM-L-07 DATE : 12-03-84



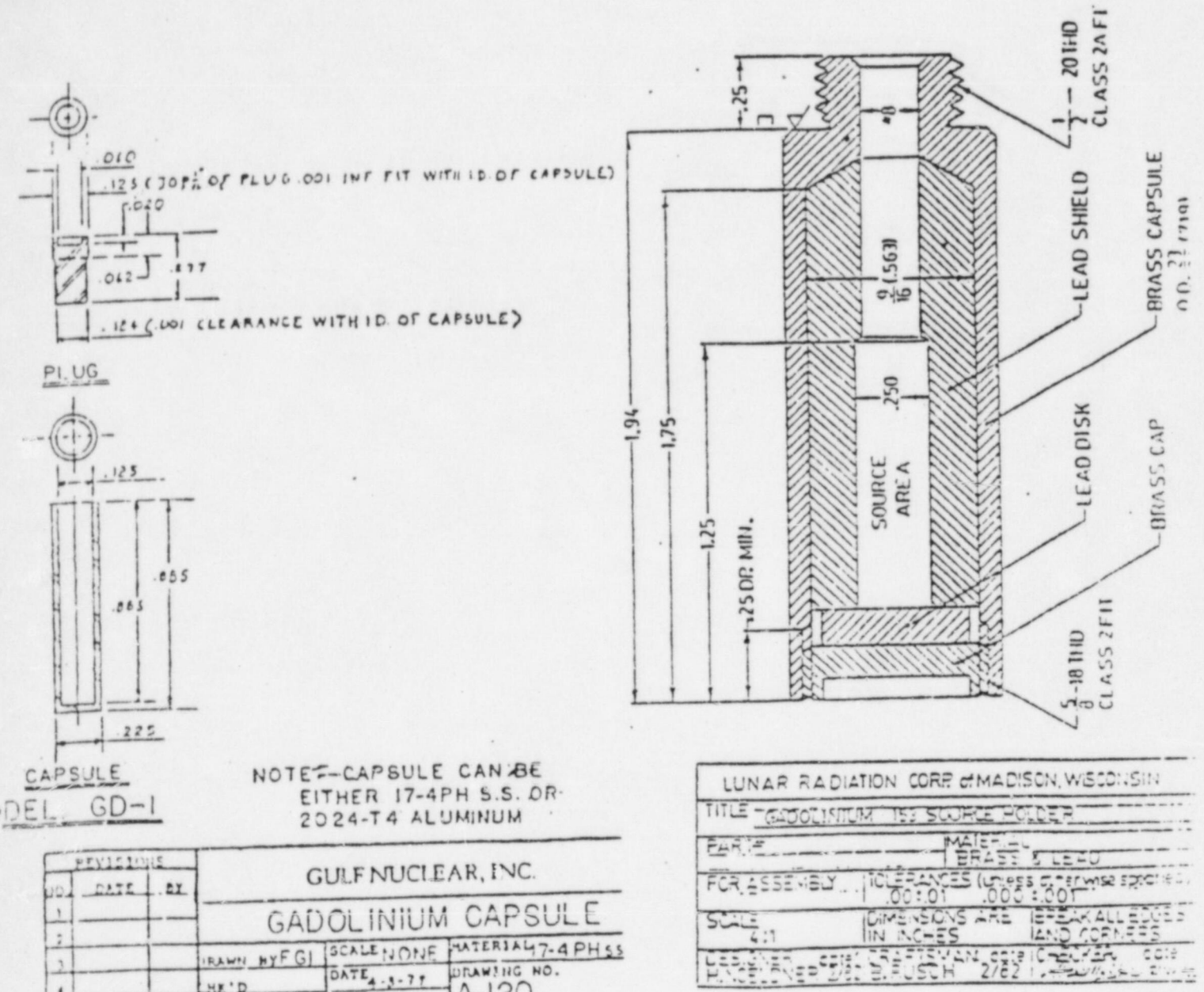
RIGHT FEMUR CALIBRATED RESULTS VERSION·01C

Large Standard	10.42	Scan Speed (mm/s)	2.5
Medium Standard	8.50	Step Distance (mm)	2.5
Small Standard	6.57	Collimation (mm)	13
Corrected R Value	1.42	Region Height (cm)	6.00
44 KeV Air Value	94494	Region Width (cm)	1.50
100 KeV Air Value	63259	Region Angle (deg)	49

Femoral Neck	: BMC (grams) = 5.54	AREA (cm^2) = 4.92
Ward's Triangle	: BMC (grams) = 2.23	AREA (cm^2) = 2.41
Trochanteric	: BMC (grams) = 5.92	AREA (cm^2) = 8.03

REGION	BMD g/cm^2	% YOUNG NORMAL	% AGE MATCHED
FEMORAL NECK	1.13	109.7	109.7
WARD'S TRIANGLE	.93	101.1	101.1
TROCHANTERIC	.74	90.7	90.7

FIGURE 1
Source Capsule and Holder for 153-Gd Capsule



REVISIONS			GULF NUCLEAR, INC.		
NO.	DATE	BY	GADOLINIUM CAPSULE		
1					
2					
3			DRAWN MYFGI	SCALE NONE	MATERIAL 17-4PH SS
4			CH'D	DATE 4-3-77	DRAWING NO. A-120
5			TRACED	APP'D	

LUNAR RADIATION CORP. MADISON, WISCONSIN		
TITLE - GADOLINIUM 153 SOURCE HOLDER		
PART #	MATERIAL BRASS & LEAD	
FOR ASSEMBLY	TOLERANCES (UNLESS OTHERWISE SPECIFIED) .00 ± .01	.000 ± .001
SCALE 4:1	DIMENSIONS ARE IN INCHES	BREAK ALL EDGES AND CORNERS
DESIGNED BY B. BUSCH 2/82	DRAWN BY	CHECKED BY

Enclosure (4)

FIGURE 2
Gd-153 Source Collimator/Holder Assembly
for DP3 Scanner

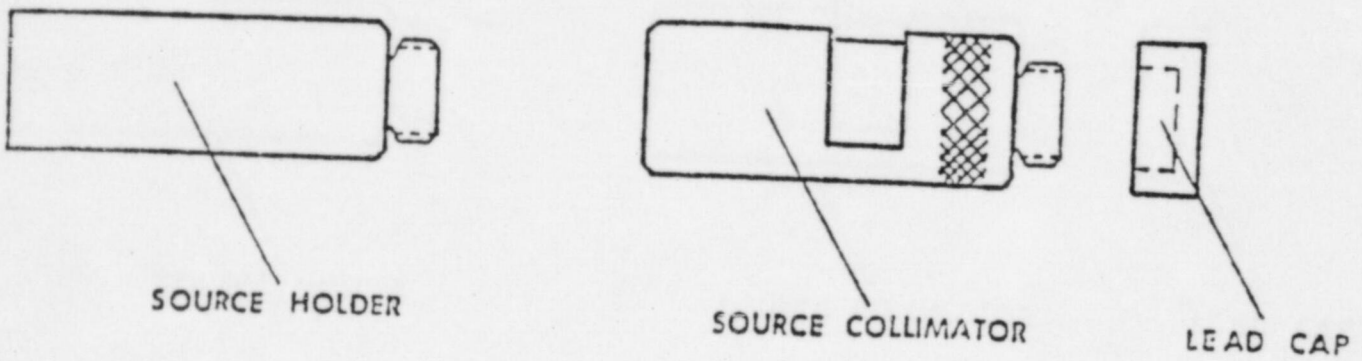
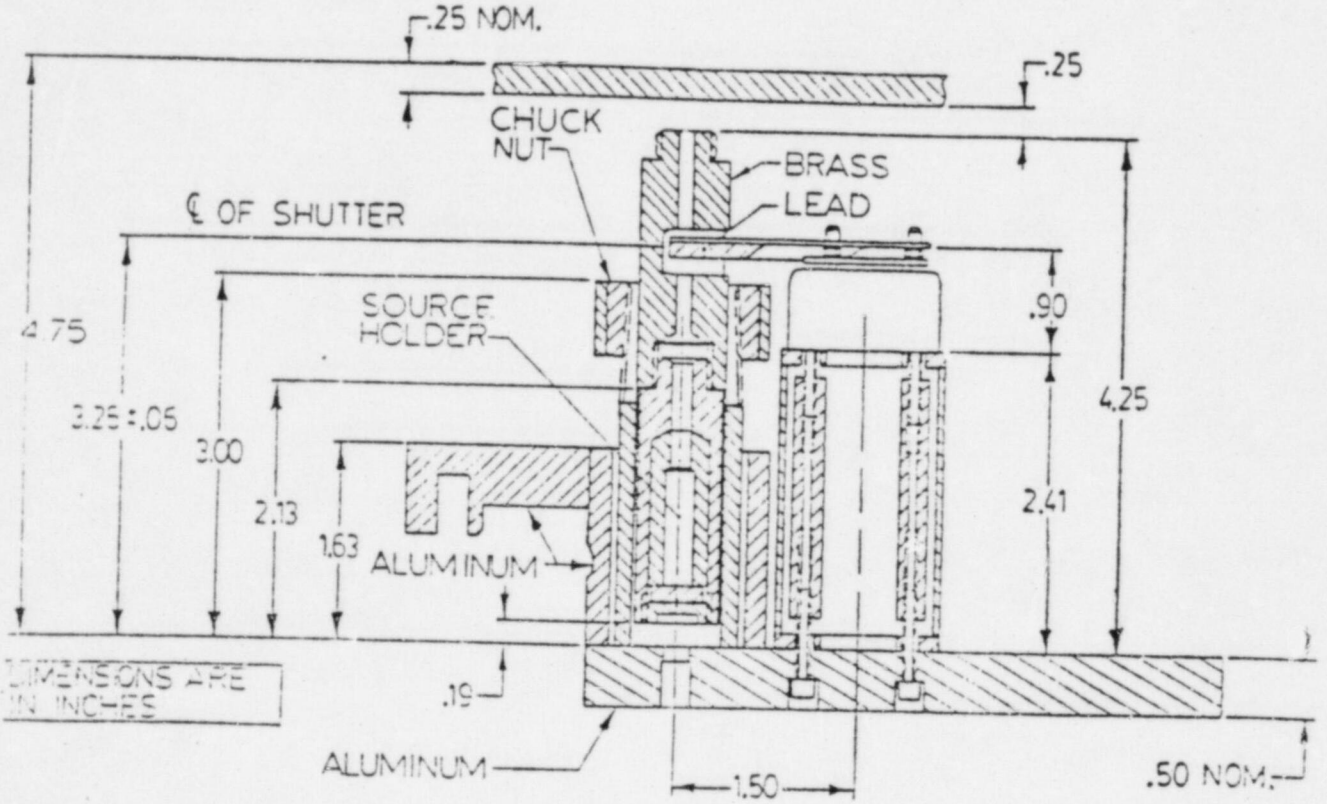


FIGURE 3
Side View of Transverse Carriage of DP3 Scanner



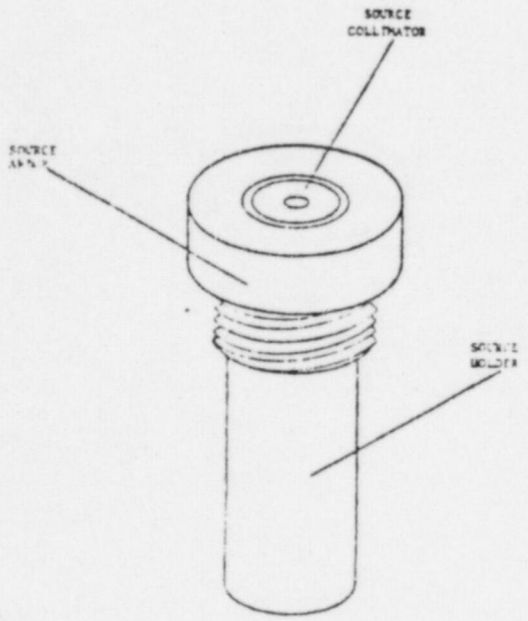


FIGURE 4
I-125 SOURCE HOLDER ASSEMBLY
FOR SP2 SCANNER

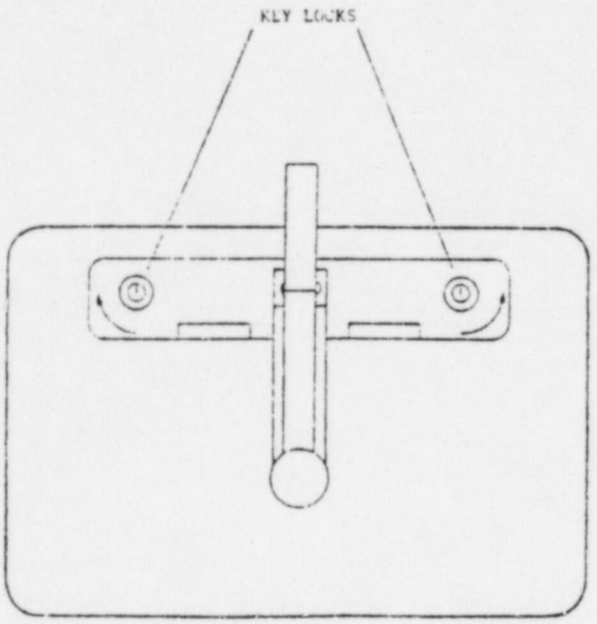


FIGURE 5
UNLOCKING SP2 TOP

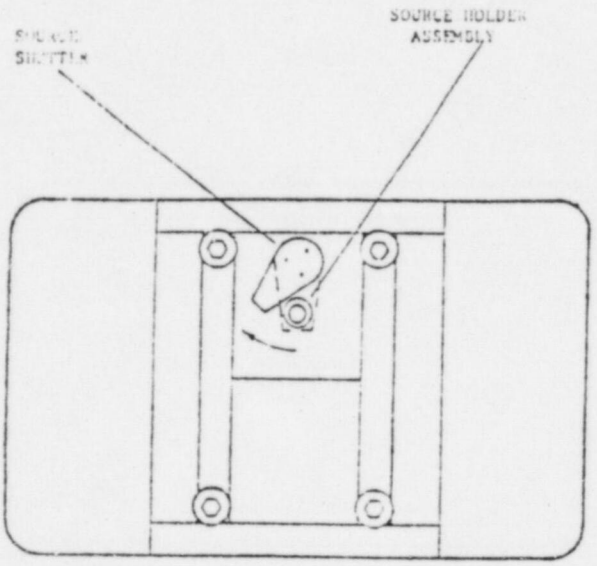


FIGURE 6
SOURCE LOCATION & REMOVAL
NOTE: "DASHED" lines refer to
shutter in "occluded" position.

DEPARTMENT OF THE NAVY
NAVAL MEDICAL COMMAND
WASHINGTON, D.C. 20372

IN REPLY REFER TO
6470/4
MEDCOM-2122
25 April 1984

From: Commander, Naval Medical Command
To: Radioisotope Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Material Safety and Safeguards, Nuclear Regulatory Commission, Washington, DC 20555

Subj: NUCLEAR REGULATORY COMMISSION BYPRODUCT MATERIAL LICENSES

1. The Navy drug screening laboratories are presently a part of the local naval hospitals. These laboratories use I^{-125} radioimmunoassay kits as authorized in the following NRC byproduct material licenses:

Naval Hospital Jacksonville	09-11026-01
Naval Hospital Portsmouth	45-01121-03
Naval Hospital Great Lakes	12-06092-01
Naval Hospital Oakland	04-00716-02
Naval Hospital San Diego	04-01369-02

'84 APR 30 P2:41

2. The drug screening laboratories will be organizationally removed from the naval hospitals and established as separate shore activities with an anticipated implementation date of 1 June 1984. The laboratories will remain at their present location and a Memorandum of Understanding (MOU) defining the responsibilities for the radiation safety program will be negotiated with the local naval hospital. The radiation safety officer of the local hospital will have the responsibility to monitor the laboratories compliance with the terms and conditions of the NRC license and with NRC regulations and will report to the commanding officer of the laboratory for radiation safety matters.

3. It is requested that the NRC licenses listed in paragraph 1 be amended to reflect the change in the status of the drug screening laboratories.

Hugh P. Scott

HUGH P. SCOTT
By direction

Copy to:
COMNAVMEDCOM SEREG Jacksonville FL
COMNAVMEDCOM MIDLANTREG Norfolk VA
COMNAVMEDCOM NEREG Great Lakes IL
COMNAVMEDCOM SWREG San Diego CA
COMNAVMEDCOM NWREG Oakland CA
CO, NAVHOSP Jacksonville FL
CO, NAVHOSP Portsmouth VA
CO, NAVHOSP Great Lakes IL
CO, NAVHOSP Oakland CA
CO, NAVHOSP San Diego CA

'84 APR 30 P4:49

17404

8409210335