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May 30, 1985

B. J. Holt, Ph.D.  
Materials Licensing Section  
U. S. Nuclear Regulatory Commission, Region III  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

RE: Amendment Request Additional Information: Control #78692

Dear Dr. Holt:

This is in response to your request dated May 8, 1985 for additional information needed in support of our amendment request dated March 15, 1985 for  $I^{125}$  and  $Gd^{153}$  bone scanning devices from Lunar Radiation Corporation.

1) The radiation safety and radioisotopes committee will only approve physicians who meet the requirement of NRC Appendix A to be an authorized user for these types of bone scanning devices, or receive 10 hours of radiation physics instruction from a radiation safety officer.

2)a) Names and titles of Medical Center individuals who will be responsible for source exchange:

Anthony Chung-Bin, Ph.D., Radiation Safety Officer  
Director, Medical Physics

Jerome E. Majewski, M.S., Physicist, Radiation Safety Officer  
Radiation Safety Office

b) Specific training on source exchange procedures will be provided during the 2 day on-site installation by a representative of LUNAR Radiation Corporation; installation of the source will not occur prior to such training.

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B. J. Holt, Ph.D. (continued)

c) During source exchange, whole body and extremity exposures will be determined using film badges and TLD finger monitors from R. S. Landauer. A study will be performed the first time utilizing separate additional film badges and rings to determine doses due to this procedure; an ionization type survey meter, G.M. survey meter, and digital dosimeters will also be used to monitor procedural doses.

c) Lunar Radiation Corporation's step by step procedures for source exchange are attached.

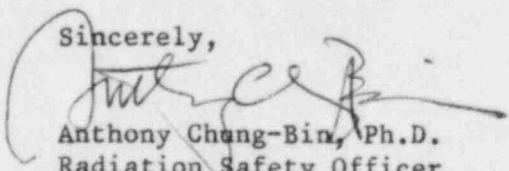
3) Sources not contained in scanners will be stored in a shielded container in labeled restricted Nuclear Medicine radioactive material storage room prior to return shipping or source exchange. Sources within scanners will be situated within restricted scan area labeled with appropriate caution signs, and kept locked when unattended or after hours, as all other areas which utilize or store radioactive materials in the Nuclear Medicine Department.

4) Used decayed sources will be returned to the manufacturer of the source for disposal; if this is not possible, they will be properly packaged and picked up by our commercial waste service, ADCO Inc., as described in the broad license application.

5) The scanners will be serviced only by the manufacturer if maintenance is required.

If you have any further questions concerning this request, please do not hesitate to call 942-5763 for Jerome Majewski or myself (942-5751).

Sincerely,

  
Anthony Chung-Bin, Ph.D.  
Radiation Safety Officer  
Director, Section of Medical Physics

JEM:bk

enclosure

## C.2 INSTALLING AND REMOVING THE SOURCE

**CAUTION:** Only personnel trained in the principles of radiation safety and protection should conduct these procedures. The technician should study the following procedures before an actual source transfer is attempted. A press-on label with the warning "CAUTION - RADIOACTIVE MATERIALS" should be displayed in a location where it can be seen by the operator, patients and/or visitors to that area where measurements are done.

**WARNING:** All steps should be conducted without tools. Use of pliers, clamps, etc. may cause irreparable damage to parts.

### C.2.a Removing the Source

1. Remove the pad if it is on the table. Using the key provided with the system, unlock the lucite insert and remove it from the table.
2. Select OPTION 5 (STATIC COUNTER) of the "DP3 SYSTEM" diskette menu to position the arm and source at the center of the window.
3. Place a lead source holder cap onto the source collimator (Fig. 10 and 11).
4. Select the "SHUTTER OPEN" command of OPTION 5. Alternatively, the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.
5. Turn the chuck ring (Fig. 12) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.
6. Slide the source collimator (which will have the source holder attached to the end of it) out of the chuck. The source collimator and holder can now be handled as a unit.
7. Holding the source collimator and source holder upright (as they are positioned in the scanner), unscrew the source holder from the collimator. Immediately put a lead cap on the source holder and tape it in place.

**CAUTION:** RADIATION PRESENT! After the collimator is removed and before the lead cap is positioned a broad beam of high intensity radiation projects from the top of the source holder. Exercise due caution.

This completes the source removal procedure.

### C.2.b Installing a Source

1. Unlock and remove the lucite insert on the scan table.
2. Load and run the "DP3 SYSTEM" diskette. Use the "shutter open" command ("O") of OPTION 5 (STATIC COUNTER). Alternatively the shutter can be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the shutter is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this (open) position.
3. Remove the lead cap from the source holder and place it on the brass collimator provided with the scanner. Thread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-thread. The source collimator and holder can now be handled as a single unit (Fig. 10).
4. Slide the source collimator/holder assembly into the source chuck (Fig. 12) so the lower pin on the collimator fits into the notch on the source chuck. The collimator shoulder should rest on the top of the chuck (not the chuck ring).
5. Use the "shutter close" command ("C") of OPTION 5 or remove the tape if the shutter is held opened manually.
6. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.
7. Verify that the shutter can swing into the notch on the collimator (Fig. 12) and fully occludes the source beam. Open and close the shutter using the "O" and "C" commands in OPTION 5 (STATIC COUNTER). If actuation is not smooth, adjust the collimator position. If actuation still is not smooth, notify LUNAR. Close the shutter.
8. Remove the source holder (lead) cap from the top of the collimator.
9. Replace and lock the lucite window. NOTE: The "HOME" position should be nearest the scan arm side of the table.
10. Monitor radiation levels around the table to insure operator safety.
11. Return to the computer's main menu and select OPTION 3 - "SCAN STANDARD AND Q/A". All measurements should yield a passing status.

This completes the source installation procedures.

### C.2.c When to Replace a Gadolinium Source

LUNAR maintains that a source should be replaced when its activity is below 30,000 counts in the 44 KeV channel. This activity is listed on the QA/QC printout along with an indication of the remaining useful life of the source.

Remember that the 44 KeV counts are based on system geometry (detector height and collimation) and values used should be indicative of most commonly used geometry.

This formula is automatically incorporated into the SCAN STANDARD AND Q/A option so that the operator will always know when the source is approaching the end of its useful life.

NOTE: This does not include lead-time required to order a source!



FIGURE 10  
Source Collimator/Holder Assembly

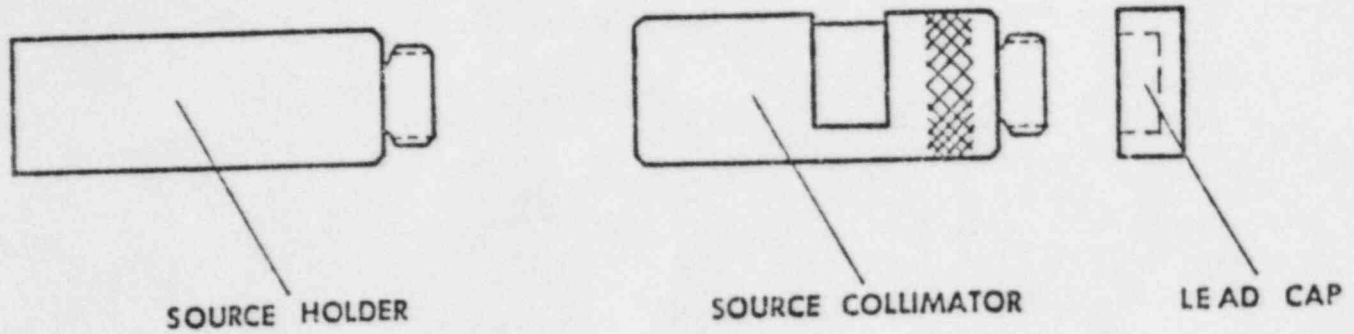
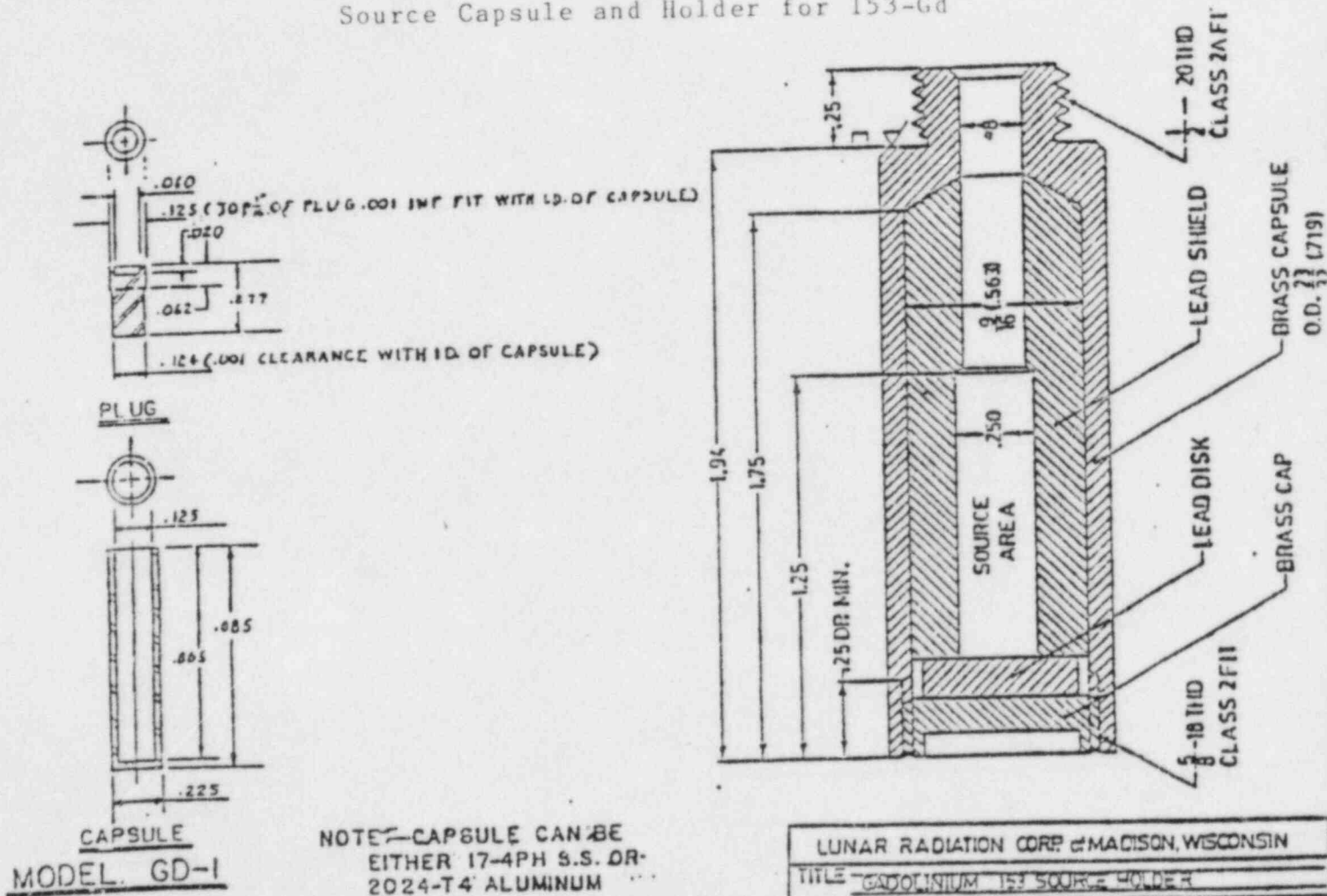


FIGURE 11  
Source Capsule and Holder for 153-Gd



LUNAR RADIATION CORP. OF MADISON, WISCONSIN	
TITLE GADOLINIUM 153 SOURCE HOLDER	
PART	MATERIAL
FOR ASSEMBLY	BRASS & LEAD
TOLERANCES (UNLESS OTHERWISE SPECIFIED)	
.00±.01	.000±.001
SCALING	DIMENSIONS ARE BREAK ALL EDGES
4:1	IN INCHES AND CORNERS
DESIGNED BY: RUSCH 2/62	

REVISIONS			GULF NUCLEAR, INC.		
ID	DATE	BY	GADOLINIUM CAPSULE		
1			DRAWN BY FGI	SCALE NONE	MATERIAL 17-4PH S.S.
2			CHK'D	DATE 4-9-77	DRAWING NO.
3			FRACED	APP'D	A-120

FIGURE 12  
Side View of Transverse Carriage Assembly

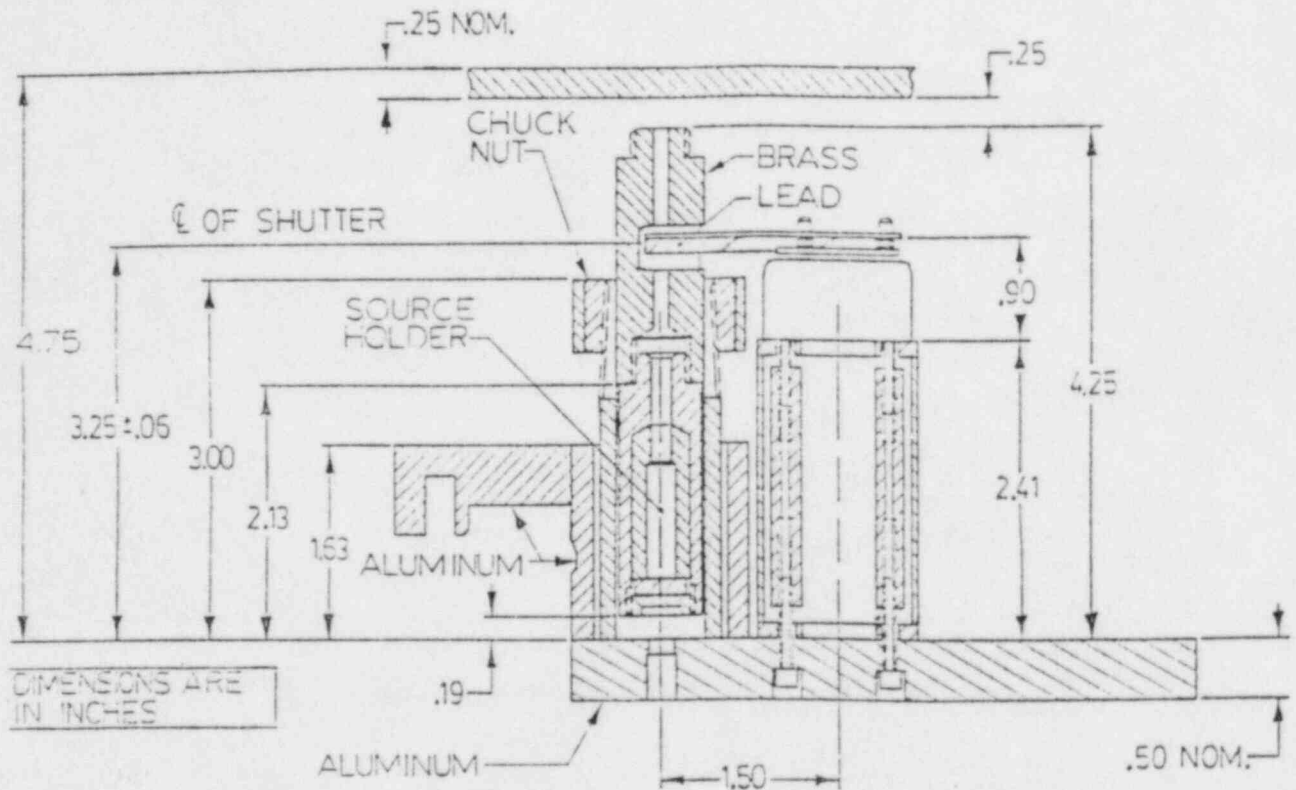


FIGURE 13  
Source Collimator Details

