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HOSPITAL · MILWAUKEE

5000 West Chambers Street · Milwaukee, WI 53210 · 414 447-2000

April 3, 1985

U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Attention: B. J. Holt
Materials Licensing Section

Reference: Control No. 78213

Gentlemen:

We are responding to your letter of March 28, 1985.

1. SOURCE EXCHANGE:

a. Person(s) resonsible: Richard L. Olson, Certified Nuclear Medicine Technologist (1972), Supervisor Nuclear Medicine Department; John B. Whitton, Radiation Safety Officer, D.A.B.R. (Therapeutic Radiological Physics, 1976).

b. Both persons will receive specific training from the supplier (Lunar Radiation Corp.) in order to carry out the source exchange following the step-by-step procedures attached to this letter. This training will be provided by the supplier during the installation period as noted in paragraph D of our letter of January 10, 1985.

c. Both persons routinely wear whole body monitors (film badges) and during source handling procedures wear extremity monitors (TLD ring badges) as supplied by Siemens Gammasonics, Inc. Both monitors will be worn during the source exchange.

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1.c. Continued

In addition the person handling the source will wear a pocket dosimeter such as a Victoreen, Model 885-1 with digital readout (mR increments). This dosimeter indicates the radiation intensity by the "chirp rate" as well as the total exposure. Radiation survey instruments will also be available.

d. Step-by-step procedures for installing and removing the source are attached. These procedures are copies from Lunar Radiation Corp., DP3 Technical Manual.

2. SECURITY:

a. The device containing the source will be operated (and stored when not in use) in Room #W177 which is part of the Nuclear Medicine Department. There are two (2) doors to this room, both of which will be posted with signs "CAUTION, RADIATION AREA, RADIOACTIVE MATERIALS, AUTHORIZED PERSONNEL ONLY" and the conventional radiation warning symbol.

At night, during weekends and holidays when department is not normally in operation, both doors will be locked. The key will only be available to authorized personnel.

Access to the source when contained in the scanner is through a locked panel in the table top. The key to remove this panel will be controlled by the Supervisor of the Nuclear Medicine Department.

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b. The source when not installed in the device:

The present policy in the Nuclear Medicine Department is to store radioactive sources in the "Fume Hood". The door to this Fume Hood is secured with a key operated padlock whenever authorized personnel are not controlling this area. A "CAUTION, RADIOACTIVE MATERIALS" sign is posted. It is planned to use this same location for the Gadolinium source whenever it is not installed in the device. This would include any time the source is removed for maintenance and repair of the device, the newly arrived replacement source and the depleted source awaiting return to the source manufacturer.

The source will be kept behind lead bricks to prevent any significant exposure. Note: The manufacturer states that the expected exposure level from a new source (1 Ci) in its holder to be approximately 50 mR per hour at the surface.

3. REPAIR AND MAINTENANCE

During the one (1) year warranty period all repair and maintenance will be provided by the manufacturer, Lunar Radiation Corporation. After the warranty period, it is expected that most of the service will be provided by our Clinical Engineering Department. The personnel in this department have had a lot of experience working with other radiation producing devices in our Diagnostic and Therapeutic Radiology Department. It is our hospital's standard practice that each supplier of equipment must provide the necessary service manuals and training to clinical engineering personnel. The devices' source-shutter is specified as being "FAIL-SAFE", (see attached P. 16, Section C.2, C.3 of the DP-3 technical manual).

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In the unlikely event the shutter fails to close, the computer screen and hard copy print-out denote FAILURE. The red indicator light should also be ON. The shutter will be closed manually following the necessary safety precautions. The manual shutter closing procedures will be posted near the devices. The source will be removed from the device before repair of this shutter closing mechanism is undertaken and not returned until completed.

We hope that all questions have been fully answered and you will expedite this amendment request.

Sincerely,

John B Whitton

John B. Whitton
Radiation Safety Officer

JBW/lb

FROM: Lunar Radiation Corp.
DP-3 Technical Manual

Pages 13,14,16
Figures 1,2,3,6
Appendix B

C. Routine Health Physics Services

C.1 Source Changes

WARNING: Only individuals trained in the principles of radiation safety and protection and the device specific radiation requirements of LUNAR scanners should conduct these procedures.

C.1.a Gd-153 Source Changes

The source is encapsulated in a metal cylinder, approximately 1 inch in length and 1/8 inch diameter. This metal capsule is inside a lead-lined brass source holder (Fig. 1). For all phases of operation, the capsule need not be removed for the source holder. During a source exhcange the entire source holder is returned. Operator exposure is minimized by never removing the capsule from the holder.

All the following steps should be performed without tools. Use of tools may cause damage to the equipment.

Procedure

1. Remove pad and the lucite insert from the table.
2. Use OPTION 5 (Static Counter, ref. User Manual) of the DP3 Spine software to position the arm and source at the center of the window.
3. Place a lead source holder cap onto the source collimator (Fig. 2)
4. Use the "shutter open" command of OPTION 5 to access the source holder/collimator assembly. Alternatively, the shutter may be manually opened. Be careful to keep hands and other body parts clear of the actual radiation beam. If the source is opened manually, do not force the shutter blade to swing more than 35 degrees; then tape the shutter in this open position during the exchanged.
5. Turn the chuck ring (Fig. 3) counterclockwise until the collimator is loose in the chuck. Do not completely loosen the chuck ring.
6. Pull the source collimator (which will have the source holder attached) out of the chuck. The source holder and collimator can now be handled as an unit.

7. Holding the source holder/collimator upright, as positioned in the scanner, unscrew the source holder from the source collimator. Put the lead cap on the source holder.

CAUTION: RADIATION PRESENT! After the collimator is removed a broad beam of radiation projects from the top of the source holder.

8. Exchange the spent source for the new source. Place the lead cap from the source holder onto the collimator. Tread the source holder onto the base of the collimator. Do not force the collimator onto the source holder or it may cross-tread. The source holder/collimator can now be handled as an unit.

9. Slide the source holder/collimator into the source chuck (Fig. 3) so that the pin on the bottem fits into the notch on the source chuck. The collimator should rest on the top of the chuck, not the chuck ring.

10. Close the shutter by using "shutter close" command of OPTION 5 or remove any tape used to hold open the shutter.

11. Verify that the shutter blade moves freely in and out of the source collimator. If necessary, adjust the location of the collimator to allow free motion.

12. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.

13. Remove the lead cap from the top of the collimator.

CAUTION: A narrow beam of radiation is now projected upward from the collimator aperture.

14. Replace the lucite insert and patient pad.

15. Monitor radiation levels around the table to insure operator safety.

16. Perform Standard Scan and QA procedure to verify proper operation.

C.1.b I-125 or Am-241 Source Changes

The I-125 source is encapsulated in a metal cylinder, 10 mm in length and 3 mm diameter. This metal capsule fits inside the brass source holder, SRC-0100-1 (Fig. 4). For all phases of operation, the capsule need not be removed for the source holder.

CAUTION: A narrow beam of radiation is now projected upward from the collimator aperture.

9. Replace the scanner top and lock into position. Plug in the power cord and turn on the system.

10. Monitor radiation levels around the table to insure operator safety.

11. Perform Standard Scan and QA procedure to verify proper operation.

If Atomic Energy of Canada Limited (AECL) sources C235 are used in AECL holder C236, then an additional source collimator is used in the arbor. This can be inserted in the arbor prior to insertion of the source holder. Use of this additional collimator reduces the beam size at the table thereby lowering radiation exposure and scattered radiation. The SRC-0100-1 source holder does not require the extra collimator since the source itself provides sufficient collimation.

C.2 Source Indicator Light

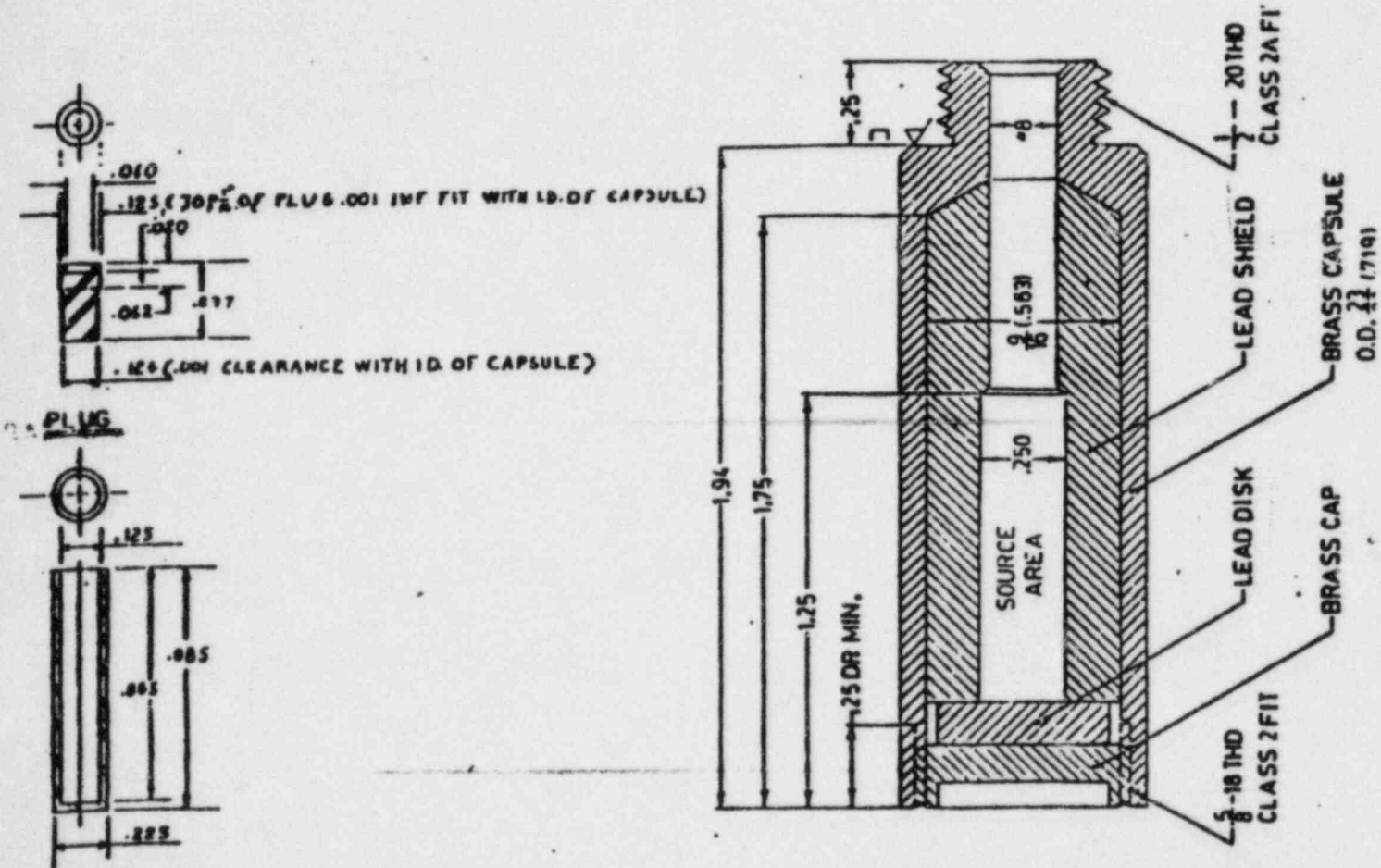
All LUNAR scanner are equipped with a red illuminated light that indicates when the shutter mechanism opens and effectively open the source. When the source is on the computer always indicates this to the operator by a continous message on the screen. The operation of the source light is checked daily by the operator during the STANDARD SCAN and QA.

C.3 Source Shutter Mechanism

The radioactive sources in all LUNAR scanner are effectively turned on/off by means of a rotary solenoid that moves a lead block in/out of the radiation beam. The operation of this shutter is verified daily by the computer during the STANDARD SCAN and QA.

The normal position of the solenoid is closed so that in the event of power failure the source will be shut off.

FIGURE 1
Source Capsule and Holder for 153-Gd Capsule



NOTE—CAPSULE CAN BE EITHER 17-4PH S.S. OR 2024-T4 ALUMINUM

REVISIONS			GULF NUCLEAR, INC.		
NO.	DATE	BY	GADOLINIUM CAPSULE		
1			DRAWN BY FGI	SCALE NONE	MATERIAL 17-4PH SS
2			CHK'D	DATE 4-8-77	DRAWING NO. A-120
3			TRACED	APP'D	
4					
5					

LUNAR RADIATION CORP. of MADISON, WISCONSIN

TITLE GADOLINIUM 153 SOURCE HOLDER

PART | MATERIAL BRASS & LEAD

FOR ASSEMBLY | TOLERANCES (UNLESS OTHERWISE SPECIFIED) .00 ±.01 .000 ±.001

SCALE 2:1 | DIMENSIONS ARE IN INCHES | BREAK ALL EDGES AND CORNERS

DESIGNED BY [illegible] DATE | CHECKED BY [illegible] DATE

HARDNESS [illegible] RUSCH 2/82

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

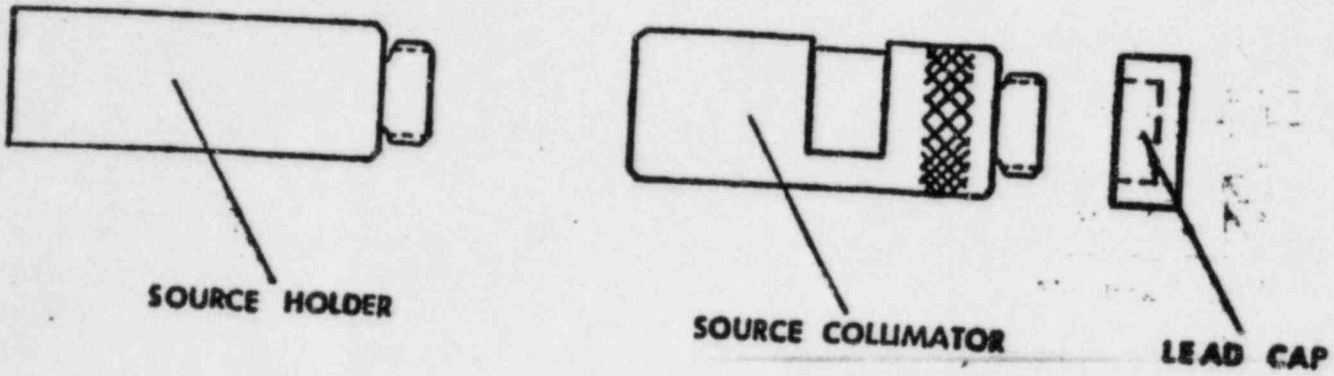
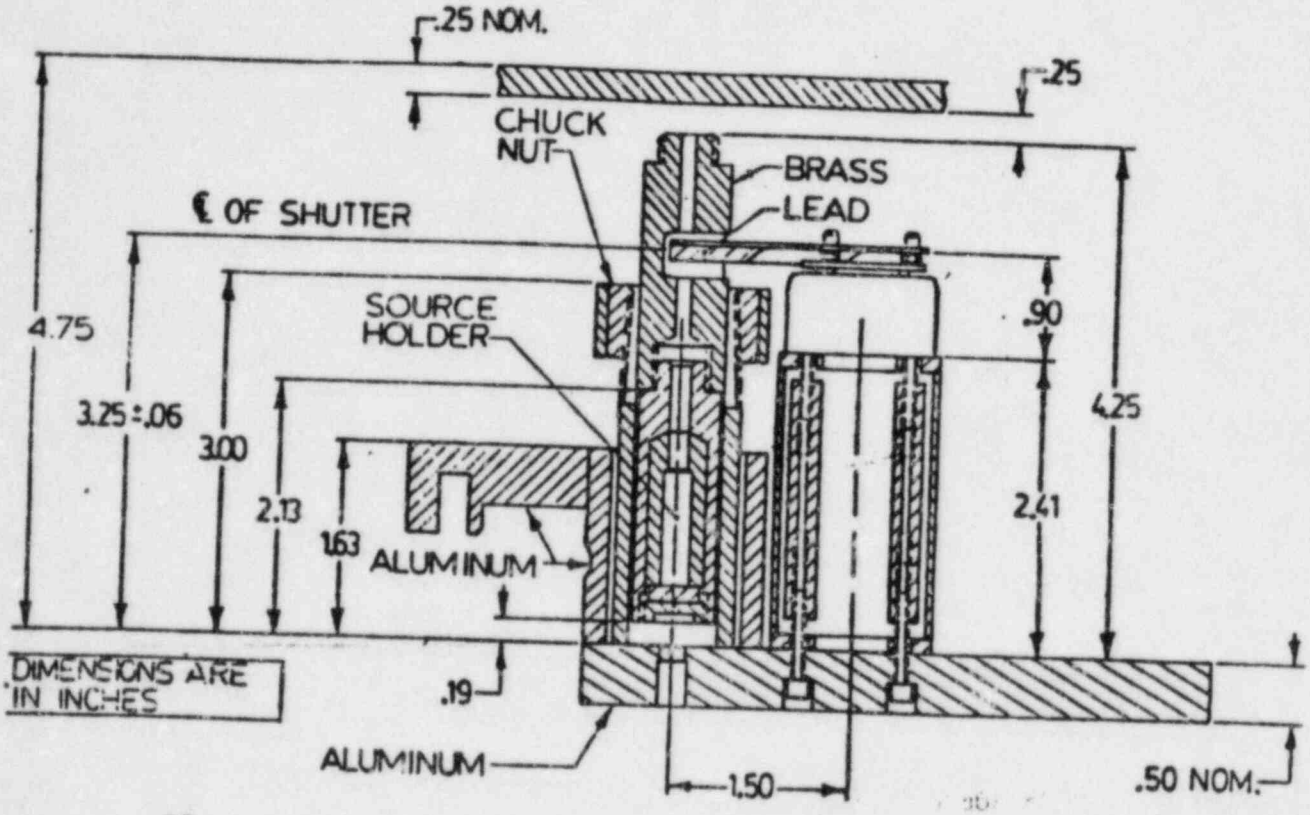


FIGURE 3
Side View of Transverse Carriage of DP3 Scanner



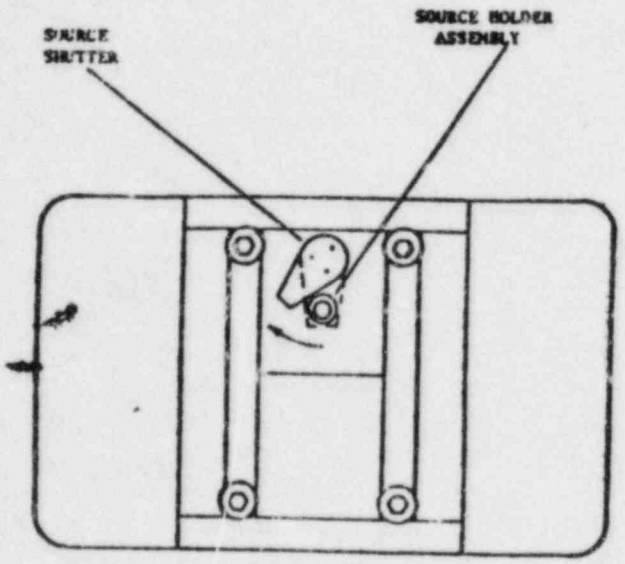


FIGURE 6
SOURCE LOCATION & REMOVAL
NOTE: "DASHED" lines refer to
shutter in "occluded" position.

APPENDIX B
DOSIMETRY

The dosimetry for the DP3 has been done using (a) thermoluminescence dosimetry, (b) a calibrated Eberline GM detector and (c) theoretical gamma-ray factors. All results are expressed for a 1 Ci source of 153-Gd (the largest activity used with DP3 system). The typical patient radiation dose to the skin from a scan procedure on the lumbar is under 30mrem while the dose to personnel is under .0001mrem/hr while operating the equipment.

The highly collimated source (a 4mm encapsulated bead) is located 9 cm below the table-top in a brass holder (1.75cm diameter). This holder provides 4mm lead shielding. The holder is further shielded by a mounting base in which it is located. The beam diameter is approximately 4.5mm at the table-top. The source is normally occluded by a 5mm thick lead shutter except when the shutter is electronically opened during scanning. An indicator light on the scanner drive mechanism assembly shows the shutter is open; shutter status is also indicated on the screen of the video display terminal. The chance of accidental exposure thereby is minimized. The procedures established for changing of sources minimize risks to radiation personnel who perform the task.

The radiation dose in the beam at the table-top was 4mrem/sec in the open beam. This was measured by TLD and using the GM detector. Any one patient area would be exposed for about 3 seconds during a scan so that the total dose to that area would be about 12mrem. The computer procedures controlling the patient scan minimize the scan length (and exposure); non-overlapping steps (each 4.5mm) are used. The radiation detector is a 6mm thick scintillation crystal coupled to a photomultiplier tube; detection efficiency is close to 100% at energies below 100keV.

The radiation dose at the table-top adjacent to the beam (shutter closed) was 1 to 2.5mrem/hour. The dose at one meter from the source (in the scanner drive as normally used but without the lead shielding of the source holder) ranged from 0.04 to 0.3mrem/hr depending on position (mean of 7 determinations - 0.2mrem/hr). With the lead shielded source holder the calculated dose is under .0001mrem/hr. During a 5-minute set-up the patient might be exposed to about 0.2mrem from the occluded source while during a 30-minute scan the scatter exposure of the patient could amount to 15mrem. The total patient exposure during one procedure is estimated to be under 15mrem for a 1ci source, and about 10mrem typically (over the source life-time).