

**Standard
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Nuclear Medicine • Radiology • Industrial Specialists

STAN BUHR
JIM MIKOWSKI
(312) 344-7308

P.O. Box 362, Manhattan, IL 60442 □ 1340 Balmoral Avenue, Westchester, IL 60153

February 18, 1985

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

Re: Amendment to NRC license no. 12-20362-01, Control # 77430

Dear Dr. Adam:

This is in follow up to our recent phone conversation concerning our pending radioactive materials license amendment application. We have answered each item using your same numerical order.

1. Re: Item 2.6-1

This is to confirm licensed material used at temporary job sites will be kept under the direct supervision of trained SNCL employees or in a locked room that is posted according to NRC regulations.

2. Re: Disposal of Waste

This is to confirm damaged gauges will be disposed by return to the manufacturer. In cases where gauge vendors are obsolete, or do not accept gauges for disposal, the gauges will be disposed through an NRC licensed commercial radioactive waste disposal firm.

3. Re: Item 6

This is to confirm client personnel will not be allowed to take part in procedures directly related to the operations requested in Item 6. F. of our pending amendment application, unless under the direct supervision and physical presence of SNCL personnel, who are specifically licensed to conduct such operations.

4. Re: Item 6. F.

Our request to install and relocate devices containing licensed material includes both specifically and generally licensed devices/sources. We confirm that we will do nothing to the gauge to interfere with the client's compliance with NRC regulation 10 CFR 31.5. We do intend to service generally licensed gauges, according to Part 31.5 regulations.

8506030093 850515
REQ3 LIC30
12-20362-01 PDR

RECEIVED
FEB 25 1985
REGION III

Enclosed please find documentation of Bob Bassett's training in installation, relocation, replacement and disposal of sealed sources containing licensed material used in Kay-Ray, Inc. devices/gauges. Please authorize Bob Bassett to perform such operations specific for all Kay-Ray, Inc. equipment for which he is certified.

Please authorize Stan Buhr and James Mikowski to exchange sealed sources in Lunar Radiation Model DP3 and SP2 Bone Mineral Analyzers. Please refer to the enclosed documentation of our training in such procedures. The detailed procedures we will follow in exchanging the iodine-125 and gadolinium-153 sources are also enclosed.

Servicing of gauges; shutter checks, maintenance of outer housing of gauge (cleaning and maintaining the integrity of the label), and electronic checks will be performed on gauges used under specific and general licenses.

Separate amendment requests to add the names of individuals to the SNCL license will address their device-specific training provided by either the manufacturer or other authorized personnel who are licensed to perform exchange and installation procedures of gauges.

5. Item 6.F.

We confirm the results of initial radiation surveys (radiation profile around the gauge), and shutter checks of devices containing licensed material will be provided to the client.

6. Re: Item 6

Personnel pocket dosimeters, in addition to TLD whole body badges, will be worn by SNCL personnel during operations described in Item 6 of our amendment application. The pocket dosimeters will be calibrated annually according to procedures described in the pending amendment application (Item 5.3 of the Radiation Safety Manual section). In addition, during source exchange procedures, SNCL personnel will wear ring TLD badges.

7. Re: Radiation Safety Manual Section; Item 6.3.A.

A radiation survey will be performed around the "free" standing source to determine if the source requires repositioning.

8. Leak test certificates provided to clients will indicate the month of the next scheduled source leak test.

9. This is to confirm SNCL does have access to a Packard, multi-sample counter Liquid Scintillation Counter for use in assaying carbon-14 and hydrogen-3 samples.

10. Bioassays will be performed when SNCL personnel handle, in open form, unsealed quantities of radioactive iodine that exceed those of Table 1 of NRC Regulatory Guide 8.20 "Applications of Bioassays for I-125 and I-131." Bioassays will be carried out in accordance with Reg.

Guide 8.20 and would include those described as Baseline, Emergency, Postoperational, and Diagnostic. The action levels for radioiodine bioassays listed in Reg. Guide 8.20 will be followed. In cases where the quantity of radioiodine to which SNCL personnel have been exposed is not known, bioassays will be performed routinely after operations.

Urine bioassays will be performed on individuals who handle or process the respective forms and amounts of tritium as listed in Table 1 of NRC "Guideline for Bioassay Requirements for Tritium", October 19, 1977. Urine samples will be assayed in a liquid scintillation counter and evaluated for action levels specified in the above-mentioned guide.

11. Re: Radiography Camera Handling Procedures; Item 9.2.b. of the Radiation Safety Manual section.

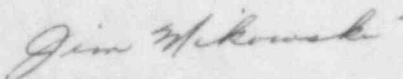
It is not the intention of SNCL to request authorization to perform radiography (nondestructive testing) services. We therefore wish to withdraw those procedures described in the above-captioned section of the amendment application. Please disregard procedures 9.2 b and d of Section IX of the Radiation Safety Manual. These procedures deal specifically with the "Malfunction of Radiography Devices" and "Damage to Radiography Device and Source Disconnect", respectively.

12. Re: Item 7 of the General Safety Procedures of the Radiation Safety Manual section.

1.25/hr should read 1.25 R/hr in this paragraph.

If additional clarification of this amendment request is needed, please call. I appreciate the time you have taken to discuss the above items with me.

Sincerely,



Jim Mikowski

LUNAR RADIATION CORP.

916 WILLIAMSON ST. • MADISON, WI 53703 • (608) 258-8545

Standard Nuclear Consultants, Ltd.
P.O. Box 362
Manhattan, Il 60442

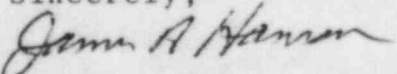
Atten: Stan Buhr and Jim Mikowski

We wish to acknowledge that on February 6, 1985, Stan Buhr and Jim Mikowski attended a formalized four hour training section at LUNAR. The following items were presented and, if appropriate, independently performed by both individuals:

- 1) Basic Physics of Absorptiometry,
- 2) Radiation Dosimetry of LUNAR's SP2 and DP3 scanners,
- 3) Source exchange for both SP2 (I-125) and DP3 (Gd-153) scanners were performed by both individuals,
- 4) Wipe testing procedures for SP2 (I-125) and DP3 (Gd-153) scanners.

This device specific training was provided by LUNAR personnal and served to familiarize the stated individuals with particular Health Physics needs and requirements of LUNAR instruments.

Sincerely,



James A. Hanson, Ph.D.
Vice President

C. DETAILED OPERATING PROCEDURES

SP-2

C.1 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 attempting an actual source transfer. The press-on label with the warning "CAUTION - RADIOACTIVE MATERIALS" should be affixed to the table of the scanner in a location where it can be seen by the operator, patients, and/or visitors to the area where measurements are done.

All steps should be conducted without tools. Do not use pliers, clamps, etc. to parts. The "source" consists of a capsule containing ^{125}I in solid form. This source is located in a brass source holder (Figure 5). Sources are not supplied by LRC.

PROCEDURE

1. Have container that the source is shipped in nearby.
2. Turn off SP2.
3. Unplug SP2 power cord.
4. Unlock the locks that hold down the top (FIG 6).
5. Remove top, do not bump the detector.
6. Turn shutter to open position and hold there. Avoid beam if a source has been installed earlier.
7. Turn source holder arbor counterclockwise to remove. (Avoid beam if source was attached previously).
8. Remove old source holder from arbor.
9. Screw protective cap (supplied with each source holder) onto old source holder. If a new source holder is not to be installed, screw the arbor back into the plate to avoid loss. Follow standard procedures for source disposal.
10. Unscrew cap from new source holder.
11. Screw source holder into the arbor.

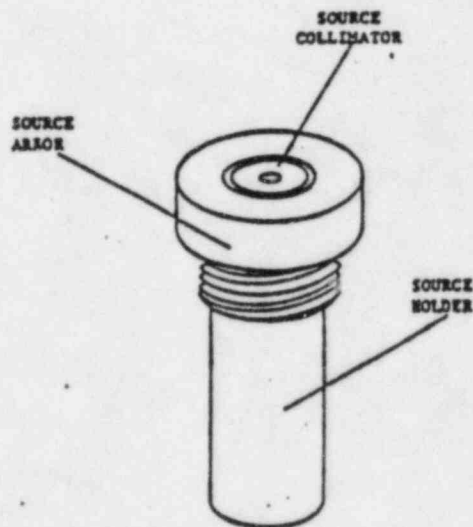


FIGURE 5
SOURCE HOLDER ASSEMBLY

12. Screw arbor into the scanner and be sure it is properly seated. Be sure the lead shutter can swing freely over the arbor.
13. Replace the top and lock into position.
14. Plug the power cord in and turn scanner on.

If the Atomic Energy of Canada Limited (AECL) sources 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 holder itself provides sufficient collimation.

Once the old source is removed, the protective cap must be screwed onto the top of the old source holder. The old source should then be packed into the original shipping container. Send the depleted source in the source holder back to the supplier of that source using the recommended shipping procedures for this type of material.

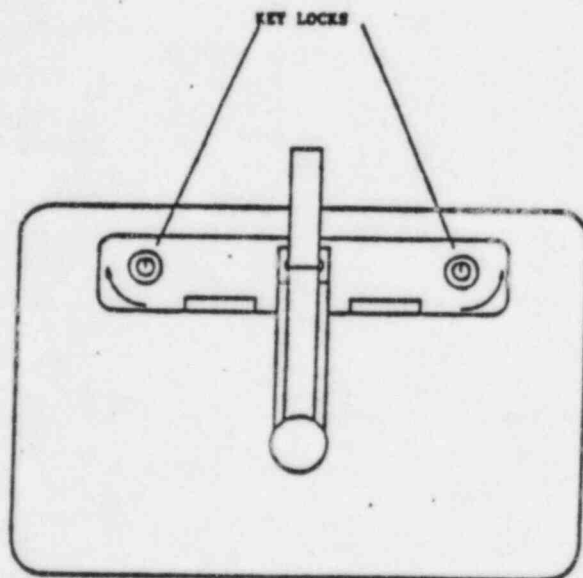


FIGURE 6
UNLOCKING SP2 TOP

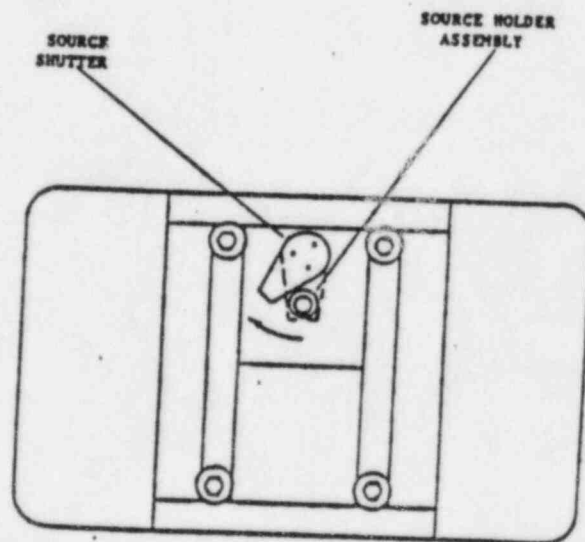


FIGURE 7
SOURCE LOCATION & REMOVAL
NOTE: "DASHED" lines refer to
shutter in "occluded" position.

C.2 INSTALLING AND REMOVING THE SOURCE - DP3

WARNING: 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. The press-on label with the warning "CAUTION - RADIOACTIVE MATERIALS" should be affixed to the table of the scanner in a location where it can be seen by the operator, patients and/or visitors to the area where measurements are done.

All steps can be conducted without tools. Use of pliers, clamps, etc. in the procedures may cause damage to parts. The "source" consists of a capsule containing gadolinium in solid form (FIG 9). This source is encapsulated in a lead-lined (4mm) brass source holder (FIG 10).

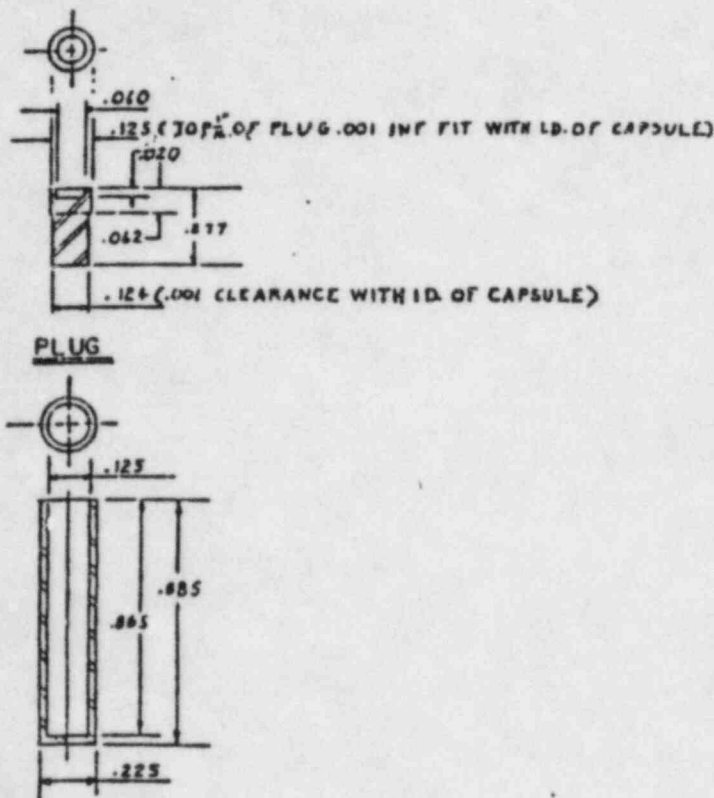
C.2.a. Removing the Source

PROCEDURE

1. Remove pad (if any) and the lucite insert from the table.
2. Use OPTION 5 (Static Counter, User Manual) of the CLUNAR program to position the arm and source at the center of the window.
3. Place a lead source holder cap onto the source collimator (FIG 11).
4. Use 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. Pull 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.
8. Holding the source collimator and source-holder upright (as they were positioned in the scanner), unscrew the source-holder from the collimator. Put a lead cap on the source holder.

CAUTION: RADIATION PRESENT! After the collimator is removed a broad beam of high intensity radiation projects from the top of the source-holder. Exercise due caution.

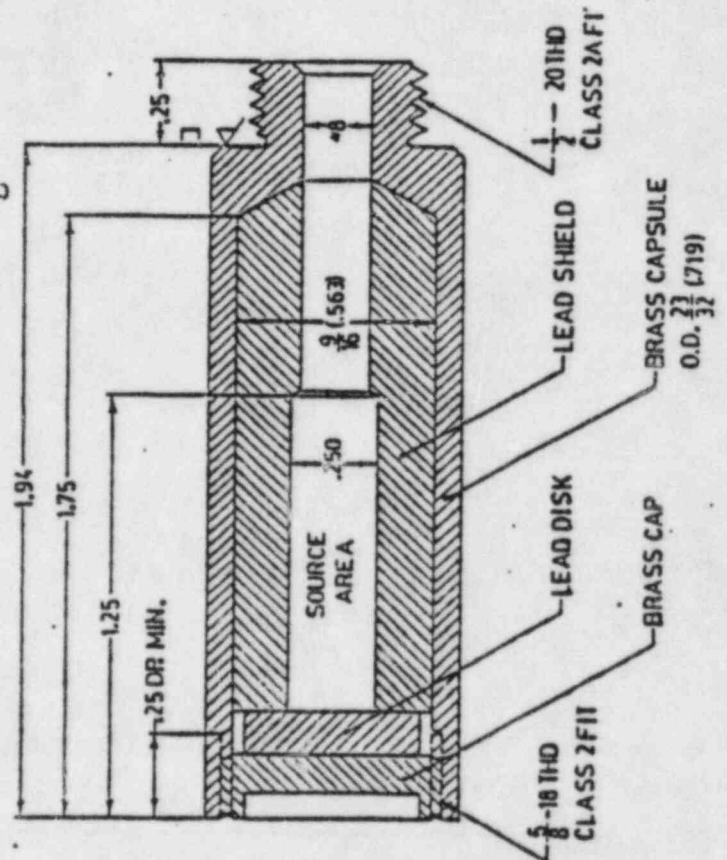
FIGURE 10
Source Holder for 153-Gd Capsule



CAPSULE
MODEL. GD-1

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

REVISONS			GULF NUCLEAR, INC.		
NO	DATE	BY	GADOLINIUM CAPSULE		
1			DRAWN BY FGI	SCALE NONE	MATERIAL 17-4 PH 53
2				DATE 4-3-77	DRAWING NO.
3			CHK'D	APP'D	A-120
4			TRACED		
5					



LUNAR RADIATION CORP. of MADISON, WISCONSIN			
TITLE <u>GADOLINIUM 153 SOURCE HOLDER</u>			
PART #		MATERIAL	
		BRASS & LEAD	
FOR ASSEMBLY		TOLERANCES (UNLESS OTHERWISE SPECIFIED)	
		.0001 .0001 .001	
SCALE 4:1		DIMENSIONS ARE BREAK ALL EDGES	
		IN INCHES AND CORNERS	
DESIGNED BY: CRAFTSMAN		DATE: 10/1/77	
CHECKED BY: BRUSH		DATE: 2/8/78	

FIGURE 11
Source Collimator/Holder Assembly

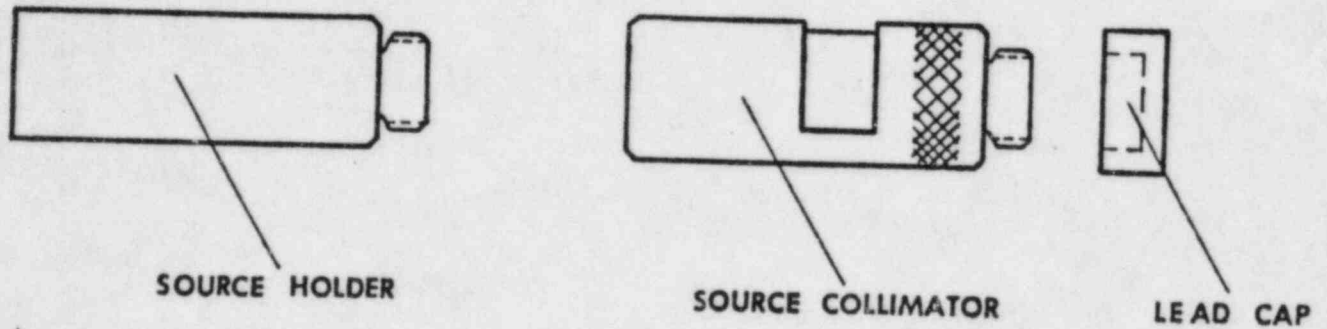


FIGURE 12
Side View of Transverse Carriage

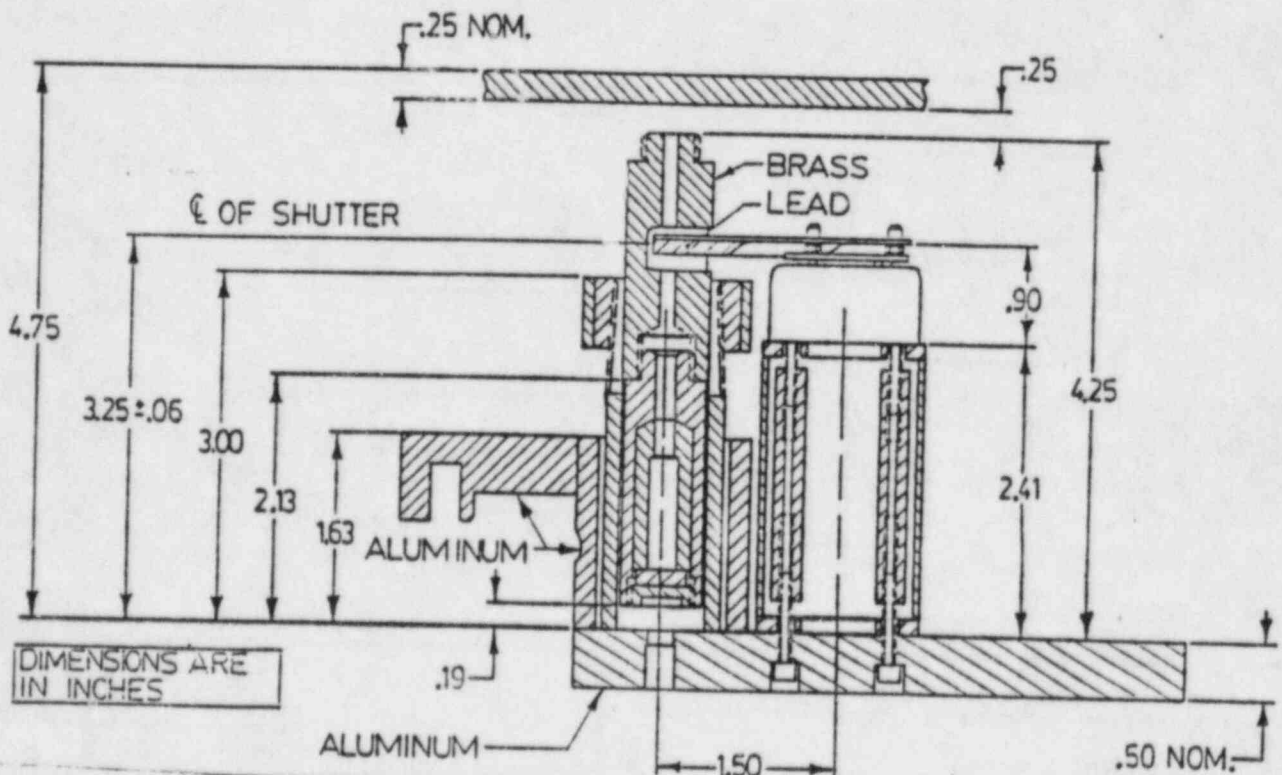
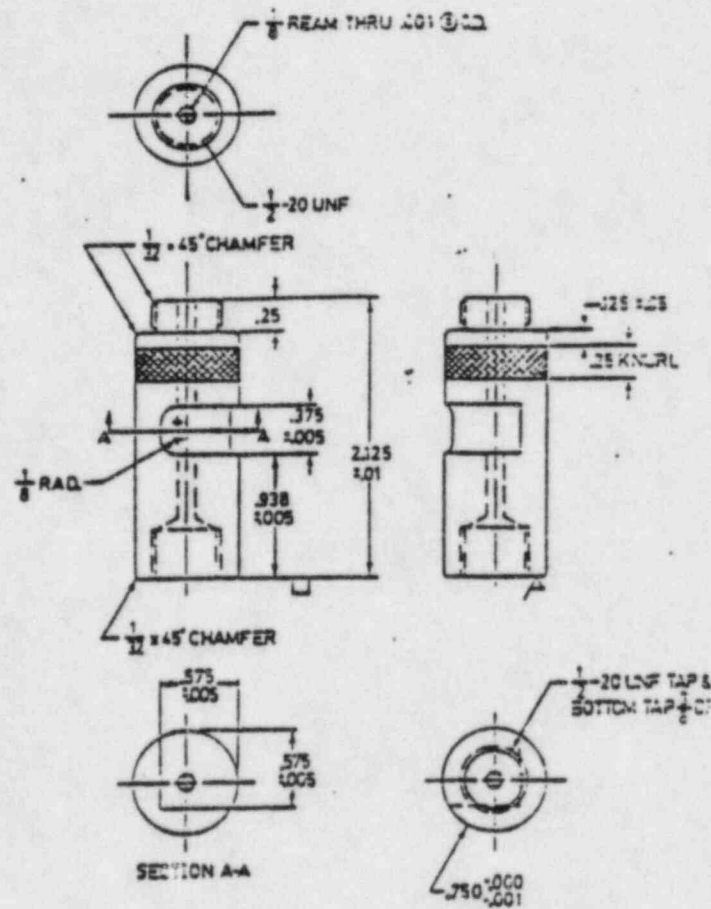


FIGURE 13
Collimator Details



LUNAR RADIATION CORP. MADISON, WISCONSIN	
TITLE DP3 SOURCE COLLIMATOR (REVISED)	
MATERIAL BRASS	
FOR ASSEMBLY .00 \pm .01 .000 \pm .001	
NONE DIMENSIONS ARE IN INCHES AND DECIMALS	
DESIGNED BY H. N. C. 2/22/81 CHECKED BY G. G. 2/82	

C.2.b Installing a Source

1. Use 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.
2. For new scanners the source holder is provided with the source. The collimator will not have a cap. Remove the collimator from the scanner.
3. Place the lead cap on the source holder onto 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 unit.
4. Slide the source collimator-holder into the source chuck (Fig. 12) so that the pin on the bottom 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 of OPTION 5 or remove the tape if the shutter is held open manually.
6. Verify that the shutter can swing into the notch on the collimator (Fig. 12).
7. Turn the chuck ring clockwise until the collimator is held firmly in the chuck.
8. Remove the source holder cap from the top of the collimator.

CAUTION: A narrow beam of intense radiation is now projected upward from the collimator aperture.
9. Check the shutter for proper operation (User Manual - Standard Scan and QA).
10. Replace the lucite insert (and place the pad on the table). Be sure the lucite insert is placed properly.
11. Monitor radiation levels around the table to insure operator safety.

This completes the source installation procedure.

LICENSING INFORMATION FOR USE
OF RADIOISOTOPES IN BONE MINERAL SCANNERS

Introduction

The uses of I-125 and Gd-153 radionuclides for bone mineral scanning requires licensing from the appropriate authority. The Nuclear Regulatory Commission administers licenses to individuals or institutions within certain states. The remaining states, the so called "agreement states", administer licenses to their own residents. Although the following information covers only the NRC regulation, most state radiation control agencies have similar requirements. Individuals within agreement states must contact their appropriate state agency for licensing information.

Major hospitals have broad NRC licenses or specific Group VI licenses. These institutions must amend their current licenses to include the use of sealed radionuclide sources for bone mineral analyzers. The institution's Radiation Safety Officer will direct the filing of an amended NRC form 313. The following information will assist in answering item 5 and 6 of form 313.

A: Radioactive materials

The appropriate source information as determined by intended clinical use should be included in item 5 of NRC form 313.

<u>Element and mass number</u>	<u>chemical and/or physical form</u>	<u>manufacturer and model number</u>	<u>amount</u>
125-I	ion exchange	AECL C234	200 mCi each 250 mCi total
153-Gd	GdO ₂	Gulf Nuclear Model GD-1	1000 mCi each 1300mCi total

During normal use only one isotope per unit will be on site. For continuity of patient scanning, the total amount listed in the license must include the summed activity of a newly received source and the decayed source to be returned to the source manufacturer.

B: Description of use (item 6 NRC 313)

The sealed sources listed above will be used in one of two types of bone mineral analyzers. There must be a direct reference to the NRC device registration number.

<u>source</u>	<u>device</u>	<u>NRC device registration</u>
125-I	Lunar SP2	NR-430-D-102-S
153-Gd	Lunar DP3	NR-430-D-101-S

C: Training and experience

By definition, broad medical licensees and Group VI licensees have users who have adequate training and experience to use radiation. Individuals planning to use Lunar's bone mineral analyzer who lack the required training and experience must approach their institution for required training.

Each Lunar bone mineral analyzer is installed by qualified expert who provide two days of installation and training. This training covers source installation, wipe testing, scan operations, and data analysis and interpretation. The institutions Radiation Safety Office must be present for instruction on source replacement and wipe testing.



KAY-RAY INC.

INDUSTRIAL PROCESS CONTROL EQUIPMENT

516 West Campus Drive • Arlington Heights, Illinois 60004 • (312) 259-5600 • TELEX: 261-085 • CABLE KAYRAY

CERTIFICATION OF TRAINING

Name: Robert W. Bassett

Company: Adco Services Inc.

The above named individual has successfully completed the INSTALLATION AND NUCLEAR RADIATION SAFETY course offered by Kay-Ray, Inc., consisting of the following curriculum:

- Principles and practices of radiation protection
- Monitoring radiation levels using Geiger counters
- Radiation exposure limits
- Radiation areas defined
- Calculating radiation levels from known gamma source size and distances
- Calculating dose rates of typical installation
- Leak testing Kay-Ray source housings
- Safety practices required for the use and handling of Kay-Ray source housings
- Installation of source housings demonstration and Hands-On installation

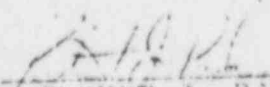
This training course consists of formal discussions, practical applications, leak testing, specific installation discussions, and hands-on installation completion with related forms for record keeping.

Certified on equipment

model 7050, 7050B, 7051, 7060, 7060SD, 7062, 7062P, 7062B, 7062BP, 7063, 7063P, 7064, 7064P, 7065, 7065P, 7067, 7080, 7100

Instructor: Raymond A. Parsons

Date: November 18, 1983


ROBERT J. BAKER
Vice President

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Nov81

CONVERSATION RECORD

TIME

2:45P

DATE

1/11/85

pp 1 of 4

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☒ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

J. Mikowski

ORGANIZATION (Office, dept., bureau, etc.)

Std. Nuc. Consult.

TELEPHONE NO.

344-7308

SUBJECT

C/W 77430

SUMMARY

1) Need procedures for storage of gauges at temporary job sites - security of gauges

2.) Methods of disposal - damaged or obsolete gauges - contaminated samples

3.) Item 6 of ltr, last paragraph excludes ^{clear} licensee from use of licensed material. Does this mean excluded from recovery operation? - clarify.

ACTION REQUIRED

(cont.)

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE

CONVERSATION RECORD

TIME 245P

DATE 1/11/85

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☒ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

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ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Std. Nuc. Consult.

SUBJECT

C/N 77430

SUMMARY

- 4) If service of generally licensed gauges is anticipated, need:
 - confirm maintenance of compliance with 10 CFR 31.5
 - confirm maintenance of compliance with 32.51a if initial installation.
- 5) need copy of "initial survey" report form, shutter check, etc.
- 6) Confirm annual response check of pocket dosimeters

ACTION REQUIRED

(cont.)

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE

CONVERSATION RECORD

TIME 245P

DATE

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1/11/85

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ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Std. Nuc. Consult.

SUBJECT

C/N 77430

ROUTING

NAME/SYMBOL

INT

SUMMARY

- 7.) Procedure "6.3" should start with a survey to assess radiation fields.
- 8.) Describe method of evaluation of low E. β emitters (contamination samples)
- 9.) Leak test certificate should show date of next scheduled leak test.
- 10.) Describe procedures for Iodine + Tritium bioassays.

ACTION REQUIRED

(cont.)

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE

CONVERSATION RECORD

TIME

2 450

DATE

1/11/85

pp. 4 of 4

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☒ OUTGOING

ROUTING

NAME/SYMBOL

INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Std. Nuc. Consult.

SUBJECT

C/N 77430

SUMMARY

11.) Clarify "1.25/hr" under 9.2 (d) #7

12.) A. Describe training w. radiography sources - should be equivalent to 40/520 hrs for radiographers as per Reg. Guide 10.6

B. Define/classify servicing/installation of sealed sources - does this really refer to gauges?

ACTION REQUIRED

Licensee will respond within 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

W. J. Adam

1/11/85

ACTION TAKEN

SIGNATURE

TITLE

DATE