

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: CA-0406-S-219-S
(Supercedes MA0476S108S)

DATE: August 6, 2001

PAGE: 1 OF 7

SEALED SOURCE TYPE: X-Ray Fluorescence Source

MODEL:

NER-372

NER-465 with three capsule designations – LE66, LE66A, and LE66B

NER-465S with three capsule designations – LE316, LE316A, and LE316B

NER-467 with three capsule designations – LE66, LE66A, and LE66B

NER-472 with three capsule designations – LE316, LE316A, and LE316B

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories (IPL)
24574 Avenue Tibbitts Avenue
Valencia, CA 91355
Phone: (818) 843-7000
Fax: (818) 843-6168

ISOTOPE: Cobalt-57 and Cedmium-109

<u>Model Number:</u>	<u>Isotope:</u>	<u>Maximum Activity</u>
NER-372	Cobalt-57	100 millicuries (3.7GBq)
NER-465	Cadmium-109(R)*	300 millicuries (11.1 GBq)
NER-465S	Cadmium-109(R)*	300 millicuries (11.1 GBq)
NER-467	Cadmium-109(A)*	100 millicuries (3.7 GBq)
NER-472	Cobalt-57	1000 millicuries (37 GBq)

* note: (R) denotes reactor grade and (A) denotes accelerator grade

LEAK TEST FREQUENCY:

Six (6) months

PRINCIPAL USE:

(U) X-Ray Fluorescence Source

CUSTOM SOURCE:

_____ YES X NO

NMS 5/2

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SEALED SOURCE TYPE: X-Ray Fluorescence Source

DESCRIPTION:

The NER-372 source consists of Co-57 as cobalt metal that is electroplated onto a 2 mil thick copper foil. The foil is then melted to form a 0.04" dia. bead, and the bead is inserted into a stainless steel capsule. A stainless steel plug is T.I.G. (Tungsten Inert Gas) welded to the capsule to form a hermetic seal. The cylindrical source capsule is 0.12" in diameter, and 0.20" in height.

The NER-465S consists of Cd-109(R) as cadmium metal that is electroplated onto 2 mil thick silver foil. The active foil is placed inside a stainless steel capsule with a 10 mil thick "window". A tungsten alloy disc is placed behind the active foil and a stainless steel cover is press fit into the capsule. The capsule and cover are T.I. G. welded together to form a hermetic seal. The capsule has three sizes having designations LE316, LE316A, and LE316B.

The NER-472 source consists of Co-57 as cobalt metal that is electroplated onto 2 mil thick nickel foil. The active foil is placed inside a stainless steel capsule with a 10 mil thick "window". A tungsten alloy disc is placed behind the active foil and a stainless steel cover is press fit into the capsule. The capsule and cover are T.I.G. welded together to form a hermetic seal. The capsule has three sizes having designations LE316, LE316A, and LE316B.

<u>Capsule Designation</u>	<u>Capsule Diameter</u>	<u>Capsule Height</u>
LE316	0.31"	0.20"
LE316A	0.45"	0.25"
LE316B	0.60"	0.33"

The NER-465 source consists of Cd-109(R) as cadmium metal that is electroplated onto 2 mil thick silver foil. The active foil is placed inside an aluminum capsule with a 6 mil thick "window". A silver disc is placed behind the active foil and an aluminum cover is press fit into the capsule. The capsule and cover are T.I.G. welded together to form a hermetic seal. The capsule has three sizes having designations LE66, LE66A, LE66B.

The NER-467 source consists of Cd-109(A) as cadmium metal that is electroplated onto 2 mil thick silver foil. The active foil is placed inside an aluminum capsule with a 6 mil thick "window". A silver disc is placed behind the active foil ad an aluminum cover is press fit into the capsule. The capsule and cover are T.I.G. welded together to form a hermetic seal . The capsule has three sizes having designations LE66, LE66A, and LE66B.

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SEALED SOURCE TYPE: X-Ray Fluorescence Source

<u>Capsule Designation</u>	<u>Capsule Diameter</u>	<u>Capsule Height</u>
LE66	0.31"	0.20"
LE66A	0.45"	0.25"
LE66B	0.60"	0.33"

LABELING:

The model NER-372 is permanently marked by engraving with the source model number. A self-adhesive identification label showing the isotope, activity, date of measurement, model number and serial number, as well as the words "Caution Radioactive Material", is affixed to the outside of the lead shield storage container.

The NER-465, NER-465S, and NER-467 sources are permanently marked by engraving with "Cd-109", serial number, model number, and trefoil symbol. A source identification label which contains the trefoil and the words "Caution Radioactive Material" is affixed to the outside of the source shield.

The NER-472 source is permanently marked by engraving with "Co-57", serial number, model number, and trefoil symbol. A source identification label which contains the trefoil and the words "Caution Radioactive Material" is affixed to the outside of the source shield.

DIAGRAM:

- NER-372: Refer to drawing numbers B002790 (Attachment 1).
- NER-465: Refer to drawing numbers 313-407 and B002606 (Attachments 2 and 3).
- NER-465S: Refer to drawing numbers 33A-047 (Attachment 4).
- NER-467: Refer to drawing numbers 313-36 (Attachment 5).
- NER-472: Refer to drawing numbers 313-37 (Attachment 6).

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SEALED SOURCE TYPE: X-Ray Fluorescence Source

CONDITIONS OF NORMAL USE:

The NER-372 point source and the NER-465, NER-465S, NER-467, and NER-472 disc sources are designed for low energy (<200 keV) gamma photon emission applications such as X-ray fluorescence. These sources are usually affixed inside portable instruments which perform X-ray fluorescence analysis. The environmental conditions are not expected to exceed conditions where electronic instruments can be safely operated.

PROTOTYPE TESTING:

The NER-372 X-ray fluorescence source has been designed and tested to qualify for ANSI N542-1977 performance classification 77C43333.

The NER-465S and NER-472 X-ray fluorescence sources have been designed and tested to qualify for ANSI N542-1977 performance classification 77C66544.

The NER-465 and NER-467 X-ray fluorescence sources have been designed and tested to qualify for ANSI N542-1977 performance classification 77C43343.

EXTERNAL RADIATION LEVELS:

NER-372

Contact to source surface	580 mR/hr/mCi
At 5 cm. from source surface	12 mR/hr/mCi
At 30 cm. from source surface	0.8 mR/hr/mCi
At 100 cm. from source surface	0.15 mR/hr/mCi

Dose rates were obtained using a calibrated Victoreen 450B ion chamber survey meter.

NER-465

Contact to source surface	23 mR/hr/mCi
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SEALED SOURCE TYPE: X-Ray Fluorescence Source

At 5 cm. from source surface	7 mR/hr/mCi
At 30 cm. from source surface	0.3 mR/hr/mCi
At 100 cm. from source surface	<0.1 mR/hr/mCi

NER-465S

Contact to source surface	6.7 mR/hr/mCi
At 5 cm. from source surface	0.5 mR/hr/mCi
At 30 cm. from source surface	<0.1 mR/hr/mCi
At 100 cm. from source surface	<0.1 mR/hr/mCi

NER-467

Contact to source surface	23 mR/hr/mCi
At 5 cm. from source surface	7 mR/hr/mCi
At 30 cm. from source surface	0.3 mR/hr/mCi
At 100 cm. from source surface	<0.1 mR/hr/mCi

NER-472

Contact to source surface	24.6 mR/hr/mCi
At 5 cm. from source surface	28 mR/hr/mCi
At 30 cm. from source surface	0.7 mR/hr/mCi
At 100 cm. from source surface	0.16 mR/hr/mCi

Dose rates were measured by TLD chip exposure.

QUALITY ASSURANCE AND CONTROL:

Source construction and assembly design details are maintained by conformance to drawings 313-36, 313-37, 313-407, 33A-047, B0022606 and B002790. All components and labels are subjected to incoming inspection and testing per written procedures. Quality Control provides test data verification and/or review for the following tests: nominal activity measurement, smear

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SEALED SOURCE TYPE: X-Ray Fluorescence Source

test measurement, visible defects caused by improper assembly, and inspection to ensure proper labeling of source and storage container. The sources are manufactured and distributed under the guidelines of Isotope Products Laboratories' quality assurance and control program. The California Department of Health Services has deemed the program acceptable for licensing purposes. A copy of the program is on file with the California Department of Health Services.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The NER-372, NER-465, NER-465S, NER-467, and NER-472 X-ray fluorescence sources are capable of withstanding normal conditions of use and they shall not be subjected to environmental conditions which exceed their ANSI N542-1977 performance classifications.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination.
- This registration certificate and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.
- The source shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission, a Licensing State or an Agreement State.
- Handling, storage, use, transfer, and disposal to be determined by the licensing authority but should be, at a minimum, in accordance with the product information pamphlet provided by the distributor.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model NER-372, NER-465, NER-465S, NER-467, and NER-472 X-ray fluorescence sources, their ANSI N542-1977 classifications, and the information and test data cited below, we conclude that the sources are acceptable for specific licensing purposes.

Furthermore, we conclude that these sealed sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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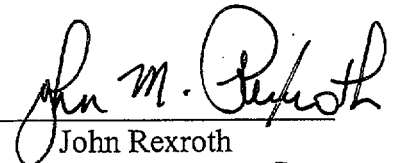
SEALED SOURCE TYPE: X-Ray Fluorescence Source

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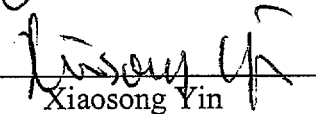
The following supporting documents for the NER-372, NER-465, NER-465S, NER-467, and NER-472 X-ray fluorescence sources are hereby incorporated by reference and are made a part of this registry document.

- DuPont Pharmaceuticals' letters dated July 29, 1999, and September 10, 1999, with enclosures thereto, and their fax dated September 2, 1999.
- DuPont Pharmaceuticals' letter dated April 30, 1999.
- DuPont Pharmaceuticals' letter dated February 15, 1999, with enclosures thereto.
- DuPont Pharmaceuticals' application dated January 16, 1997, with enclosures thereto.
- DuPont Pharmaceuticals' letters dated March 24, 1995, October 6, 1994, September 17, 1993, January 24, 1989, October 28, 1988, and September 19, 1988.
- Isotope Products Laboratories' letter July 26, 2000 with enclosures thereto.

DATE: August 6, 2001 REVIEWED BY: _____


John Rexroth

DATE: August 6, 2001 CONCURRED BY: _____


Xiaosong Yin

ISSUING AGENCY: California Department of Health Service

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCE

NO.: CA-0406-S-219-S

DATE: August 6, 2001

ATTACHMENT: 1

(Supersedes MA0476S108S)

REV. NO.	NO.	REVISION	BY	DATE	APPROVED
A		REVISE PER CDCO NO. 92205-178	JCS	6/11/99	

NOTES

- SOURCE MATRIX IS CD-57 AS Cd METAL ELECTROPLATED ON 2 MIL THICK COPPER FOIL TO FORM A BEAD AND INSERTED INTO OUTER CAPSULE. CAPSULE COVER CONTACTS BEAD DURING ASSEMBLY TO RESTRAIN ACTIVE MATRIX.
- NOMINAL ACTIVITY TO BE 13 MCI (+15%, -10%) REFERENCED TO LABEL DATE. TOTAL CD-56/58 CONTENT TO BE 0.02% MAX OF TOTAL CD-57 CONTENT.
- ANSI NS42-1977 PERFORMANCE CLASSIFICATION 77C43233.
- LEAK TEST PER ANSI NS42-1977 PROCEDURES A2.1 (SHEAR TEST) OR A2.3 (IMMERSION TEST). LIMIT TO BE 1 X 30⁻⁹ LCI.
- FINAL ASSEMBLY MAY CONSIST OF A SOURCE IN A 1/8" THICK LEAD SHIELD (452089) WITH 1/2" FOAM ABOVE AND BELOW SOURCE AND SECURED WITH A SHIELD CAP (452075). AFTER IDENTIFICATION LABEL TO OUTSIDE OF LEAD SHIELD. LEAD SHIELD TO BE WRAPPED WITH KIRKPACK AND PLACED INTO WHITE PLASTIC CAN (452993) WITH CAP (452987). AFTER IDENTIFICATION LABEL TO OUTSIDE OF WHITE CAN. LABELLING AND INSERTS PER LABELLING BLD.
- MAXIMUM ACTIVITY FOR THE NER-372 SOURCE TO BE 100 MCI.

PART OR EQUIPMENT NO.	DESCRIPTION	REV.	QTY
318L STN. STL	DuPont Pharmaceuticals Company		
8002789	SOURCE ASSEMBLY	1/2/94	A
8002790	NER-372 PROTOTYPE SOURCE ASSEMBLY (RMD INC.)		
8002790	HEAD N.T.S.	B	8002790

SECTION A-A

ENGRAVING DETAIL

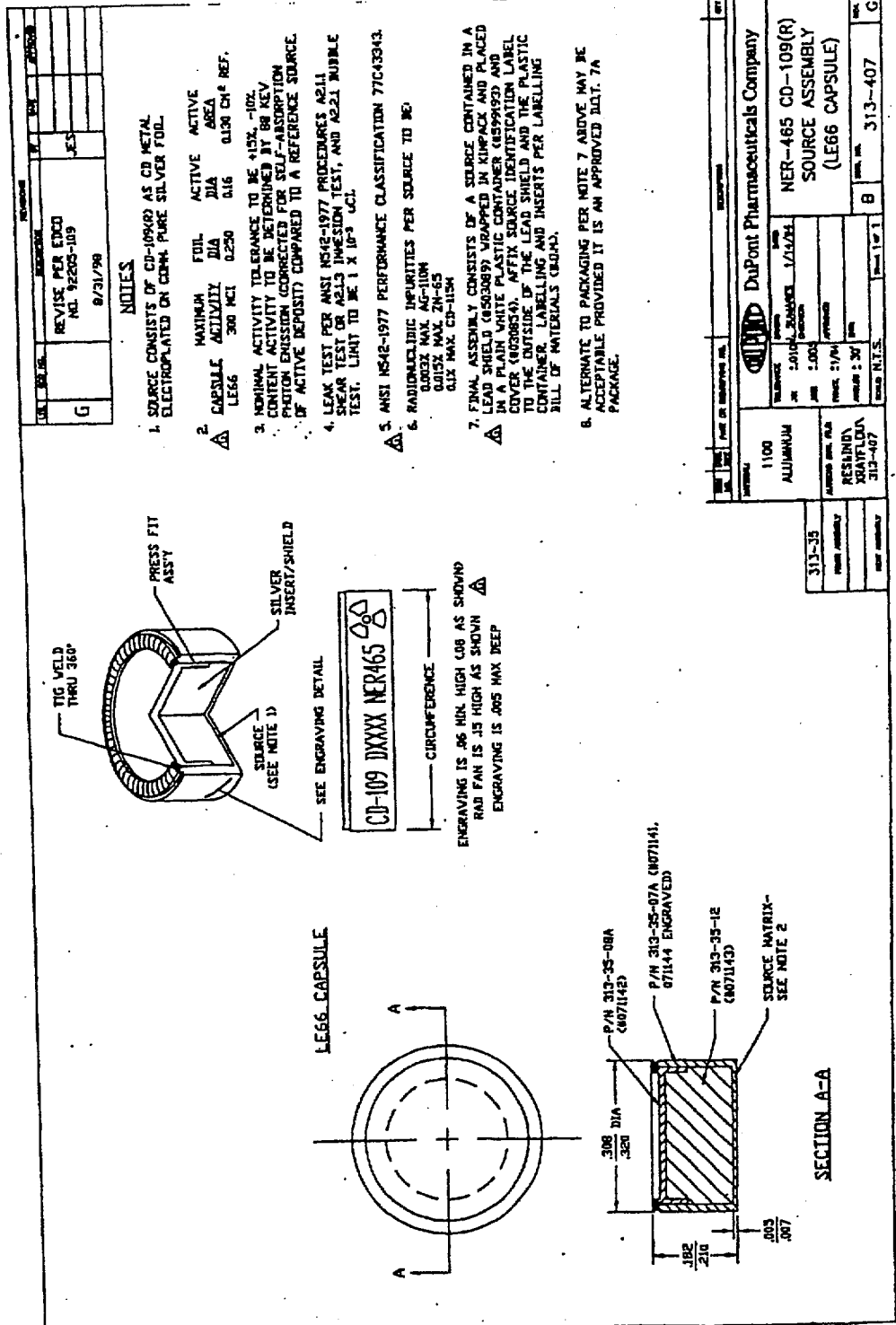
NOTE: LASER ENGRAVE NER372 INTO CAPSULE AS SHOWN AS MUCH X .005 MAX. DEEP - WIDTH FACTOR = 0.5

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ATTACHMENT: 2



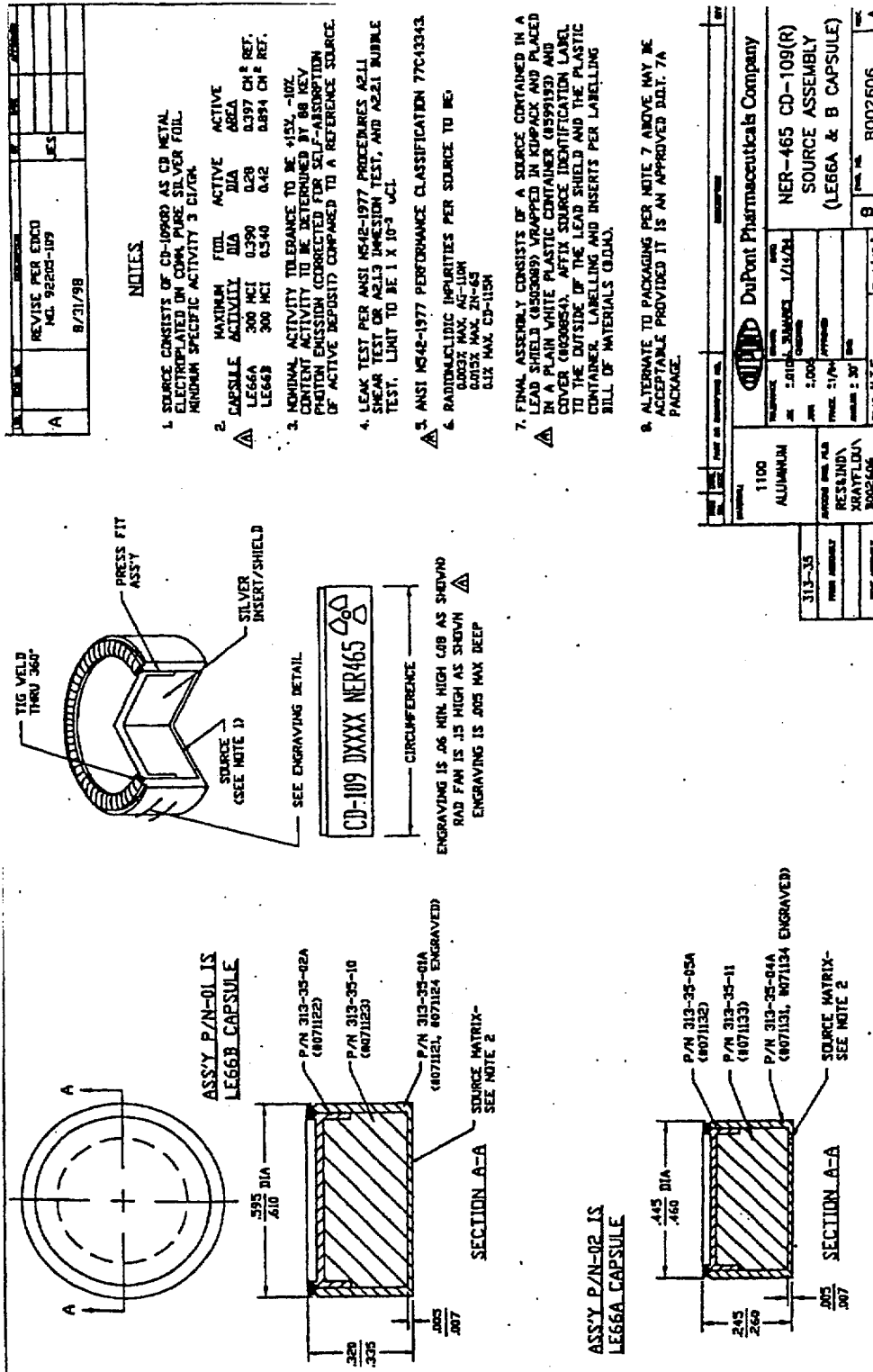
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES

SAFETY EVALUATION OF SEALED SOURCE

NO.: CA-0406-S-219-S
(Supercedes MA0476S108)

DATE: August 6, 2001

ATTACHMENT: 3

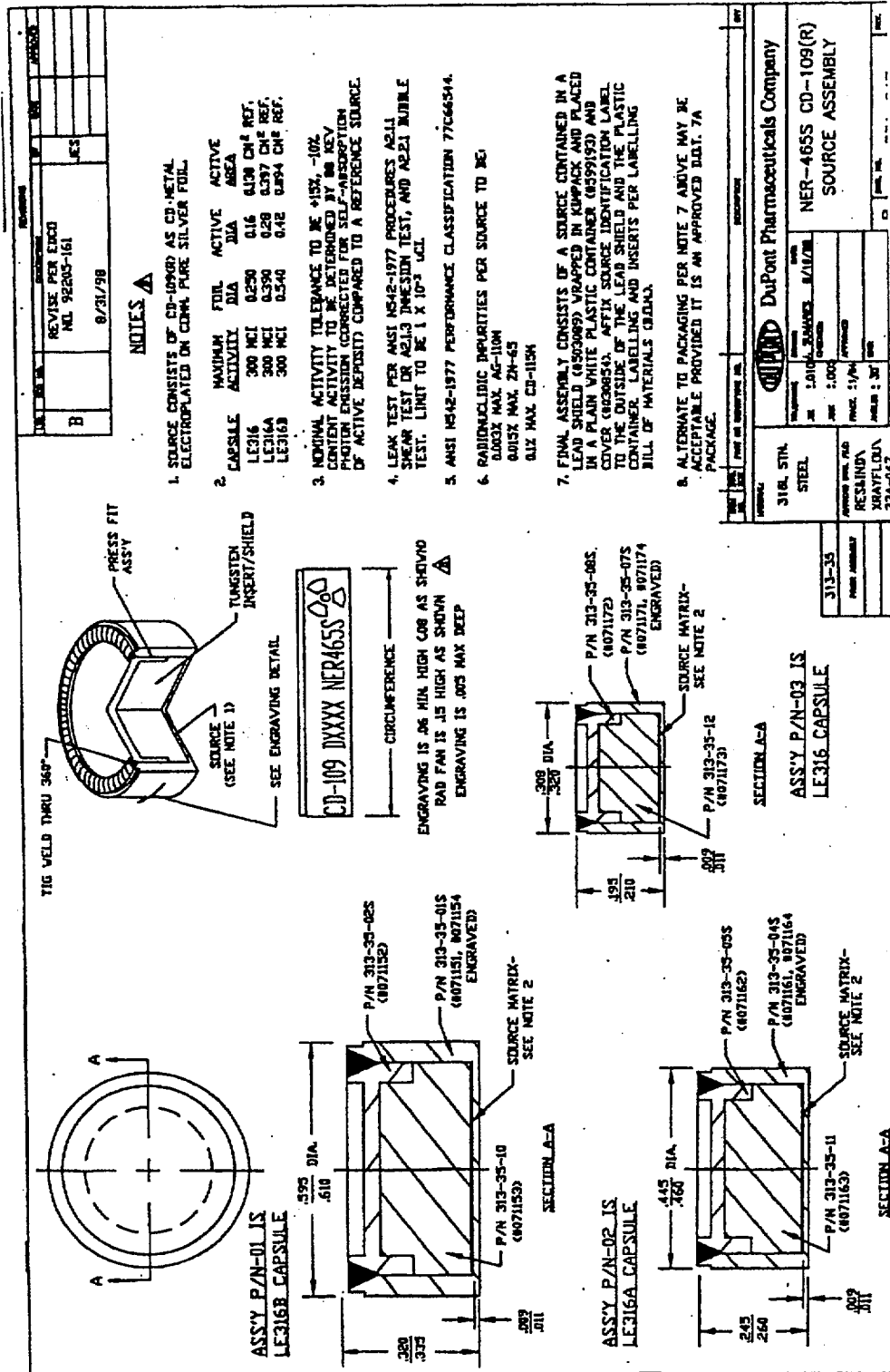


REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCE

NO.: CA0406S219S
(Supercedes MA0476S108)

DATE: August 6, 2001

ATTACHMENT: 4



NOTES

1. SOURCE CONSISTS OF CD-109(R) AS CD-METAL ELECTROPLATED ON COPPER PURE SILVER FOIL.
2. CAPSULE ACTIVE AREA

MAXIMUM ACTIVITY	DIAMETER	ACTIVE AREA
300 MCI	0.250	0.16 CM ² REF.
300 MCI	0.330	0.28 CM ² REF.
300 MCI	0.540	0.84 CM ² REF.
3. NOMINAL ACTIVITY TOLERANCE TO BE +15%, -10%. CONTENT ACTIVITY TO BE DETERMINED BY 90 KEV PHOTON EMISSION CORRECTED FOR SELF-ABSORPTION OF ACTIVE DEPOSIT COMPARED TO A REFERENCE SOURCE.
4. LEAK TEST PER ANSI N542-1977 PROCEDURES A2.11 SHEAR TEST OR A2.13 IMMERSION TEST, AND A2.21 RUBBLE TEST. LIMIT TO BE 1×10^{-3} UCL.
5. ANSI N542-1977 PERFORMANCE CLASSIFICATION 77C66514.
6. RADIOLOGIC IMPURITIES PER SOURCE TO BE

0.003X MAX. AC-110M
0.015X MAX. ZN-65
0.12X MAX. CD-115M
7. FINAL ASSEMBLY CONSISTS OF A SOURCE CONTAINED IN A LEAD SHIELD (4500099) WRAPPED IN KOMPACT AND PLACED IN A PLAIN WHITE PLASTIC CONTAINER (4599193) AND COVER (460854). AFFIX SOURCE IDENTIFICATION LABEL TO THE OUTSIDE OF THE LEAD SHIELD AND THE PLASTIC CONTAINER. LABELLING AND INSERTS PER LABELLING BILL OF MATERIALS (1040).
8. ALTERNATE TO PACKAGING PER NOTE 7 ABOVE MAY BE ACCEPTABLE PROVIDED IT IS AN APPROVED DIST. 7A PACKAGE.

REV.	DATE	DESCRIPTION

DuPont Pharmaceuticals Company	
316L STN. STEEL	NER-4655 CD-109(R) SOURCE ASSEMBLY
DESIGNED BY: J. J. JAMES	DATE: 11/10/78
DRAWN BY: J. J. JAMES	DATE: 11/10/78
CHECKED BY: J. J. JAMES	DATE: 11/10/78
APPROVED BY: J. J. JAMES	DATE: 11/10/78

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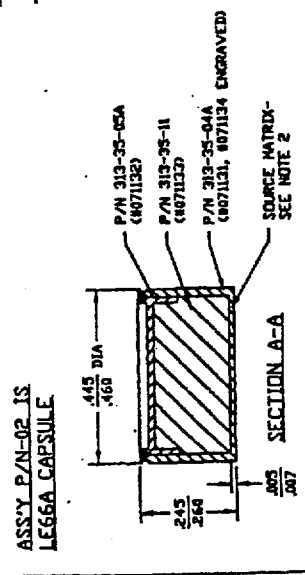
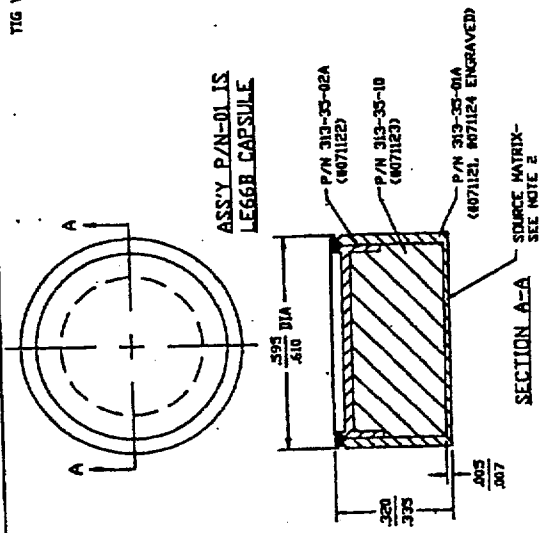
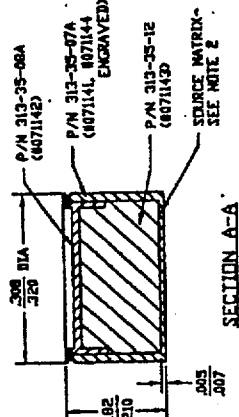
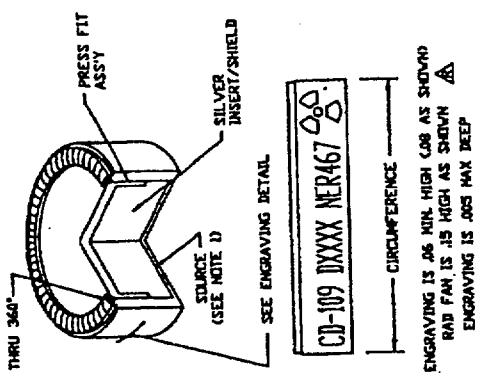
ATTACHMENT: 5

REVISE PER EDCO NO. 92205-100 8/31/98	JCS
R	

NOTES

- SOURCE CONSISTS OF CD-109(A) AS CD METAL ELECTROPLATED IN COPPER PURE SILVER FOIL.
- | MAXIMUM ACTIVITY | FOIL DIA | ACTIVE AREA |
|------------------|----------|----------------------------|
| LE66 100 MCI | 0.250 | 0.130 CM ² REF. |
| LE66A 100 MCI | 0.390 | 0.397 CM ² REF. |
| LE66B 100 MCI | 0.540 | 0.894 CM ² REF. |
- NOMINAL ACTIVITY TOLERANCE TO BE +15%, -10%. CONTENT ACTIVITY TO BE DETERMINED BY 60 KEV PHOTON EMISSION CORRECTED FOR SELF-ABSORPTION. OF ACTIVE DEPOSIT COMPARED TO A REFERENCE SOURCE.
- LEAK TEST PER ANSI N412-1977 PROCEDURES A2.11 SHEAR TEST OR A2.13 DIMENSION TEST, AND A2.21 BUBBLE TEST. LIMIT TO BE 1 X 10⁻⁹ C/L.
- ANSI N542-1977 PERFORMANCE CLASSIFICATION 77C43343.
- RADIOISOTOPIC IMPURITIES PER SOURCE TO BE:

Co	0.1X
Fe	0.1X
Cr	0.1X
Ni	0.1X
Mn	0.1X
Cu	0.1X
Zn	0.1X
Pb	0.1X
Bi	0.1X
Ag	0.1X
Cd	0.1X
Sn	0.1X
As	0.1X
Sb	0.1X
Te	0.1X
Se	0.1X
Mo	0.1X
W	0.1X
V	0.1X
Nb	0.1X
Ta	0.1X
P	0.1X
Si	0.1X
B	0.1X
Al	0.1X
Mg	0.1X
Ca	0.1X
Na	0.1X
K	0.1X
Li	0.1X
H	0.1X
O	0.1X
- FINAL ASSEMBLY CONSISTS OF A SOURCE CONTAINED IN A LEAD SHIELD (1503089) WRAPPED IN KIMPACK AND PLACED IN A PLAIN WHITE PLASTIC CONTAINER (1899193) AND COVER (1030854). ATTIX SOURCE IDENTIFICATION LABEL TO THE OUTSIDE OF THE LEAD SHIELD AND THE PLASTIC CONTAINER LABELLING AND INSERTS PER LABELLING BILL OF MATERIALS (1000).
- ALTERNATE TO PACKAGING PER NOTE 7 ABOVE MAY BE ACCEPTABLE PROVIDED IT IS AN APPROVED I.D.I.T. 7A PACKAGE.



1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36

DuPont Pharmaceuticals Company	
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36
NER-467 CD-109(A) SOURCE ASSEMBLY	
313-35	313-36
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36
1100 ALUMINUM	RESIN/INDY XRAY/FLDN 313-36
313-35	313-36

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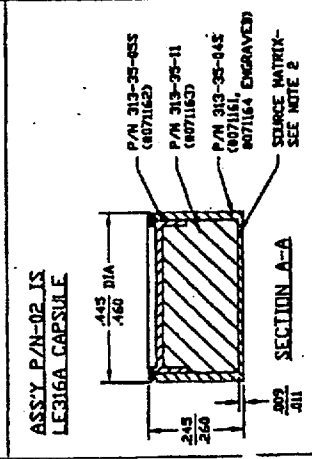
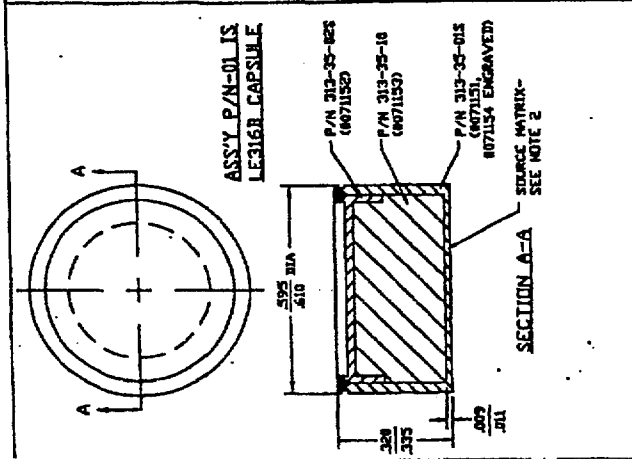
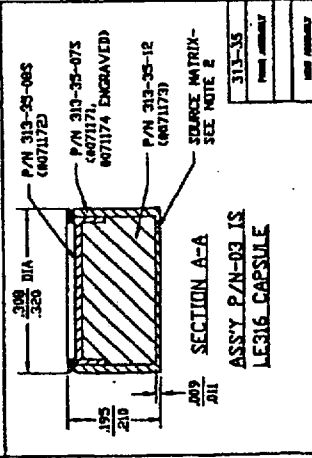
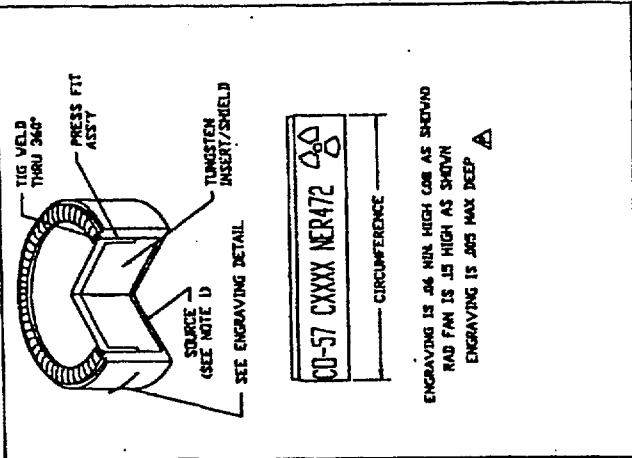
ATTACHMENT: 6

REV	DATE	DESCRIPTION	BY	CHK	PROB
P		REVISE PER ENCO NO. 92205-151	JES		
	8/21/98				

NOTES

- SOURCE MATRIX CONSISTS OF CO-57 AS CO METAL - ELECTROPLATED ON 2 MIL THICK NICKEL FIBRILS.
- CAPSULE FOIL DIA ACTIVE DIA
0.250 0.16
LE316A 0.350 0.28
LE316B 0.540 0.42
- MAXIMUM ACTIVITY CONTENT TO BE 1000 MCI.
- NOMINAL ACTIVITY TOLERANCE TO BE +15% -JOK REFERENCED TO LABEL DATE.
- LEAK TEST PER ANSI N542-1977 PROCEDURES A211 SHEAR TEST OR A213 IMMERSION TEST, AND A222 BUBBLE TEST. LIMIT TO BE 1 X 10⁻⁹ UCI.
- ANSI N542-1977 PERFORMANCE CLASSIFICATION 77066544.
- TOTAL CO-56/58 CONTENT SHALL BE < 0.2% OF TOTAL CO-57 CONTENT. REPORT CO-56 AND CO-58 IMPURITIES ON CERTIFICATE.
- FINAL ASSEMBLY CONSISTS OF A SOURCE IN A POLYSTYRENE TUBE WITH 1/8" LEAD CAP. AFFIX SOURCE IDENTIFICATION LABEL TO OUTSIDE OF TUBE. SOURCE AND TUBE IS HANDLING ARE PLACED INTO A 3/8" THICK LEAD SHELD (ENCAPSED WITH FOAM AT TOP AND BOTTOM OF TUBE). AFFIX SOURCE IDENTIFICATION LABEL TO OUTSIDE OF LEAD SHELD. LABELLING AND INSERTS PER LABELLING BILL OF MATERIALS (BOM).
- ALTERNATE TO PACKAGING PER NOTE 8 ABOVE MAY BE ACCEPTABLE PROVIDED IT IS AN APPROVED DUTY 7A PACKAGE.

		DuPont Pharmaceuticals Company	
316L STN. STEEL	PART NO. NER-472 CO-57 SOURCE ASSEMBLY	DATE 12/2/98	REV. B
APPROVED FOR RELEASE 313-037	APPROVED FOR RELEASE 313-037	APPROVED FOR RELEASE 313-037	APPROVED FOR RELEASE 313-037



Department of Health Services
Radiologic Health Branch
P.O. Box 942732, MS 178
Sacramento, CA 94234-7320



MR Fredrick STURZ, Section Chief
Source Containment of Devices Branch
OFFICE OF Nuclear MATERIAL Safety & Safeguards
U.S. NRC
PI-37
Washington DC 20555