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ELGEMS

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TO : Seung Lee – NRC fax 301-415-5369
FROM : Sergio Steinfeld – Elgems
CC : Jim Beebe – GEMS fax 414-548-5197

Dear Mr. Lee

21/10/99

The letter bellow (12 pages) provides the required information you asked in your E-mail of 12/10/99. The answers are in bold letters just after your question.

The following appendices are attached

- Lead Shipping Container – QC instructions D/N 410-3102-0303 (pages 5,6,7)
- DuPont Letter – Subject : Information for Gd-153 Source (pages 8,9,10,11)
- Test Report – Radiation Leakage from the Transmission Source Lead Shipping Container (page 12)

Let me clarify some important points regarding to the source shipping path:

- a) **The SS&D registration certificate MA-0476-S-117 is the certification of the Transmission line source manufactured by DuPont.**
- b) **This thin line source is glued by DuPont to a source holder. All this procedure was already explained in the original submission file on April 99, page 3 – “ Description of the shielding and method for securing the source in device.”**
The information about the gluing procedure, materials and methodology, was explained in page D-3, appendix D, of the original submission file (letter from DuPont).
- c) **This source holder is inserted by DuPont into a lead shipping container. This lead shipping container is manufactured by Elgems and provided to DuPont for this purpose. The engineering drawings of this lead shipping container were included in appendix H of the original submission file (page H-4 , ASSY18 - 119170000).**
There is another engineering drawing of the lead shipping container in the attached DuPont letter (page 11 , B003564 /sheet 2).
- d) **Then, DuPont accommodate one lead shipping container into a carton box. DuPont will send two carton boxes to the site. The information of**

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this carton box was explained in appendix H, page H-3, on the original submission file. A engineering drawing of the box is attached to this letter (see letter from DuPont, page 11, No. B003564/sheet 2 - FINAL TYPE A PACKAGE)

- e) In the site, following the instructions in the MG ATC Service Manual, section 3.5, the field engineer will remove the source holder from the lead shipping container and insert it into the Rod device. This procedure is done for each Rod device.

Now, to your specific questions :

1. The SS&D registration certificate MA-0476-S-117-S dated 4/1/1999 stated that lead storage tube is no longer described in the certificate. Please clarify the following:
1. Who is responsible for manufacturing the lead shipping container having two line sources? Provide the QA/QC for the lead shipping container.

a) The lead shipping container has only one source holder with the thin line source glued. This lead shipping container is manufactured by Elgems.

QA/QC on Elgems

- All the parts of the lead shipping container are inspected according to the production engineering draws (see the original submission file, appendix H, page H-4 / H-17).
- After completion of the assembly, the unit is inspected before sending it to DuPont (see attached document pages 5,6,7 - Source Shipping Container - QC instructions D/N 410-3102-0303).

Note: Elgems products are manufactured and tested in accordance to FDA's Good Manufacturing Practices (GMP), ISO 9001 (quality system standard) and EN46001 (quality system standard for medical devices) . See Appendix I in the original submission file.

QA/QC on DuPont

- Attached the answer letter of DuPont, pages 8,9,10 &11, (Fax dated October 15, 1999) with the subject : Information for Gd-153 source. Important note : DuPont named the lead shipping container as *lead shield* and the carton box as the *shipping box*.

From the letter :

"After the source is loaded into the source holder and lead shield, the following quality control check are performed:

1. The orientation of the source holder is confirmed to be corrected.

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2. A wipe test of the surface of the shield is performed and the acceptance limit is 0.0005 uCi
3. A visual inspection for accuracy of the source label and inserts is performed. "

b) The carton box is manufactured by DuPont.

QA/QC

- From the letter of DuPont :

" After the source and shield are packaged in the shipping box, the following checks are performed :

1. The DOT label is properly applied.
2. The external radiation level is within regulatory limits."

2. Provide the details for the shipping container label and the organization that is responsible for ensuring the accuracy and correctness of the lead shipping containers

The labels are defined as follows:

a) On the lead shipping container, the label details are

- Warning Message & Symbol (Radioactive Material)
- Transmission Line Source
- NES 8429 Radionuclide :Gd-153
- Activity: 16.6 GBq Date : -/-
- Lot Number : S8429XXX-GXXXX
- Manufacturer (DuPont)

A sample of this label can be found on Appendix E, Labels, page E-7 on the original submission file.

b) On the carton box, the label details are (see attached in the DuPont Letter, page 9, a copy of the DOT label) :

- Warning Message & Symbol (Radioactive Material)
- Contents : Gd153
- Activity : 16.6 GBq

Note 1 : Both labels are manufactured by DuPont. DuPont is responsible for ensuring the accuracy and correctness of the labels.

Note 2: A manufacturing report is included into the carton box. I sent you a copy of this evaluation sheet attached to my letter of 25/8/99.

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3. The Appendix H shows the details of a source container. Clarify if this is shipping container to be used for transporting the raw sources to the users.

Appendix H (page H-4/17) shows the engineering drawings of manufacturing and assembly of the lead shipping container.

As explained before, DuPont will accommodate the lead shipping container into a carton box which, will be used for transporting the source to the user.

4. How is the thin source supported inside the lead shipping container? Provide the details for the supporting mechanism.

The thin source is glued to a groove on a source holder (page 3 on the original submission file - "Description of the shielding and method for securing the source in device").

The information about the gluing procedure, materials and methodology, was explained in page D-3, appendix D, of the original submission file (letter from DuPont).

5. The page F-14 reveals the corrected radiation profile with a source. Write the radiation profile for two sources with the maximum allowed activity of 540 mCi.

Attached Test Report (page 12) : Radiation Leakage from the Transmission Source Lead Shipping Container.

If you have any questions, please call me at (972) 4 8563642 (fax 972-4-577662) or send me an E-mail to sergio_steinfeld@elgems.com .

Regards
Sergio Steinfeld



ELGEMS

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Part : P/N 1191700005 -- MG ATC Lead Shipping Container

Date : _____

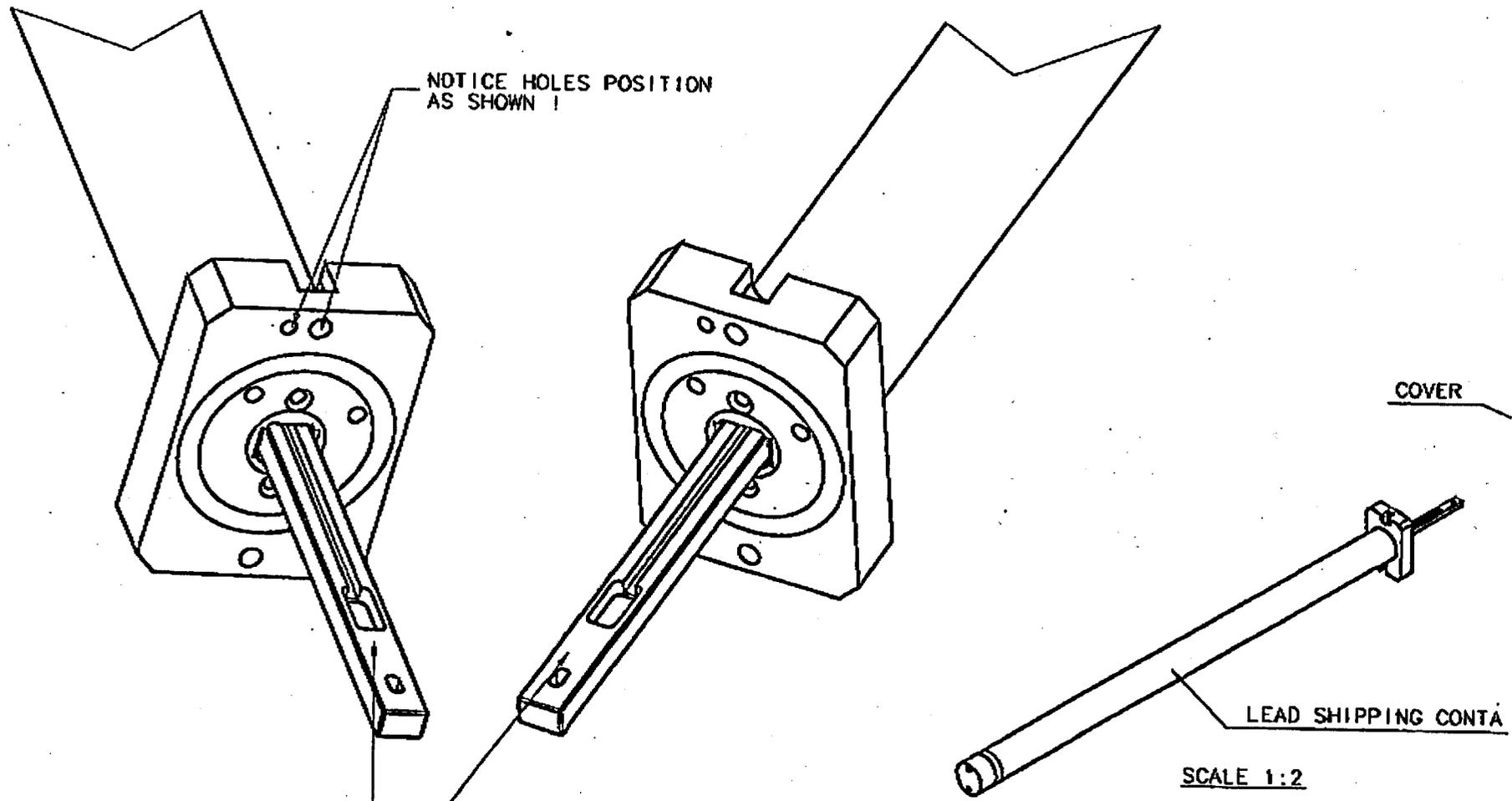
Checked by : _____

Signature : _____

Test	Expected Result	Pass/Fail
Visually check the assembled part for any external damage	No external damage	
Check if any internal parts are loose and if any screws are not fully tightened.	No internal parts loose. Screws fully tightened.	
Disassembled the cover from the container and manually insert the source holder p/n 119040005 all the way in (see drawing MEC-005512).	Insertion/removing should be smooth with no internal obstacles or friction.	

DOCUMENT NAME: Lead Shipping Container -QC instructions	D/N: 410-3102-0303	REV: 0
PRINTING DATE: 8/3/98	PAGE 2 OF 2	File Name: F:\APPS\ARCHIVE\3102\41031020303.DOC

ZONE	DESCRIPTION	APPR.	DATE
	NEW DOCUMENT		28.09.98



THIS FACE MUST BE UP !
SOURCE HOLDER P/N 119040005

DESIGNER	DANNY E.	DATE	28.09.98	EUROPEAN PROJECTION	EQUIPMENT	ASSEMBLY NAME
REVISION	DANNY E.		28.09.98	DEFAULT DIMENSIONS : MIL	MG-ATC	LEAD SHI
CHECKER	VOSSI A.			FINISH		No. 119.1
APPROVAL	VOSSI A.				SCALE	NAME
					1.0:1.0	SOURCE HOLDER MOUNTIN
 POB 170 Tirat HaCarmel 30200 ISRAEL				TOL. NOT SPECIFIED :	DR. THE	DRAWING No.
					2	MEC-005512-
Project : MG-DIMY. Item : MEC05512. 14-01-99 18:46				LAST BY	SHEET 1 OF 1	
				Old Part number :		

October 15, 1999

To: Ron Brown

From: John Sumares

John Sumares

Subject: Information for Gd-153 Sour

Post-It® Fax Note	7671	Date	10/20/99	# of pages	4
To	SERGIO STEINFELD	From	R. BROWN		
Co./Dept.	ELGEMS	Co.	DUPONT		
Phone #		Phone #			
Fax #	972 4 8577 662	Fax #	978 663 0351		

The following information may be provided to 'Elgems' in order for NRC to complete the evaluation of their line source holder.

LABELING INFORMATION - NRC had requested to add a line for "maximum activity" on our source labels.

I spoke with Seung Lee on 10/8/99 about this request. I explained to him that all source identification labels have nominal activity and date. These labels had been reviewed by NRC and approved. I gave him the Gd-153 line source registration number so that he may review this information. Mr. Lee stated that he would speak with other reviewers at NRC and call me on 10/12. During the week of 10/12 to 10/15 I have been unable to speak with Seung Lee to obtain his response, but I will continue to call him.

LABEL FOR CARTON BOX - Elgems wants a copy.

Attached is a copy of the DOT label which is applied to the outside of the carton box for shipping sources.

QUALITY CONTROL OF LEAD SHIELDS AND SHIPPING CONTAINER

After the source is loaded into the source holder and lead shield, the following quality control checks are performed:

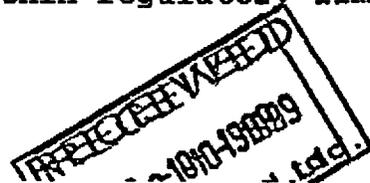
1. The orientation of the source holder is confirmed to be correct.
2. A wipe test of the surface of the shield is performed and the acceptance limit is 0.0005 µCi.
3. A visual inspection for accuracy of the source label and inserts is performed.

The QC inspection report, an internal document, indicates the testing and inspection performed on a source and that a source meets specifications.

After the source and shield are packaged in the shipping box, the following checks are performed:

1. The DOT label is properly applied.
2. The external radiation level is within regulatory limits.

Cc: K. Allberg
G. Tercho





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MG AC Project

Radiation Leakage from the Transmission Source Lead Shipping Container.

Wednesday 13 October 1999

In the table below it is represented the radiation exposure from 2 transmission sources with the maximum allowed activity of 540 mCi for each one, shielded into lead shipping containers and placed inside shipping cartoon box. The maximal values of the radiation exposure rate are represented at contact handling to the center, front and rear side of the container.

	Radiation exposure rate [mrem/hour]
Background	0.006
Front end	0.020
Rear end	0.041
Center	0.014

Leonid Tsukerman, Ph.D
Radiation Safety Officer.

Steinfeld Sergio

From: Steinfeld Sergio
Sent: 16:35 1999 21 יום חמישי אוקטובר
To: Seung Lee (E-mail); James Beebe (E-mail)
Cc: Tsukerman Leonid
Subject: MG ATC Response letter

Dear Mr. Lee

I just fax you the response letter (12 pages) to your E-mail of 12/10/99.

The letter includes :

- page 1,2,3,4 – answers to the questions
- page 5,6,7 – Lead shipping container –
QC instructions d/n 410 3102 0303
- pages 8,9,10,11 – DuPont Letter : Information for
Gd-153 source & QC
- page 12 – Test Report – Radiation Leakage from the
transmission Source Lead Shipping Container.

**In order to facilitate you the review,
please stamp together**

- pages 1,2,3 & 4 (Answers)
- pages 5,6 & 7 (Elgems QC)
- pages 8,9,10 & 11 (DuPont Letter)

**If some of the pages is not clear , let me know in order to re-send.
If you have any question , please send me back an E-mail.**

THANK YOU

**Regards
Sergio Steinfeld**