



st. MARGARET's hospital

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Spring Valley, Illinois 61362

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Sisters of Mary
of the Presentation

John H. Schaper
Chief Operations Officer

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Chief Executive Officer

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Chief Financial Officer

September 25, 1985

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Rd.
Glen Ellyn, IL. 60137

Applicant Def 11 III
Check No. 36899
Amount/Fee Category 8120 (7C)
Type of Fee AMD
Date Check Rec'd 10/10/85
M/CG

U.S. NRC
LIC. FEE MGMT. BRANCH

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RECEIVED

Re: Amendment to Materials license no. 12-15562-01

Gentlemen:

This is in request of amendment to the above-referenced materials license to add authorization for I-125 single photon (forearm) and Gd-153 dual photon (spine) bone absorptiometry devices.

Please add a possession limit of 500 millicuries for the I-125 sources, each source not to exceed 250 millicuries. We request this higher possession limit to provide coverage for times when sources are being exchanged, and to provide coverage for the variability in source activity at time of receipt.

These sources are to be used in a single photon forearm bone mineral analyzer from Lunar Radiation Corporation, Norland, Nuclear Data, Nova Diagnostic Systems, or any other NRC approved supplier. The sources will be received only from an NRC approved supplier such as New England Nuclear, AECL or Amersham.

Please add a possession limit of 2.0 Curies for Gadolinium-153 sealed sources (GD Series), each source not to exceed 1.3 Curies. We request this possession limit to provide for times when sources are being exchanged and to provide for variability when sources are received from the supplier. The Gd-153 sources will be obtained from an NRC approved supplier such as Gulf Nuclear, Amersham, or New England Nuclear. They will be used in a dual photon spine scanner from Lunar Radiation Corporation, Novo Diagnostics Systems, Norland, Nuclear Data or any other NRC approved system.

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REGION III

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REG3 LIC30
12-15562-01 PDR

CONTROL NO. 79906

DEDICATED SERVICE SINCE 1903



Attached is a sketch describing the room which is planned for use of the instruments containing the radioactive materials. The entrance door will be locked whenever authorized personnel are not present. When not in use, the instruments will be locked to prevent use and access to the sources. Keys to the instruments and to the room will only be available to authorized personnel.

Source Holder Exchanges:

Manufacturer's instructions for source holder installation and exchanges will be followed, (see enclosed). These are contained in the device registration documents DP3 NR-430-D-101-S and SP2 NR-430-D-102-S. At no time, other than source exchanges, will sources be removed from the shielded holders.

Source holder exchanges will only be performed by individuals who have received device-specific training concerning the radiation safety precautions needed. One such organization which has had device-specific training for the Lunar devices is Standard Nuclear Consultants, Ltd. (NRC License no. 12-20362-01), whose credentials are on file with your agency. After receiving device-specific training, Mildred Monroe, M.D. (Radiation Safety Officer) and Ken Miller of the Radiology Department will be responsible for source exchanges.

The devices will be serviced only by the manufacturer or other NRC/Agreement State authorized organizations.

Disposal of unused sealed sources will follow one or more of the following methods:

- a. Return to supplier.
- b. Transfer to an NRC licensed commercial waste disposal service.
- c. Transfer to other authorized recipient.

Leak Testing:

Leak tests on the I-125 sources will be performed semi-annually and on the Gd-153 sources annually according to the frequencies specified in the above device registration documents. The leak tests will be performed with the standard Nuclear Consultants, Ltd. Leak Test Kit-1 as described in that firm's license no. 12-20362-01. We also request authorization to use any other leak test kit from other individuals or companies which are authorized by the NRC to perform these services.

We will follow the radioactive material receipt procedures described in our current application

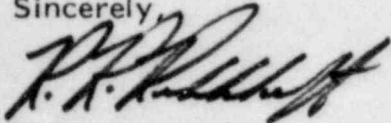
All other aspects of our radiation safety program remain unchanged.

Our \$120 hospital check , payable to the "U.S. Nuclear Regulatory Commission" is enclosed to cover the amendment application processing fees.

Should additional information be needed to complete this amendment request, please contact Standard Nuclear Consultants, Ltd. directly at (312) 344-7308.

Thank you.

Sincerely,



Kelby Krabbenhoft
President
St. Margaret's Hospital

KK/pdr

Enclosure:

CONTROL NO. 79906

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 (Fig. 13), 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 assembly enclosure), 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 system. 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.

FIGURE 10
Source Collimator/Holder Assembly

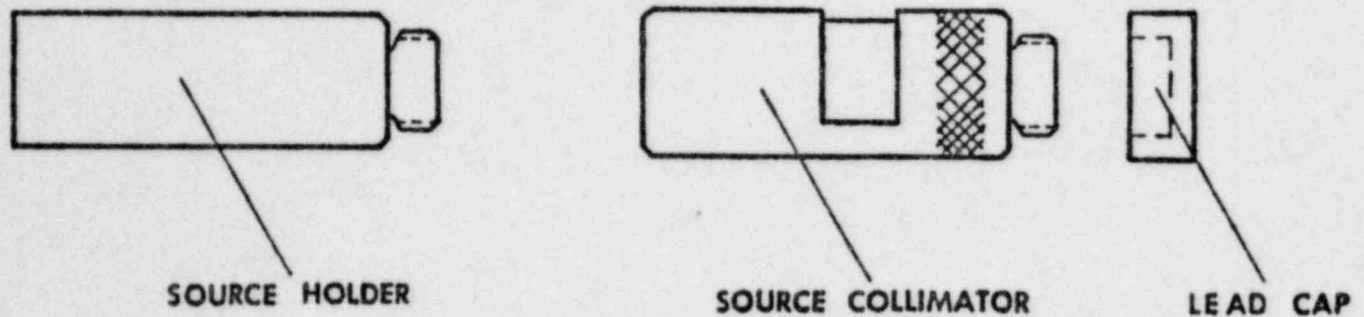
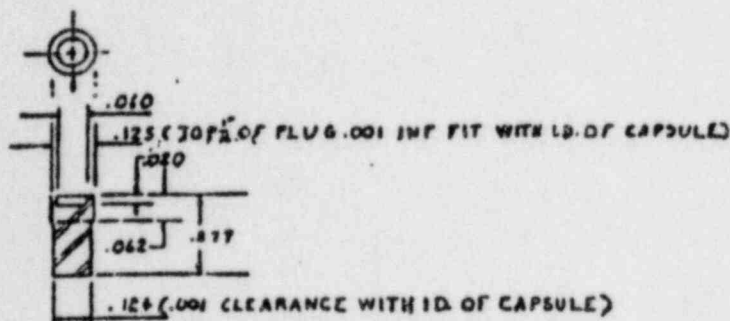
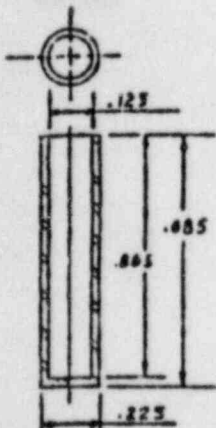


FIGURE 11
Source Capsule and Holder for 153-Gd

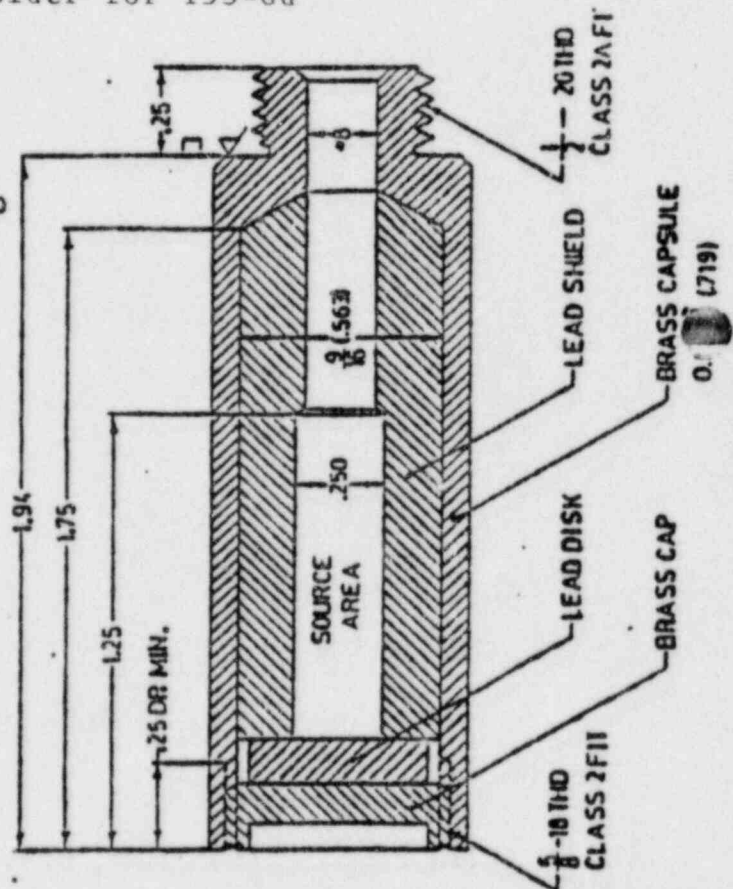


PLUG



CAPSULE
MODEL GD-1

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



LUNAR RADIATION CORP. of MADISON, WISCONSIN	
TITLE <u>GADOLINIUM 153 SOURCE HOLDER</u>	
PART #	MATERIAL
	BRASS & LEAD
FOR ASSEMBLY	TOLERANCES (UNLESS OTHERWISE SPECIFIED)
	.001:01 .0005:001
SCALE	DIMENSIONS ARE IN INCHES
4:1	ALL EDGES AND CORNERS
DESIGNED BY: J. R. BUSH 2/62	
CHECKED BY: J. R. BUSH 2/62	

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

FIGURE 12
Side View of Transverse Carriage Assembly

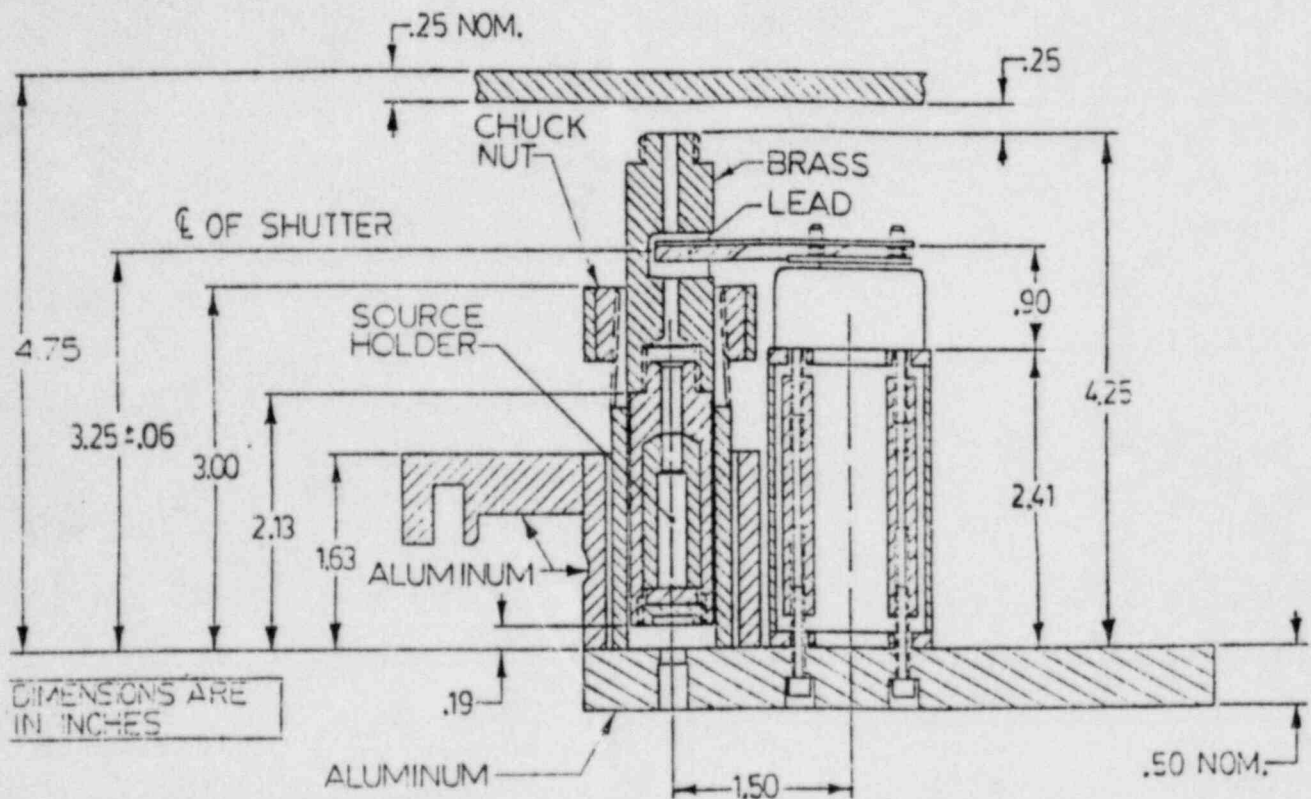
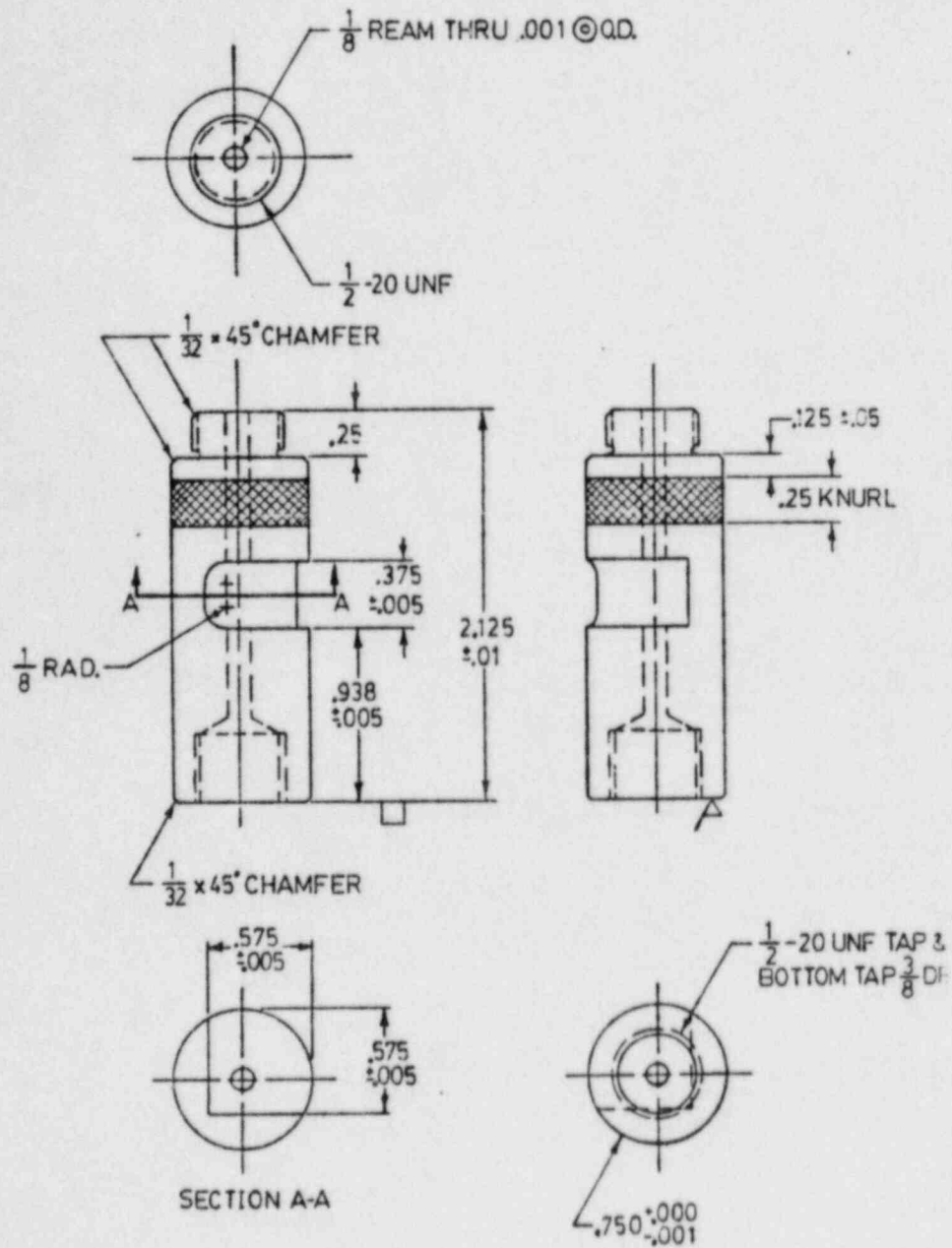


FIGURE 13
Source Collimator Details



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!

C.3 ADJUSTING DETECTOR HEIGHT

The radiation count rate is directly proportional to the distance between the table top and the detector collimator (Tabletop-to-Collimator Distance, TCD). Since the beam of radiation is slightly divergent, a lowered detector defines a larger solid angle, hence a greater fluence rate. A higher count rate yields a greater precision in results.

The detector should normally be kept in one position. A TCD of 28 cm is optimal, as most patients will fit under this height. If a patient does not fit, then the detector may be raised by following these procedures.

C.3.a Raising the Detector

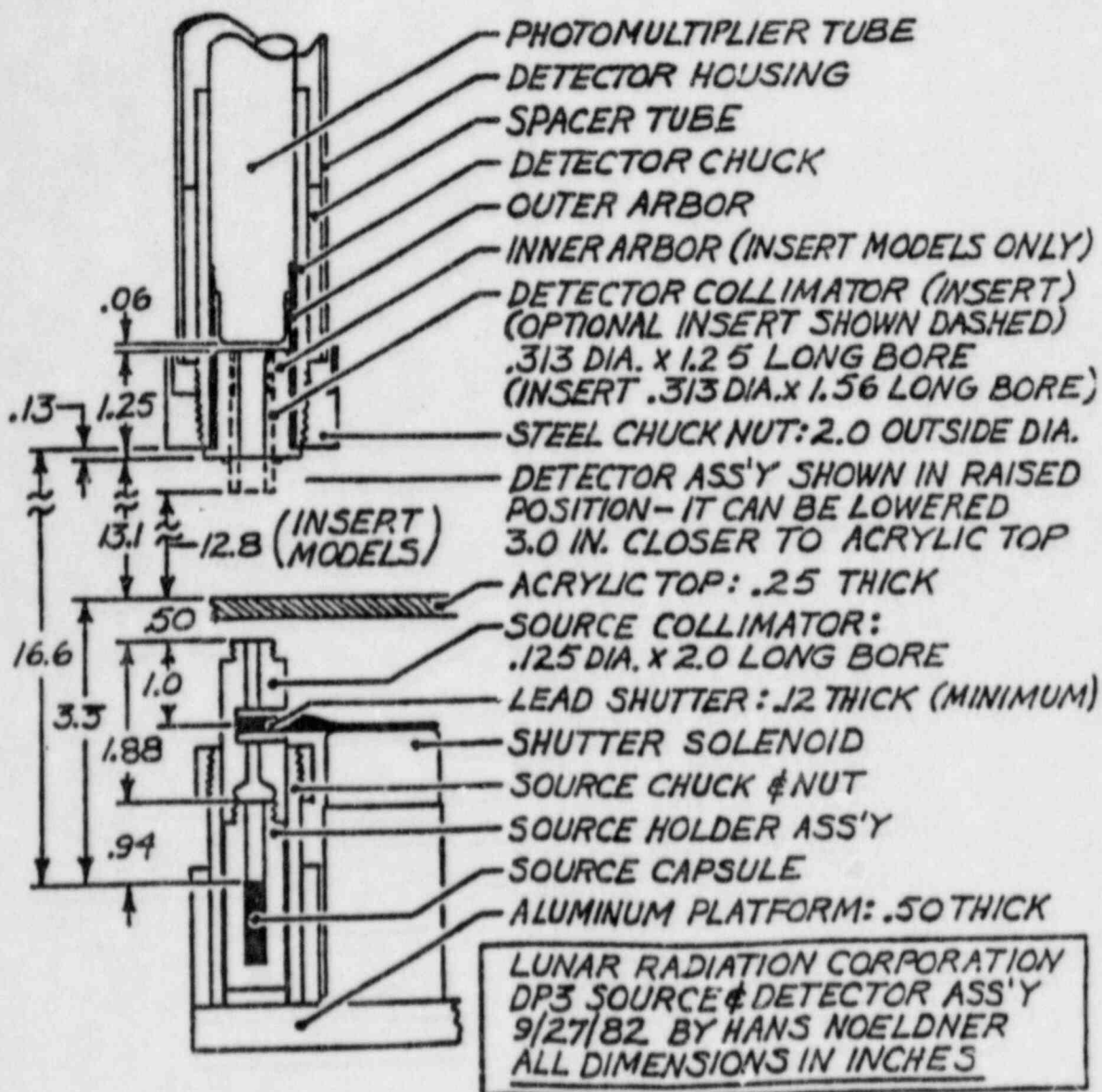
1. Grasp the detector chuck ring and turn in a counterclockwise direction to loosen it until the detector slides freely up and down (Fig. 14). DO NOT USE ANY TOOLS - HANDS ONLY. WARNING: Do not apply excessive force to the scanner arm or damage may result. Do not rotate the detector tube.
2. Slide the detector up into the detector housing until the desired height is attained. Record this height (TCD) in your QA/QC log book.
3. Tighten the chuck ring. Be sure the detector is clamped firmly.
4. If the patient still does not fit under the detector, then a "tummy flattener"(rib-belt) may be required. The belt should not have any metal in the scan area.

The patient may now be scanned. Note that the STANDARD values (BM and WIDTH) for a patient scan must correspond to those obtained at that particular detector height. If you anticipate scanning excessively large patients, a good procedure is to run OPTION 3 - SCAN STANDARD AND Q/A at two different detector heights. Keep one QA/QC logbook with values obtained at 28cm, and another logbook with values obtained at the maximum TCD (31.5cm).

C.3.b Lowering the Detector

1. Loosen the detector chuck ring.
2. Gently slide the detector down to its original height. Record the height in your QA/QC logbook.
3. Retighten the chuck ring. Be sure the detector is clamped firmly.
4. Measure and record the TCD.

FIGURE 14
Drawing of Source and Detector Assemblies



Outside Wall

Stair Well

Control's

Scan Table

Bone Analyzer

Hallway

Pharmacy
Storage room

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