



Ohio Imaging
Nuclear Medicine Division

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April 4, 1995

Fax

216-475-2975

David T. Tang, M.E.
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Source Containment and Device Branch
Division of Industrial & Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555-0001

Dear Sir:

In response to your letter of March 15, 1995 referencing our application dated February 14, 1995, requesting a device evaluation for the registration of the model STEP transmission line source holding device of our manufacture, please accept the following supporting information in the order requested:

1. On March 27, 1995 a complete radiation profile was determined surrounding the STEP device with line sources containing Co-57, Gd-153, and Tc99m installed. Measurements were made at distances of 5 cm, 30 cm, and 100 cm from the line source and repeated for all three operational modes, i.e. shutter closed, open and calibration. In addition, measurements were made to determine the attenuative effect of each of the three tin filters on a Tc99m beam emerging from the fan collimator in the open shutter mode. The sources used included the following:

Gd-153	36.0 mCi on 3/27/95
Co-57	4.24 mCi on 3/27/95
Tc99m-99m	31.0 mCi on 3/27/95 (@ 2:20 p.m. EST)

The radiation levels given in the tables below have been adjusted from those measured at the above activities to those that would have been measured had the source activity been:

Gd-153	86.25 mCi (a multiplier of 2.40 was used)
Co-57	28.75 mCi (a multiplier of 6.78 was used)
Tc99m	23.0 mCi (a multiplier of 0.74 was used)

Background was subtracted from all values before the correction was applied.
The survey meter used was an:

Eberline G-M, Model ASP-1
Equipped with an energy compensating probe, Model HP-270
Last calibrated on 7/21/94
Battery check: OK
Operational check source reading at calibration: 1.2 mr/hr
Operational check source reading on 3/27/95: 1.2 mr/hr
Background: 0.010 - 0.012 mr/hr

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PDR RC *
SSD PDR

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Radiation measurements were made from six aspects, i.e. at the specified distances from each end of the source and at the specified distances from the middle of the source at 0, 90, 180 and 270 degrees. The distances are from the sources and not the device surfaces. As a result, those entries in the tables below followed by the letter "c" were made with the G-M probe held on contact with the device because the 5 cm distance was within the device housing itself and therefore inaccessible for measurement purposes.

For clarification, the surfaces of the STEP device through which the source distance was measured were as follows:

- #1 - The contact sensor face
- #2 - The housing side closest to the "CAL" label on the shutter position indicator.
- #3 - The housing top surface
- #4 - The housing side closest to the "OPEN" label on the shutter positions indicator.
- #5 - The end where the source is installed
- #6 - The end where the device is attached to the gantry

Using Gd-153

Distance

Shutter Position

	<u>5 cm</u>	<u>30cm</u>	<u>100cm</u>
<u>Closed</u>			
#1	.00 c	.00	.00
#2	.03	.02	.00
#3	.07 c	.00	.00
#4	.12	.03	.02
#5	.00 c	.00	.00
#6	.05 c	.01	.02

Calibrate

#1	.22 c	.05	.00
#2	.07	.04	.01
#3	.12 c	.00	.00
#4	.02	.02	.00
#5	.02 c	.01	.00
#6	.02 c	.00	.00

Open

#1	11.00 c	4.30	1.08
#2	.12	.01	.01
#3	.26 c	.10	.02
#4	.17	.04	.00
#5	.19 c	.02	.02
#6	.41 c	.03	.00

All values in mr/hr above background

Using Co-57

<u>Shutter Position</u>	<u>Distance</u>		
	<u>5 cm</u>	<u>30cm</u>	<u>100cm</u>
<u>Closed</u>			
#1	1.83 c	.61	.07
#2	3.19	.27	.03
#3	3.19 c	.27	.07
#4	3.59	.41	.14
#5	0.14 c	.08	.03
#6	0.14 c	.05	.00
<u>Calibrate</u>			
#1	3.05 c	.95	.08
#2	3.32	.41	.09
#3	3.46 c	.33	.08
#4	2.37	.20	.01
#5	0.41 c	.09	.00
#6	0.39 c	.04	.00
<u>Open</u>			
#1	7.05 c	2.31	.54
#2	1.97	0.56	.10
#3	2.78 c	0.31	.07
#4	4.27	0.33	.01
#5	0.22 c	0.14	.03
#6	0.20 c	0.03	.03

All values in mr/hr above background

Using Tc99m

<u>Shutter Position</u>	<u>Distance</u>		
	<u>5 cm</u>	<u>30cm</u>	<u>100cm</u>
<u>Closed</u>			
#1	.01 c	.00	.00
#2	.01	.00	.00
#3	.01 c	.01	.00
#4	.03	.01	.00
#5	.03 c	.01	.00
#6	.06 c	.00	.00
<u>Calibrate</u>			
#1	1.10 c	.36	.11
#2	0.04	.01	.00
#3	0.07 c	.01	.00
#4	0.02	.00	.00
#5	0.07 c	.00	.00
#6	0.14 c	.00	.00
<u>Open</u>			
#1	5.91 c	1.62	.44
#2	0.03	0.01	.00
#3	0.88 c	0.03	.00
#4	0.04	0.01	.00
#5	0.21 c	0.01	.00
#6	0.44 c	0.03	.00

All values in mr/hr above background

FILTERMEASURED ATTENUATION AT 140 KEV

None	O
#1 (.040" Sn)	39%
#2 (.020" Sn)	25%
#3 (.010" Sn)	15%

2. It is estimated the annual extremity radiation dose to the operators will be as follows:

A. Regular use of 86.25 mCi (75mCi + 15%) of Gd-153	0.1r / year
B. Regular use of 28.75 mCi (25mCi + 15%) of Co-57	0.3r / year
C. Regular use of 23.0 mCi (20 mCi + 15%) of Tc99m	7.0r / year

The above estimates are predicated on the following assumptions:

- A. For all radionuclides, the STEP device will be installed and removed from the gantry on a daily basis.
- B. The Gd-153 and Co-57 sources will be exchanged annually. Finger contact with the old source on removal and transfer to a storage pig will be of one minute duration. An additional minute will be required to reload the STEP device with a new source.
- C. The Tc99m containing line source will be prepared on a daily basis. Filling the tube will require two minutes. Finger contact in removing the decayed tube and inserting the newly charged tube will require ten seconds each.
- D. Extremity exposures received when installing and removing the shutter closed STEP device from the gantry will be based on a five minute maximum handling time.
- E. By actual measurement using three TLD ring badges mounted at 0, 90, & 180 degrees on a 3/4 inch diameter wood dowel rod and a 33.6 mCi Gd-153 line source held parallel and on contact with the dowel rod for a timed period of 147 minutes, the maximum mid-source exposure was 3.12 mr/min/mCi. The exposure rate at 2.0 cm from the end of the source where it would normally be grasped was experimentally determined to be 25% of the mid-source rate or 0.78 mr/min/mCi.
- F. By calculation, the contact exposure rate for Co-57 at 2.0 cm from the source end will be 5.58 mr/min/mCi.
- G. By calculation, the contact exposure rate for Tc99m at 2.0 cm from the source end will be 5.08 mr/min/mCi.
- H. By calculation, the exposure rate for Tc99m at 10cm from a point source will be 0.13 min/mCi.
- I. Only one individual will be involved in source and/or device handling.

CALCULATIONS

Gd-153

Source exchange (insertion)

$$0.78 \text{ mr/min/mCi} \times 1 \text{ min/year} \times 86.25 \text{ mCi} = 67.3 \text{ mr / year}$$

Decayed source exchange (removal)

$$0.78 \text{ mr/min/mCi} \times 1 \text{ min/year} \times 30.3 \text{ mCi} = 23.6 \text{ mr / year}$$

STEP device handling

$$0.12 \text{ mr/hr} \div 60 \text{ min /hr} \times 5 \text{ min} \times 260 \text{ days/year} = 2.6 \text{ mr / year}$$

$$\text{Total} \quad 93.5 \text{ mr / year}$$

Co-57

Source exchange (insertion)

$$5.58 \text{ mr/min/mCi} \times 1 \text{ min/year} \times 28.75 \text{ mCi} = 160.4 \text{ mr / year}$$

Decayed source exchange (removal)

$$5.58 \text{ mr/min/mCi} \times 1 \text{ min/year} \times 11.3 \text{ mCi} = 63.1 \text{ mr / year}$$

STEP device handling

$$3.6 \text{ mr/hr} \div 60 \text{ min/hr} \times 5 \text{ min/year} \times 260 \text{ days/year} = 78.0 \text{ mr / year}$$

$$\text{Total} \quad 301.5 \text{ mr / year}$$

Tc99m

Source preparation

$$0.13 \text{ mr/min/mCi} \times 2 \text{ min/day} \times 260 \text{ day/year} \times 23 \text{ mCi} = 1555 \text{ mr/year}$$

Source exchange (insertion)

$$5.08 \text{ mr/min/mCi} \times 0.167 \text{ min/day} \times 260 \text{ day/year} \times 23 \text{ mCi} = 5073 \text{ mr/year}$$

Decayed source exchange (removal)

$$5.08 \text{ mr/min/mCi} \times 0.167 \text{ min/day} \times 260 \text{ days/year} \times 1.5 \text{ mCi} = 330 \text{ mr/year}$$

STEP device handling

$$0.08 \text{ mr/hr} \div 60 \text{ min/hr} \times 5 \text{ min} \times 260 \text{ days/year} = 1.7 \text{ mr/year}$$

$$\text{Total} \quad 6959.7 \text{ mr/year}$$

The above extremity exposure estimates assume a worst case in source handling. One minute handling times in exchanging the Gd-153 and Co-57 sources were chosen only because the handler's proficiency at source exchange will be limited due to its requirement at only annual

intervals. The actual time required to effect source exchange from removal and stowing of the decayed source to insertion of a new source was about ten seconds.

Tc99m source preparation and handling times were also estimated high. The times given above are based on the observation of an individual preparing and inserting a Tc99m source whose experience was limited to about a dozen occurrences. Daily or at least several times weekly preparations will increase operator proficiency such that handling times will be reduced to perhaps 50% of those given above. The extremity exposures received should be reduced proportionately.

Lastly, since there are STEP units already in use in several institutions throughout the United States, an examination of extremity exposures being received by individuals working with STEP at two separate imaging centers was conducted. TLD finger badge exposure reports were reviewed for time periods before STEP, after beginning with STEP using Tc99m, and after beginning with STEP using Co-57. These exposures were reduced to mr/month and are summarized in the table below. The number of days in which patients were examined using STEP is given in parenthesis.

	CLEVELAND AVG mr/month	MIAMI AVG. mr/month
Before STEP	126	15
After STEP (Tc99m)	136(9)	20 (8)
After STEP (Co-57)	.	30 (11)

As can be seen, the actual exposures being recorded are only a small fraction of the estimated maximums or the 50r/year permitted.

3. Enclosed please find engineering drawing number 101881 "source holder" as requested. The drawing is labeled proprietary and designated as addendum #2A.
4. Attached as addendum #4A is a report summarizing the results of a 26000 cycle test of the STEP shutter mechanism. 26000 cycles is the estimated number of times the device shutter will be operated in a busy nuclear medicine section over a ten year period. The estimate is predicated on a case load of:

10 patients per day
 x 1 cycle per patient
 x 5 days per week
 x 52 weeks per year
 x 10 years = 26000 cycles

5. The inner cylinder diameter is specified to 0.2615 ± 0.0035 inches. The sealed sources to be used are specified to be a maximum 0.25 inches outside diameter leaving a clearance of approximately 0.010 inches. This allows a straight source to be freely inserted into and freely withdrawn from the inner cylinder.

Proper function of the STEP unit requires the source to be positioned securely so the emerging fan beam is reproducible. Enlarging the inner cylinder diameter would compromise this required feature.

Instructions given in the Operator's Guide do address the issue of source insertion and removal in the form of a caution not to use excessive force (Addendum #7, chapter 5, page 5-1). If a source is bent prior to or during insertion such that it will not slide out freely, the Operator's Guide, (after the addition of a second **caution** on page 5-4) will point out that the source end is equipped with a #6 x32 internal thread that will allow the use of a 2 1/2 inch long #6 x 32 machine screw (provided) to be used as a tool to facilitate source removal. See the attached addendum 7B for the Operator's Guide proposed wording change.

The bend test (ANSI N433.1) on the sealed sources has not been done.

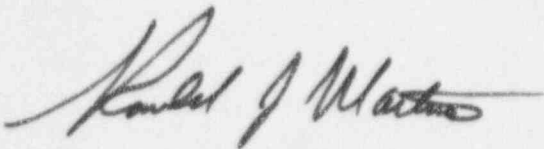
6. A proposed modification of page 5-5 of the Operator's Guide is enclosed as addendum #7A to address the issue of safe source removal.
7. The caution symbol referenced in section 3.3 3.2 of our submission is located as described in section 3.3.3.1 and shown on page 6 of addendum #1. The inadequacy of this caution labeling is acknowledged and will therefore be supplemented with a durable label affixed to the smooth top surface of the source holder as shown on the attached addendum #1, page 5, revised as of March 31, 1995. An expanded example of the label for legibility purposes is attached as addendum #1A.

In addition, a proposed modification of page 5-4 of the Operator's Guide is enclosed as addendum #7C to address the matter of source storage container labeling.

8. Picker Ohio Imaging is manufacturing its STEP transmission line source holding device under the Food and Drug Administration's Good Manufacturing Practices program.

I trust the above and attached addenda will enable continued review of our device evaluation request. If further information is required, I can be reached at (216) 473-7651.

Sincerely,



Ronald J. Martone
Manager of Regulatory Affairs

CC: Hugh Morgan, Jeff Power

1 Executive Summary

An accelerated life test was conducted on the STEP Source Housing Assembly to validate the claim of ten years life. After experiencing a single soft failure, the unit was cleaned and lubricated and the life test restarted. The equivalent of more than twelve years of operation was then simulated. The unit functioned without failure until the test was stopped after 32,000 cycles. Post test analysis indicated that the unit was completely functional and radiation secure.

2 Introduction

The purpose of this test was to demonstrate a useful 10 year life of the mechanical components of the STEP Source Housing. The worst case estimate of the STEP Source Housing 10 year life is 26,000 cycles, calculated as follows:

$$1 \text{ cycle/patient} \times 10 \text{ patients/day} \times 5 \text{ days/week} \times 52 \text{ weeks/year} \times 10 \text{ years}$$

One cycle consists of the shutter opening once and then closing once. In order to achieve timely results, an accelerated life test was conducted where in the STEP Source Housing was cycled at approximately 600 cycles per hour until more than 26,000 cycles had been accumulated. Since this was a test of the integrity of the radiation safety mechanisms, two conditions were considered failures:

1. **Soft Fault** - The shutter fails to automatically return to the closed position from the open position. The shutter can be closed using the manual override knob.
2. **Hard Fault** - The shutter fails to automatically return to the closed position from the open position. The shutter can not be closed using the manual override knob.

Special test software was written which: cycled the STEP Source Housing at the test rate, tracks the number of cycles completed, monitors whether the STEP shutter is OPEN or CLOSED, and reports a fault if the shutter, after being OPEN, fails to return to the CLOSE position by the end of the cycle.

2 Procedure

1. A STEP unit was drawn from stock and inspected for any obvious defects. The test STEP unit was tested and adjusted to meet functional specifications.
2. The test STEP unit was installed on a Prism 3000 System and the test software was loaded. The test system was verified to be operating properly.
3. The life testing was begun with a shutter duty cycle of 2 seconds open and 4 seconds closed. The STEP System was monitored for faults.
4. In the event that a fault might occur, the test would be suspended to determine the cause of the failure. Once the problem was analyzed and corrected, the test would either continue, restart or terminate as appropriate.
5. At the conclusion of the test, the test STEP unit was inspected for stress, wear and fatigue and the observations were recorded..

3 Results

1. After 6472 cycles a soft fault occurred. After being open, the shutter failed to completely close. The shutter remained hung up in a partially open position, neither opening or closing further under computer control. The shutter was then easily closed using the manual shutter control knob at the front of the unit.

Failure analysis revealed that a dry bearing condition was found to exist between the outer journal of the shutter pinion and its support bearing. This condition inhibited rotation of the pinion, not allowing the shutter to return to the fully closed position. This condition was corrected by cleaning the pinion journal and the bearing surfaces and applying a minimal amount of a very light lubricant (a type of petroleum jelly). This lubrication procedure will be added to the initial assembly procedure of the unit.

The test STEP unit was then re-installed on the Prism 3000 System and the life test was restarted.

2. After an additional 32,000 cycles (for a total of 38,472 cycles), no additional faults occurred.

4 Post Test Analysis

At the completion of the life test, the STEP Unit was removed from the Prism 3000 and inspected for stress, wear and fatigue. The unit was found to be completely functional and radiation secure. The Source Housing Assembly was disassembled and its components individually inspected with the following observations noted:

1. Shutter movements operated normally.
2. Lock to unlock movements of the shutter and housing locking ring operated normally.
3. A slight amount of "fret corrosion" was found at the drive coupling / retaining ring contact area. (A stainless steel coupling against a spring steel retaining ring - light contact).
4. A slight amount of "fret corrosion" was found to be present at the shutter knob pivot shaft. This had no detrimental effect on shutter operation.

Next the shutter drive mechanism was examined and also found to be functioning normally. It was then disassembled and inspected with the following observations noted:

1. Dirt and gumminess were found in the solenoid bore and plunger. This was attributed to the anticipated wear of the solenoid damper disc (black felt pad) attached to the face of the solenoid.
2. The shutter rotation rack was dry and gummy at the upper bushing location adjacent to the solenoid plunger. (Possible migration from the solenoid bore condition as noted in 1.)
3. The condition of the shutter pinion and its outer bearing, which was lubricated after the soft fault, was found to be satisfactory.
4. The solenoid damper disk and plunger stop disk exhibited a minor flattening due to solenoid plunger impact.
5. All other inspected parts exhibited no wear.

ITEM #5

Proposed addition of a second caution block on Page 5-4 of the Operator's Guide.



CAUTION

IF YOU ARE USING A SEALED SOURCE AND THE SOURCE DOES NOT SHAKE OUT EASILY, INSERT THE 2 1/2 INCH LONG #6 X 32 MACHINE SCREW (PROVIDED IN THE STEP KIT) INTO THE THREADED END OF THE SOURCE AND PULL THE SEALED SOURCE OUT OF THE HOLDER.

ADDENDUM #7B
PICKER OHIO IMAGING
DATE PREPARED 3/21/95
REVISION #1

ITEM #6

Proposed rewording of the cautionary statement found on Page 5-5 of the STEP Operator's Guide

CAUTION



DO NOT APPLY FORCE WHEN INSTALLING OR REMOVING THE SOURCE FROM THE SOURCE HOLDER. INTERNAL DAMAGE TO THE SOURCE HOLDER OR THE SEALED SOURCE ITSELF MAY RESULT. IF THE SOURCE DOES NOT INSTALL OR REMOVE EASILY, IMMEDIATELY CONTACT THE RADIATION SAFETY OFFICER AND YOUR SERVICE ENGINEERING REPRESENTATIVE.

**ADDENDUM #7A
PICKER OHIO IMAGING
DATE PREPARED 3/21/95
REVISION #1**

ADDENDUM #1
PICKER OHIO IMAGING
DATE PREPARED: 3/31/95
REVISION #1

STEP Source Holder

The STEP source holder is a shielded mechanized device inside of which the transmission source is located. The source holder incorporates a mechanical shutter which allows the isotope activity to be transmitted, and a collimator which focuses the transmitted activity at detector #3. The source holder also incorporates a number of mechanical safety features which prohibits the accidental opening of the shutter unless the source holder is correctly installed to the STEP drive.

SOURCE HOLDER INSTALLATION

To install the source holder, perform the following:

1. Rotate the gantry to place the STEP drive at the 2:00 position. This position is not critical, but is suggested for easy access to install the source holder. You may position the gantry elsewhere if you feel that a different position will offer you easier access.
2. Using two hands, mount the source holder to the STEP drive. Be careful to verify that the locating pins and shutter engagement hardware all line up properly.
3. With one hand supporting the source holder, turn the large locking ring approximately 45° clockwise. The source holder will be locked to the STEP drive.

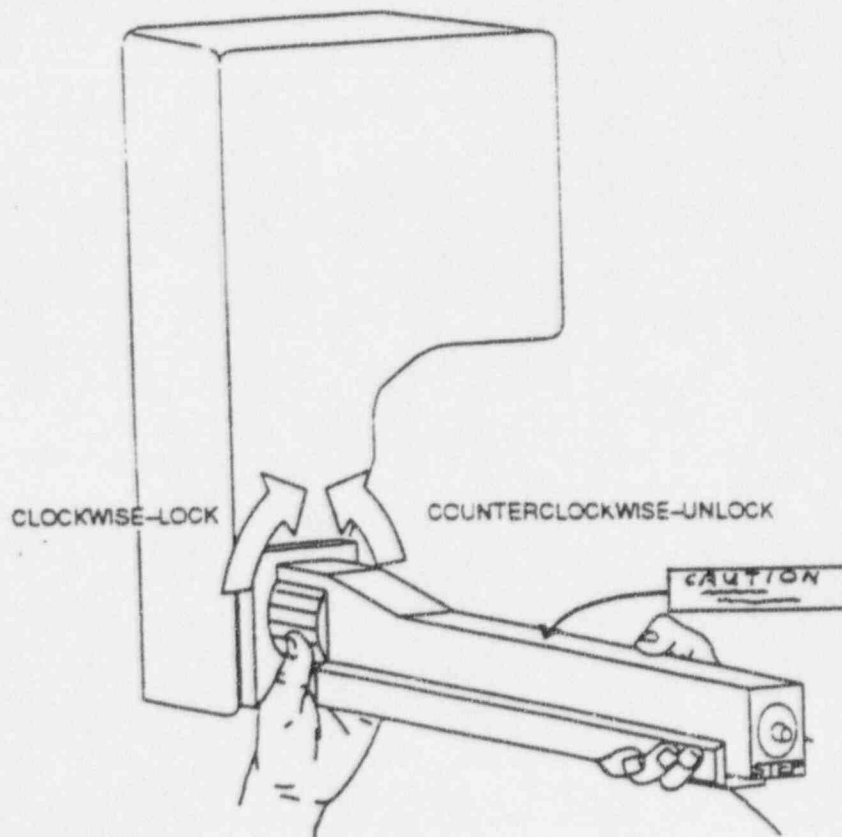



Figure 1-1

Source Holder Installation and Removal

Proposed wording on a label to be applied to the smooth top surface of the source holder as shown on Page 1-3 of the Operator's Guide.

Contains:		Gd-153, Maximum 75mCi	CAUTION RADIOACTIVE MATERIAL	
	or	Co-57, Maximum 25mCi		
	or	Tc99m, Maximum 20mCi		
Refer to STEP Operator's Guide for safe handling instructions				
The U.S. Nuclear Regulatory Commission has approved distribution of this STEP Device to persons licensed to use byproduct material identified in 10CFR 35.87 or persons who hold an equivalent license issued by an agreement state.				

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ITEM #7

Proposed rewording of item #9 as found on Page 5-4 of the STEP Operator's Guide.

9. Store the line source in the hot lab in the manufacturer's original shipping shield or equivalent complete with caution and content labeling.

**ADDENDUM #7C
PICKER OHIO IMAGING
DATE PREPARED 3/21/95
REVISION #1**



Ohio Imaging
Nuclear Medicine Division
23060 Miles Road
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Telephone: (216) 473-3000

Facsimile Cover Sheet

To:	Ms. Traci Kime
Company:	USNRC Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Safety
Phone:	310-415-5799
Fax:	301-415-5369
From	Ronald J. Martone
Company:	Picker International Ohio Imaging/Nuc.Med.Div.
Phone:	216-473-7651
Fax:	216-475-2975
Date	May 2, 1995
Total # of pages	2

Attached is an enlargement of a portion of our drawing C140406 Rev A showing the amended wording of our STEP device label as you requested by phone this morning for Mr Baggett. I hope that the enlargement allows the fax to be legible. If not, please let me know and I will mail a copy.

I assume I will be receiving a mailed copy of Mr. David Tang's letter of April 27th which had the registration certificate attached. We need it because our faxed copy is streaked due to a problem in our machine. If it was not mailed, would you please FAX me another copy to a different machine-at 216-475-2975?

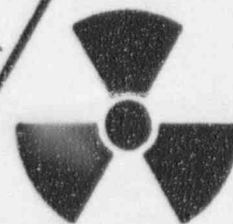
Thank you for your assistance

Ronald J. Martone
cc: Jeff Power, Hugh Morgan

Ø.30

RADIOACTIVE
VIEW I.

CAUTION RADIOACTIVE MATERIAL



Use byproduct material identified

9

8

Contains

or
or

Gd-153, Maximum 75mCi
Co-57, Maximum 25mCi
Tc-99m, Maximum 20mCi

Refer to STEP Operator's Guide for safe handling instructions
The U.S. Nuclear Regulatory Commission has approved distribution of this STEP device to persons licensed to use byproduct material identified in 10 CFR Part 20 or persons who hold an equivalent license issued by an agreement state.

10.0

TOLERANCE

.x
.xx
.xxx
.xax'x'
UNLESS

Note

(±.05)