

Monday, November 27, 2017

*Br. 2*

Betsy Ullrich  
Senior Health Physicist  
US NRG Region I Office  
2100 Renaissance Boulevard, Suite 100  
King of Prussia, PA 19464  
(610) 337-5040

Subj: **Amendment to NRC Radioactive Materials License 32-35165-01** / *03038762*

Dear Ms. Ullrich:

Siemens Medical Solutions respectfully requests to add Se-75 as a radioactive isotope of use. The details of this isotope are listed below:

Form:	Sealed Point Source
Activity:	10 mCi each source / 300 mCi total

The Se-75 xSPECT Quant Calibration/Peaking Source Kit contains:

4.25 mCi (+/- 15%) Se-75 point source  
40 uCi (+/- 20%) Se-75 point source.

Included are the sealed source registries for each of the two Se-75 sources. Please feel free to contact me with any questions or concerns.

With best regards,



Digitally signed by Daut Matthew  
DN: serialNumber=Z003D62C,  
givenName=Matthew, sn=Daut,  
o=Siemens, cn=Daut Matthew  
Date: 2017.11.27 14:56:02 -05'00'

Matthew Daut

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Sr. Manager EHS  
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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCES  
(AMENDED IN ITS ENTIRETY)

NO.: CA0406S173S

DATE: 04 February 2016

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SEALED SOURCE TYPE: Pen Point Marker or Calibration Source

MODEL:

**3239**

PP Series

**PHI Series**

MANUFACTURER/DISTRIBUTOR:

Eckert & Ziegler Isotope Products  
dba Isotope Products Laboratories  
24937 Avenue Tibbitts  
Valencia, CA 91355  
(661) 309-1010 (voice)  
(661) 257-8303 (fax)

or

Eckert & Ziegler Cesio  
Radiova 1  
102 27 Prague 10  
Czech Republic

or

Eckert & Ziegler Nuclitec GmbH  
Gieselweg 1  
38110 Braunschweig  
Germany

or

Eckert & Ziegler Analytics  
1380 Seaboard Industrial Boulevard  
Atlanta, GA 30318

ISOTOPE:

Cobalt-57

Gadolinium-153

**Selenium-75**

Sodium-22

MAXIMUM ACTIVITY:

600 microcuries (22.2 MBq ) for PP-057;

5 millicuries (185 MBq) for PHI Series

600 microcuries (22.2 MBq )

**6 millicuries (222 MBq)**

600 microcuries (22.2 MBq )

LEAK TEST FREQUENCY:

Six (6) Months

PRINCIPAL USE:

(X) Medical Reference Source

CUSTOM SOURCE:

☐ Yes ☒ No

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
**SAFETY EVALUATION OF SEALED SOURCES**  
**(CORRECTED PAGE 2 – MARCH 24, 2016)**

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**SEALED SOURCE TYPE:** Pen Point Marker or Calibration Source

**DESCRIPTION:**

The sources are singly encapsulated and constructed of either aluminum or stainless steel. The maximum dimensions are 0.375" diameter by 5.4" long. The activity is contained in a resin bead or ceramic cane which is sealed with an inactive epoxy. The sources use a threaded cap and handle assembly that is sealed with a permanent thread adhesive. The PP Series is provided with a brass shield that is threaded in place.

The source activity range shall be  $\pm 15\%$  for all models.

Table 1 describes the source model identification scheme.

**Table 1. Model Identification Scheme**

Product Code / Model	Description
PP-xxx-yyyU	Pen Point source, where "xxx" represents the nuclide mass number and "yyy" represents the activity of the source in microcuries.
E.g., PP-057-100U is a pen point marker source which contains 100 $\mu$ Ci of Co-57.	
PHI-XXXX	Calibration source, where "PHI" represents a point source and "XXXX" is a numeric designation.
E.g., PHI-0129 is a point source which contains 5 mCi of Co-57.	

**LABELING:**

The source is engraved or labeled with the manufacturer or manufacturer's logo, nuclide, activity, and serial number. The reference date may be included as space permits. The brass shield is labeled with "Eckert & Ziegler Isotope Products", nuclide, nominal activity, serial number, reference date, trefoil, and the words, "CAUTION-RADIOACTIVE MATERIALS".

The source storage and shipping container is labeled with the radiation symbol, nuclide, activity, serial number, reference date, and the words, "CAUTION-RADIOACTIVE MATERIALS". In addition, a label is affixed to the storage or shipping container that states, "CA DPH has approved distribution of this source to persons licensed to use radioactive material identified in Cal Code Regs. title 17, §30170-§30237 & in 10 CFR 35.65, 35.400, 35.500, & 35.600 as appropriate, & to persons who hold an equivalent license issued by the US NRC or an Agreement State. See IFU for additional instructions, as applicable."

**DIAGRAM:**

Attachment 1: Model PP Series (capsule 1915) Drawing  
Attachment 2: Model PHI Series (capsule 3239) Drawing

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SEALED SOURCE TYPE: Pen Point Marker or Calibration Source

CONDITIONS FOR NORMAL USE:

The source is designed and manufactured for use as a reference point for patient positioning or image orientation or as a component of a medical gamma camera system in the nuclear medicine department of a hospital or clinic by trained personnel.

The sources should not be subjected to conditions of normal use which require a higher rating than ISO 2919:2012, classification of ISO/12/C22212.

Other applications such as research and development are acceptable provided that the sources are not subject to environmental conditions exceeding those stated below. Typical useful life of the source is dependent on the nuclide:

Nuclide	Typical Useful Life (years)
Cobalt-57	2
Gadolinium-153	2
Selenium-75	1
Sodium-22	5

PROTOTYPE TESTING:

The prototype sources of the PP Series pen point marker source design passed the performance tests for a classification of ISO/99/C22212. The prototype sources of the 3239 source design passed the performance tests for a classification of ISO/12/C22212. This meets the rating of ISO/12/C22212 for "Calibration source activity greater than 1 MBq" as defined in ISO 2919:2012, "Radiation protection—Sealed radioactive sources—General requirements and classification".

EXTERNAL RADIATION LEVELS:

The external radiation levels from the Co-57 and Se-75 sources were calculated using 'Microshield, Version 5.05'.

The external radiation levels from the Gd-153 and Na-22 pen point marker sources were calculated using the following data references:

Decay Data: NUDAT database 12 Aug 03 version, National Nuclear Data Center, Brookhaven National Laboratory.

Attenuation Data: NIST, J. H. Hubbell and S. M. Seltzer. The attenuation values are taken from the June 2004 photon interaction database at the National Institute of Standards and Technology, and the energy

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SEALED SOURCE TYPE: Pen Point Marker or Calibration Source

transfer values are based on the new calculations by Seltzer described in Radiation Research 136, 147 (1993).

Taylor's Method Build-up Factors: S. Buscaglione and R. Manzini, "Build-up Factors: Coefficients of the Equation of J.J. Taylor", Oak Ridge National Laboratory Report ORNL-tr-80.

Source calculations (assuming an active diameter of 0.030 inches (0.76 mm) with the activity evenly distributed) were chosen to approximate exposure rates for the PP Series pen point marker source at the three standard distances of 5 cm, 30 cm, and 100 cm.

External radiation levels at the surface of the pen point marker sources (distance of 0 cm) were calculated using 'Varskin, Version 3.0.1', for Model PP Series without shield.

Exposure rates (mR/hr) were calculated with the respective maximum activity, plus tolerance, as listed below.

**Table 2. External Radiation Levels**

Model Number	Nuclide	Activity	Distance from Source (cm) and Exposure Rate (mR/hr)			
			0 cm	5 cm	30 cm	100 cm
PP-057 (without shield)	Co-57	690 $\mu$ Ci	12,700	14.95	0.4299	0.03901
PP-057 (with shield)	Co-57	690 $\mu$ Ci	Not calculated	1.355	0.04703	0.004344
PP-153 (without shield)	Gd-153	690 $\mu$ Ci	4,610	28.58	0.79	0.07
PP-153 (with shield)	Gd-153	690 $\mu$ Ci	Not calculated	2.21	0.09	0.01
PP-022 (without shield)	Na-22	690 $\mu$ Ci	10,500	373.24	10.37	0.93
PP-022 (with shield)	Na-22	690 $\mu$ Ci	Not calculated	147.16	5.92	0.56
3239	Co-57	5.75 mCi	N/A	117.2	3.332	0.2994
3239	Se-75	6.90 mCi	N/A	537.6	15.30	1.379

## QUALITY ASSURANCE AND CONTROL:

Program: The EZIP Quality Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B) and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records,

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source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders.

Activity: Activity levels are held to within +15%/-15% of nominally desired activity.

Eckert & Ziegler Isotope Products maintains a quality management system, which has been deemed acceptable for licensing purposes by the California Department of Public Health. A copy of the program is on file with the California Department of Public Health.

The manufacturing of Models PP Series and 3239 sources and related operations are carried out in manufacturing processes consistent with the current Good Manufacturing Practices Final Rule, Quality System Regulation, 21 CFR 820, under the supervision of the Quality Operations group at Eckert & Ziegler Isotope Products.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Distribution: The source shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- Leak Test: Sources with activities greater than 100 microcuries shall be leak tested at intervals not to exceed six (6) months using techniques capable of detecting 185 Becquerels (0.005 microcuries) of removable contamination.
- Use: The PP Series and 3239 sources are intended to be used by trained personnel in a laboratory or clinical environment for nuclear imaging applications. They should not be subjected to conditions exceeding their ISO 2919:2012 classification of ISO/12/C22212.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Public Health.

SAFETY ANALYSIS SUMMARY:

Based on a review of the Model PP Series and 3239 sealed sources, their ISO classification, and the information and test data cited below, we conclude that the source is acceptable for licensing purposes.

Furthermore, we continue to conclude that the source would be expected to maintain its 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: Pen Point Marker or Calibration Source

REFERENCES:

The following supporting documents for the Model PP Series and 3239 sealed sources are hereby incorporated by reference and made part of this registry document:

1. Isotope Products Laboratories Quality Assurance Manual.
2. Isotope Products Laboratories letters dated November 29, 1994, and May 12, 1995.
3. Isotope Products Laboratories letters dated April 16, 1998, and May 14, 1998, with attachments thereto.
4. Isotope Products Laboratories letters dated April 8, 2004, May 6, 2004, and May 26, 2004, with attachments thereto.
5. Eckert & Ziegler Isotope Products letters dated August 5, 2008, and October 29, 2008, with attachments thereto.
6. Eckert & Ziegler Isotope Products letters dated 14 May 2013, with attachments thereto.
7. Eckert & Ziegler Isotope Products letters dated 20 January 2016, with attachments thereto.

ISSUING AGENCY: California Department of Public Health

DATE: February 4, 2016

REVIEWED BY:

Mina Goeders  
Mina Goeders, Ph.D.

DATE: February 4, 2016

CONCURRED BY:

John F. Fassell  
John Fassell, CHP

# REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

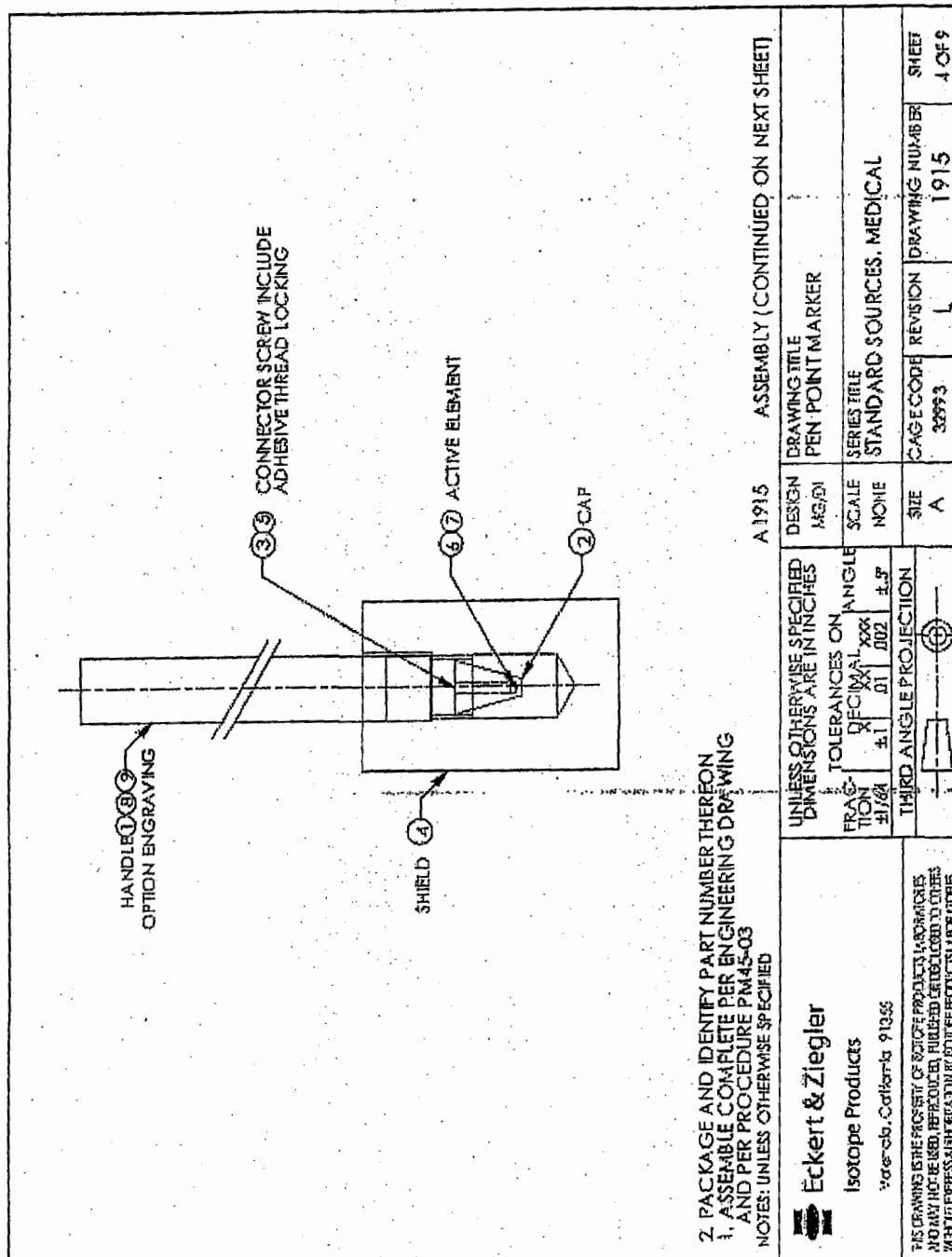
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ATTACHMENT: 1 of 2

SEALED SOURCE TYPE: Pen Point Marker or Calibration Source

Model PP Series (Capsule 1915)





# REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

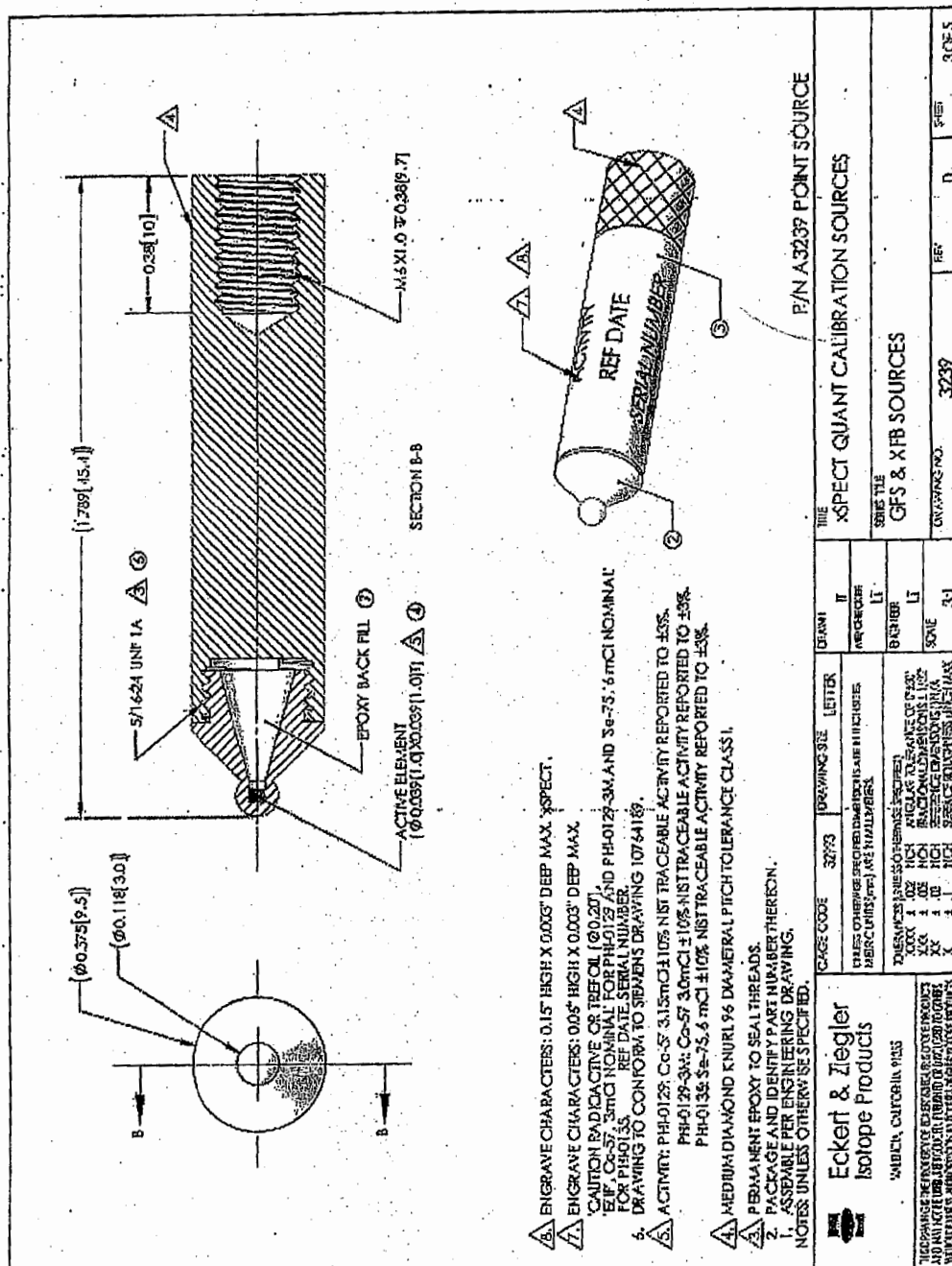
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SEALED SOURCE TYPE: Pen Point Marker or Calibration Source

Model 3239 (Capsule 3239)



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**(Supersedes MA1059S350S)**

**SEALED SOURCE TYPE:** Gamma Calibration Source

**MODEL:**

GF Type D or M Series (formerly GF-XXXD  
or GF-XXXM Series)  
CAL26aa Series  
**CDC.PLS**  
**MED3505**  
**MMS10 & MMS16**  
POSK Series  
POSN Series  
SM Series & ISM Series  
3888 & 3916

**MANUFACTURER / DISTRIBUTOR:**

Eckert & Ziegler Isotope Products  
dba Isotope Products Laboratories  
24937 Avenue Tibbitts  
Valencia, CA 91355  
(661) 309-1010 (voice)  
(661) 257-8303 (fax)  
or  
Eckert & Ziegler Analytics  
1380 Seaboard Industrial Boulevard  
Atlanta, GA 30318  
or  
Eckert & Ziegler Cesio  
Radiova 1  
102 27 Prague 10  
Czech Republic  
or  
Eckert & Ziegler Nuclitec GmbH  
Gieselweg 1  
D-38110 Braunschweig  
Germany

**ISOTOPE:**

Americium-241

Radium-226

Thorium-228

Uranium-235

Uranium (Natural)

Any Gamma Emitter **including multinuclide mixtures** with atomic number from 3 to 83

**MAXIMUM ACTIVITY:**

500 microcuries (18.5 MBq)

500 microcuries (18.5 MBq)

500 microcuries (18.5 MBq)

5 microcuries (185 kBq)

5 microcuries (185 kBq)

2 millicuries (74 MBq)

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**SEALED SOURCE TYPE:** Gamma Calibration Source

**LEAK TEST FREQUENCY:**

Six (6) months

**PRINCIPAL USE:**

(I) Calibration Sources

(X) Medical Reference Sources

(AB) Medical Diagnosis

**CUSTOM SOURCE:**

☐ Yes ☒ No

**DESCRIPTION:**

The source consists of a deposited metal salt onto a disc or foil made of plastic, aluminized mylar, polyimide (plastic), titanium, platinum, or a 300 series stainless steel disc with maximum dimensions of 0.50 inch thickness and 2.0 inches overall diameter. The active diameter is a minimum of 0.02 inches. The source is sealed with an epoxy fill, self-adhesive polyimide, or by sandwiching a metal foil between two self-adhesive polyimide discs. Alternatively, two metal foils or a disc and plug of the same metal may be sealed by fusion welding. Sources made with aluminized mylar and polyimide discs may be encased in an aluminum support ring to maintain source integrity.

The gamma emitters including **multinuclide mixtures** with atomic numbers from 3 to 83 shall not exceed the exposure rate of Co-60 as noted in the "External Radiation Levels" section. The source activity range shall be +20% and -15% for all models.

Table 1 lists the source model identification scheme used for sources within this series.

**Table 1. Source Model Identification Scheme**

Model Number	Maximum Thickness	Overall Maximum Diameter
(b)GF-XXX Type D or Type M	0.50"	1.5"
(b)GF-aaaa	0.50"	1.5"
CAL26aa(d)	0.50"	1.5"
CDC.PLS	0.20"	0.50"
MED3505	0.50"	2.0"
MMS10-XXX-YYZ	0.50"	1.5"
MMS16-XXX-YYZ	0.50"	1.5"
(b)SM-XXX-YYZ	0.50"	1.5"
ISM-XXX-YYZ	0.50"	1.5"
POSK-XXX or POSN-XXX	0.05"	0.50"
3888	0.05"	0.50"
3916	0.05"	1.5"

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**SEALED SOURCE TYPE:** Gamma Calibration Source

Model Number	Maximum Thickness	Overall Maximum Diameter
aaaa	0.50"	1.5"
aa or aaaa = Numeric designation; (b) = Private label or dedicated model (optional); (d) = additional descriptor (optional); XXX = Mass Number; YY = Amount of activity; Z = Units of activity; MED = Medical source; MMS = multimodal source		

**REVIEWER'S NOTE:** Spot marker sources sold under Model No. SM-057 is consolidated within this registry and supersedes SS&DR No. CA0406S169S. Gamma calibration sources sold under Model No. GF-XXX Type M Series are consolidated within this registry and supersede SS&DR No. CA0406S111S. Gamma calibration sources sold under North American Scientific Industries (NASI) Models CAL2601, CAL2602, and CAL2603 are consolidated within this registry and supersede SS&DR No. CA0510S111S. Gamma calibration sources sold under QSA Global, Inc. Model CDC.PLS is consolidated within this registry and supersedes SS&DR No. MA1059S350S.

This SS&DR sheet CA0406S106S represents the transfer of the North American Scientific Industries (NASI) SS&DR sheet CA0510S111S. The gamma calibration sources listed on SS&DR No. CA0510S111S will now be manufactured as Models CAL26aa Series and no longer be commercially manufactured or distributed by NASI. This SS&DR sheet CA0406S106S represents the transfer of Model CDC.PLS. Model CDC.PLS listed on SS&DR No. MA1059S350S will now be manufactured by EZIP and no longer be commercially manufactured or distributed by QSA Global, Inc.

**LABELING:**

The sources are either engraved or labeled with the information listed on Table 2. Due to the dimensional limitations, inherent to the source, the manufacturer's name or logo and the standard radiation caution symbol may not be included on the source.

**Table 2. Labeling**

Labeling information	Engraved on the source	Source Label or Source Container	Storage / Shipping Container Label (Optional)
<b>Manufacturer or Manufacturer's Logo</b>		X	X
Nuclide	X	X	X
Nominal Activity	X	X	X
Serial Number	X	X	X
Reference Date	X	X	X
<b>RADIOACTIVE MATERIAL</b>		X	X
Radiation Symbol			X

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**SEALED SOURCE TYPE:** Gamma Calibration Source

In addition, when this source is manufactured for medical reference use, a label is affixed to the storage or shipping container that states, "CA DPH has approved distribution of this source to persons licensed to use radioactive material identified in Cal Code Regs. title 17, §30170- §30237 & in 10 CFR 35.65, 35.400, 35.500, & 35.600 as appropriate, & to persons who hold an equivalent license issued by the US NRC or an Agreement State. See IFU for additional instructions, as applicable."

**DIAGRAM:**

Attachment 1:	1001 Type D Disk Source
Attachment 2:	1006 CAL26aa Disk Source
Attachment 3a and 3b:	1202 Type M Disk Source (in optional support ring)
Attachment 4a and 4b:	1905 SM Spot Marker Source
Attachment 5:	1937 ISM Spot Marker Source
Attachment 6a:	1941 MMS10 Multimodal Spot Marker Source
Attachment 6b:	1941 MMS16 Multimodal Spot Marker Source
Attachment 7a and 7b:	1944 MED3505 Right and Left Marker Source
Attachment 8:	2305 POSN Positron Source
Attachment 9:	2306 POSK Positron Source
Attachment 10:	3888 Gamma Calibration Disk Source
Attachment 11:	3916 Gamma Calibration Disk Source
Attachment 12:	VZ-2134 Gamma Source

**CONDITIONS FOR NORMAL USE:**

The source is designed and manufactured for use as a calibration source. Calibration applications may include energy compensation and/or medical reference. For energy compensation applications, the source is intended to be used within a logging tool or other tool components, as a reference source. The source is also designed and manufactured for checking the performance of detectors, gamma cameras, and other instruments used in a hospital, laboratory, or clinical environment by trained personnel. The spot markers are used to trace radiological images in a laboratory or clinical environment by trained personnel.

Models GF Type D and Type M Series, MED3505, MMS10, MMS16, and SM and ISM Series, POSK and POSN Series, and 3888 should not be subjected to conditions of normal use which require a higher rating of ISO/12/C22212. Model CAL26aa Series shall not be subjected to conditions exceeding their ANSI N542-1977 classification of ANSI 77C23313. Model 3916 shall not be subjected to conditions exceeding its' ISO 2919: 2012 classification of ISO/12/C66545 for activity less than or equal to 100  $\mu$ Ci or ISO/12/C3312 for activity greater than 100  $\mu$ Ci. **Model CDC.PLS shall not be subjected to conditions exceeding its' ANSI N542-1977 classification of ANSI 77C66646.** Other applications of a research and development nature are acceptable provided that the calibration sources are not subjected to environmental conditions exceeding those listed above. **Typical useful life of the calibration source is dependent on the nuclide, but shall not exceed five years for the single nuclide sources and one year for the multinuclide sources.**

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**SEALED SOURCE TYPE:** Gamma Calibration Source

<u>Nuclide</u>	<u>Typical Useful Life (years)</u>
Americium-241	5
Barium-133	5
Cadmium-109	2
Cesium-137	5
Cobalt-57	2
Cobalt-60	5
Gadolinium-153	2
Germanium-68	2
Radium-226	5
Sodium-22	5
Thorium-228	5
Uranium-235	5
Uranium (Natural)	5
Yttrium-88	5
<b>Multinuclide mixture</b>	<b>1</b>

**PROTOTYPE TESTING:**

The prototype sources for Models GF Type D and Type M Series, SM and ISM Series, MMS10, MMS16, POSK and POSN Series, and 3888 source design passed the performance tests for a classification of ISO/99/C22212 per ISO 2919: 1999. **Based on its similarities to Models SM, and MED3505 have been assigned a test classification of ISO/12/C22212 in accordance with ISO 2919: 2012, section 4.3.** Representative samples for Model CAL26aa source design passed the performance tests for a classification of ANSI 77C23313 per ANSI N542-1977. The prototype sources for Model 3916 source design passed the performance tests for a classification of ISO/99/C66545 for activity less than or equal to 100  $\mu$ Ci or ISO/99/C3312 for activity greater than 100  $\mu$ Ci per ISO 2919: 1999. **The prototype sources for Model CDC.PLS source design passed the performance tests for a classification of ANSI 77C66646 per ANSI N542-1977.** All models meet or exceed the required ratings of ISO/12/C22212 for "Calibration source activity > 1 MBq" as defined in ISO 2919: 2012.

**EXTERNAL RADIATION LEVELS:**

The external radiation levels from the calibration sources were calculated using 'Microshield Version 5.05'. Source calculations representing the different materials in the thinnest source (0.010"H) with the activity uniformly distributed were chosen to approximate exposure rates for Models GF Type D and Type M Series, CAL26aa Series, CDC.PLS, MED3505, MMS10, MMS16, SM and ISM Series, POSK and POSN Series, 3888, and 3916 at the 3 standard distances of 5 cm, 30 cm, and 100 cm. The exposure rates in mR/hr are calculated with the respective maximum activities plus tolerance, as listed below.

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**SEALED SOURCE TYPE:** Gamma Calibration Source

**Americium-241 Calibration Sources** – Maximum Activity plus tolerance = 600 microcuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	3.641	3.661
30 cm	0.1043	0.1051
100 cm	.009610	0.009746

**Barium-133 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	274.2	275.0
30 cm	7.818	7.856
100 cm	0.7112	0.7188

**Cadmium-109 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	96.42	97.39
30 cm	2.744	2.809
100 cm	0.2482	0.2639

**Cesium-137 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	304.7	304.7
30 cm	8.666	8.665
100 cm	0.7824	0.7823

**Cobalt-57 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	52.21	52.30
30 cm	1.490	1.492
100 cm	0.1358	0.1360

1.1

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**SEALED SOURCE TYPE:** Gamma Calibration Source

**Cobalt-60 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

<u>Distance from Source (mR/hr)</u>	<u>Plastic Window Calibration Source</u>	<u>Titanium Window Calibration Source</u>
5 cm	1,211	1,210
30 cm	34.42	34.40
100 cm	3.104	3.102

**Gadolinium-153 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

<u>Distance from Source (mR/hr)</u>	<u>Plastic Window Calibration Source</u>	<u>Titanium Window Calibration Source</u>
5 cm	80.39	80.84
30 cm	2.302	2.320
100 cm	0.2119	0.2148

**Germanium-68 Calibration Sources** – Maximum Activity plus tolerance 2.4 millicuries

<u>Distance from Source (mR/hr)</u>	<u>Plastic Window Calibration Source</u>	<u>Titanium Window Calibration Source</u>
5 cm	510.2	510.1
30 cm	14.51	14.50
100 cm	1.310	1.309

**Radium-226 Calibration Sources** – Maximum Activity plus tolerance = 600 microcuries

<u>Distance from Source (mR/hr)</u>	<u>Plastic Window Calibration Source</u>	<u>Titanium Window Calibration Source</u>
5 cm	0.7891	0.7902
30 cm	0.02248	0.02252
100 cm	0.002041	0.002046

**Sodium-22 Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

<u>Distance from Source (mR/hr)</u>	<u>Plastic Window Calibration Source</u>	<u>Titanium Window Calibration Source</u>
5 cm	1,109	1,109
30 cm	31.53	31.52
100 cm	2.845	2.843



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**(Supersedes MA1059S350S)**

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**SEALED SOURCE TYPE:** Gamma Calibration Source

**Thorium-228 Calibration Sources** – Maximum Activity plus tolerance = 600 microcuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	0.2147	0.2152
30 cm	0.006129	0.006145
100 cm	0.0005594	0.0005612

**Uranium-235 Calibration Sources** – Maximum Activity plus tolerance = 6 microcuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	0.1761	0.1764
30 cm	0.005019	0.005027
100 cm	0.0004557	0.0004566

**Uranium (Natural) Calibration Sources** – Maximum Activity plus tolerance = 6 microcuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	0.00007928	0.00007965
30 cm	0.000002271	0.000002283
100 cm	0.0000002093	0.0000002108

**Multinuclide Calibration Sources** – Maximum Activity plus tolerance = 2.4 millicuries

Distance from Source (mR/hr)	Plastic Window Calibration Source	Titanium Window Calibration Source
5 cm	300.8	301.7
30 cm	8.538	8.600
100 cm	0.7671	0.7817

**QUALITY ASSURANCE AND CONTROL**

**Program:** The EZIP Quality Manual details the quality control of these sources from raw materials to finished product. The program is designed to satisfy 10 CFR Part 50 (B) and is ISO 9001 and ISO 13485 certified. The program covers design and document control, purchasing, training, calibration records, source numbering, production, incoming raw materials, assay quality control, leak testing, and confirming orders. Activity levels are held to within +20%/-15% of nominally desired activity.

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SEALED SOURCE TYPE: Gamma Calibration Source

Eckert & Ziegler Isotope Products maintains a quality system, which has been deemed acceptable for licensing purposes by the California Department of Public Health. A copy of the program is on file with the California Department of Public Health.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- These sources shall be distributed to persons specifically licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.
- Sources which contain greater than 100  $\mu\text{Ci}$  of beta/gamma emitting material shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcuries (185 Bq) of removable contamination. Source loadings of less than 100  $\mu\text{Ci}$  are exempt from leak testing by the Issuing Agency. Leak testing shall be in accordance with the individual requirements of the radiation control agency which exercises regulatory authority.
- Models GF Type D and Type M Series, **MED3505**, **MMS10**, **MMS16**, SM and ISM Series, POSK and POSN Series, and 3888 shall not be subjected to conditions exceeding their ISO 2919: 2012 classification of ISO/12/C22212. Model CAL26aa Series shall not be subjected to conditions exceeding their ANSI N542-1977 classification of ANSI 77C23313. Model 3916 shall not be subjected to conditions exceeding its' ISO 2919: 1999 classification of ISO/99/C66545. Model **CDC.PLS** shall not be subjected to conditions exceeding its' ANSI N542-1977 classification of ANSI 77C66646.
- The registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Public Health.

SAFETY ANALYSIS SUMMARY

Based on a review of Models GF Type D and Type M Series, CAL26aa Series, **CDC.PLS**, **MED3505**, **MMS10**, **MMS16**, SM and ISM Series, POSK and POSN Series, 3888, and 3916 sealed sources, its ISO / ANSI classification, and the information and test data cited below, we continue to conclude that the source is acceptable for licensing purposes.

Furthermore, we continue to conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions, which might occur during uses specified in this certificate.

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF SEALED SOURCES  
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**SEALED SOURCE TYPE:** Gamma Calibration Source

**REFERENCES:**

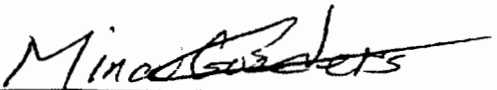
The following supporting documents of Models GF Type D and Type M Series, CAL26aa Series, MED350S, MMS10, MMS16, SM and ISM Series, POSK and POSN Series, 3888, and 3916 are hereby incorporated by reference and made part of this registry document:

1. EZIP Quality Manual (current copy on file with the issuing agency).
2. Isotope Products Laboratories' letter draft registration and supporting documents dated October 14, 1991 and October 28, 1991.
3. Isotope Products Laboratories' letters dated April 16, 1998 and May 14, 1998 with attachments thereto.
4. Isotope Products Laboratories' letters dated May 25, 2006 and June 23, 2006, and July 25, 2006 with attachments thereto.
5. Eckert & Ziegler Isotope Products' letters dated 23 February and 08 April 2009 with attachments thereto.
6. Eckert & Ziegler Isotope Products' letters dated 27 October 2010 and 25 February 2011 with attachments thereto.
7. Eckert & Ziegler Isotope Products' letters dated 12 December 2011 with attachments thereto.
8. Eckert & Ziegler Isotope Products' letters dated 23 July 2015 with attachments thereto.

**ISSUING AGENCY:** California Department of Public Health

**DATE:** September 10, 2015

**REVIEWED BY:**

  
**Mina Goeders, Ph.D.**

**DATE:** September 10, 2015

**CONCURRED BY:**

  
**John Fassel, CHP**

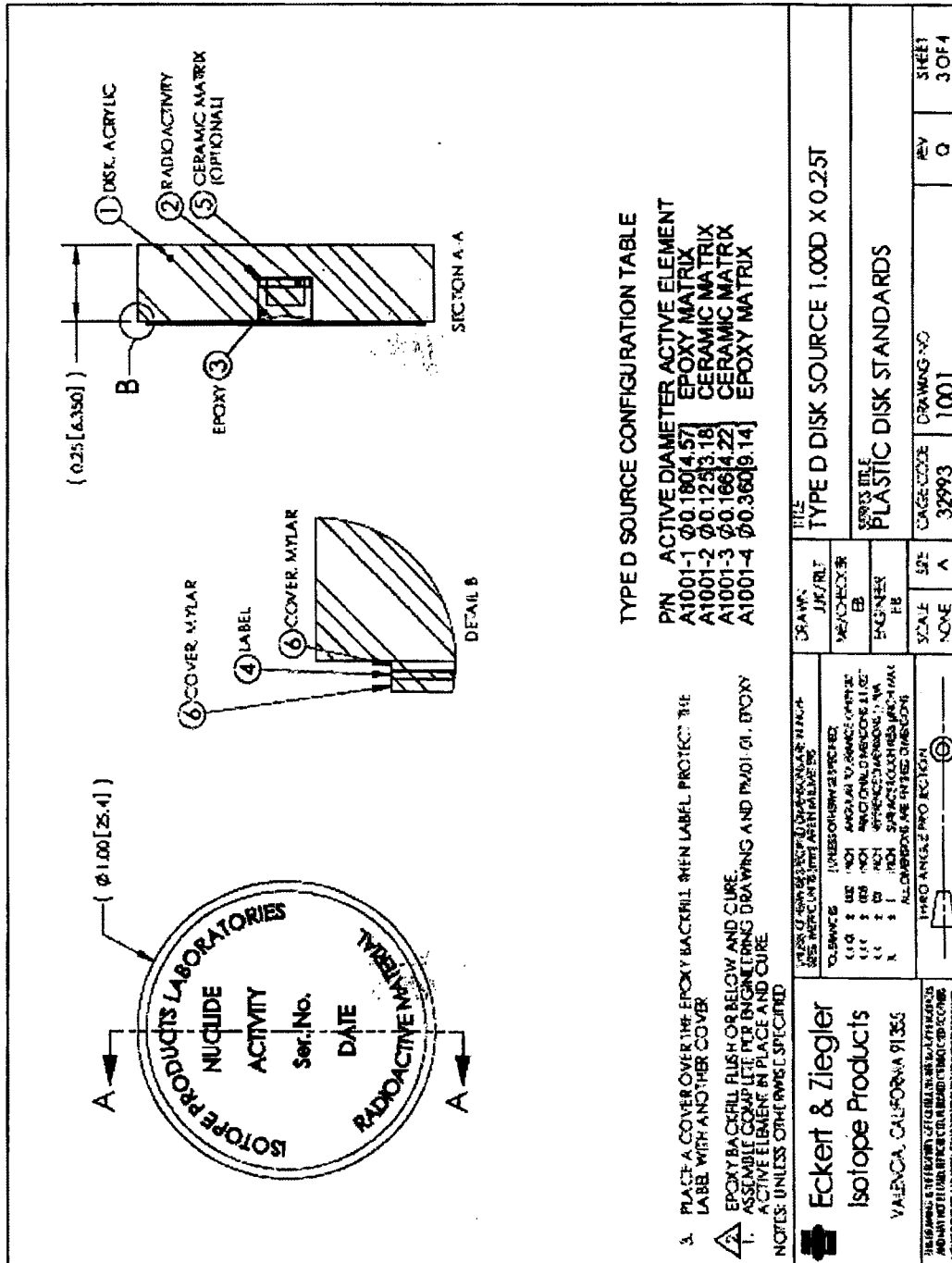
# REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

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ATTACHMENT: 1

## Model Type D Disk Source





SECTION G-G

ACTIVE ELEMENT 0.125 DIAMETER

RING AND DISK







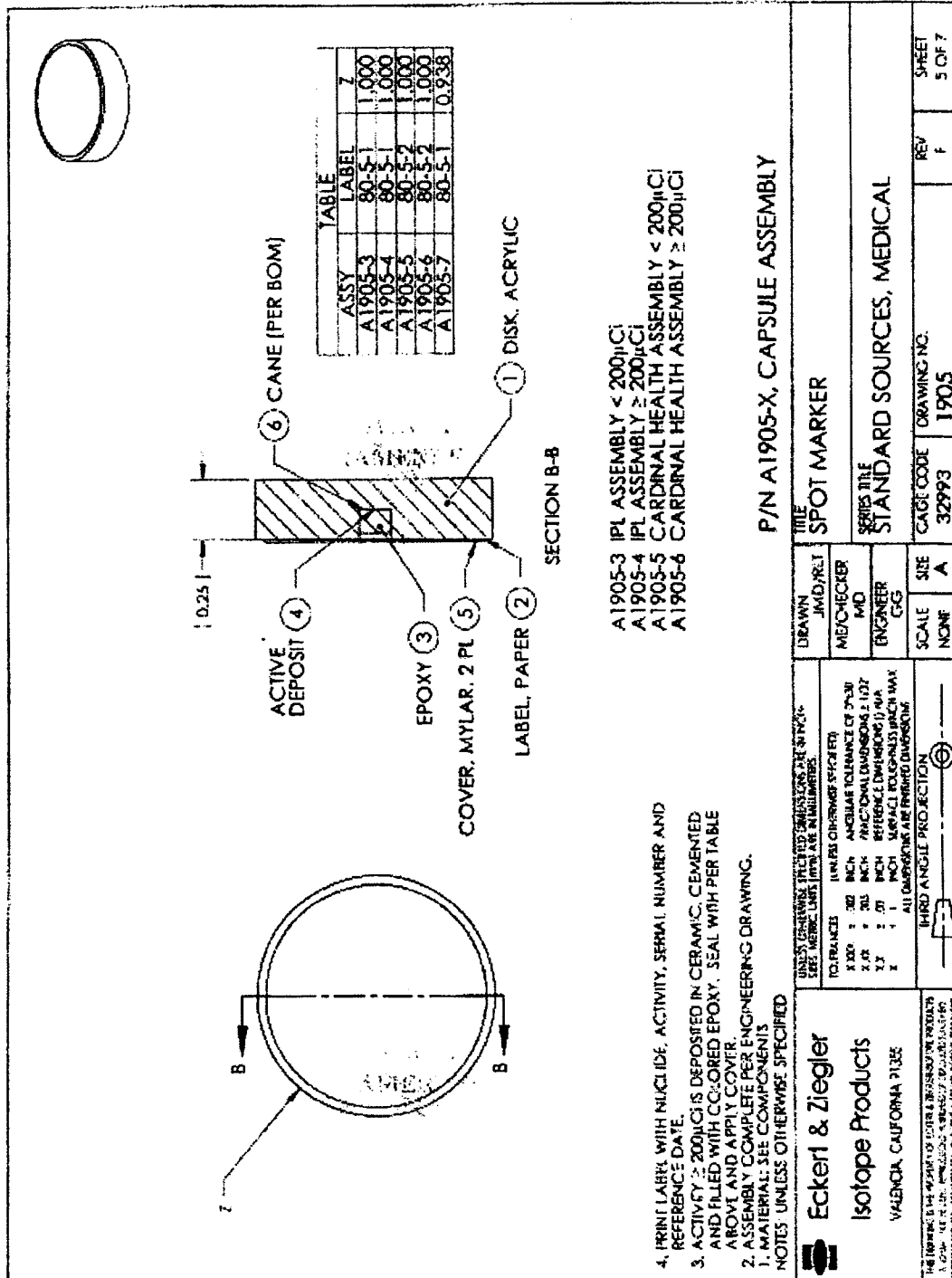
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NO.: CA0406S106S

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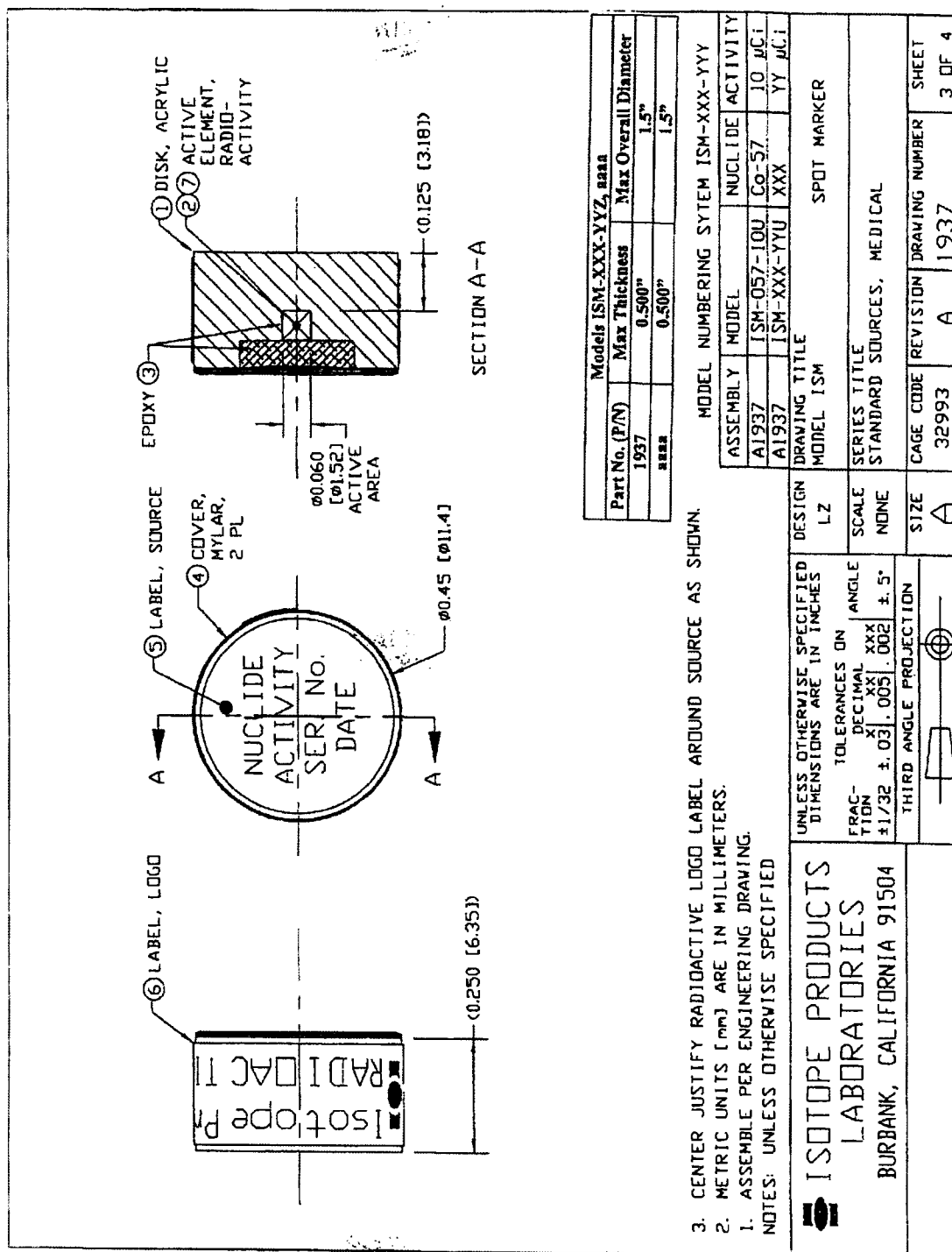
ATTACHMENT: 4b

## Model SM Spot Marker



ATTACHMENT: 5

### Model ISM Spot Marker



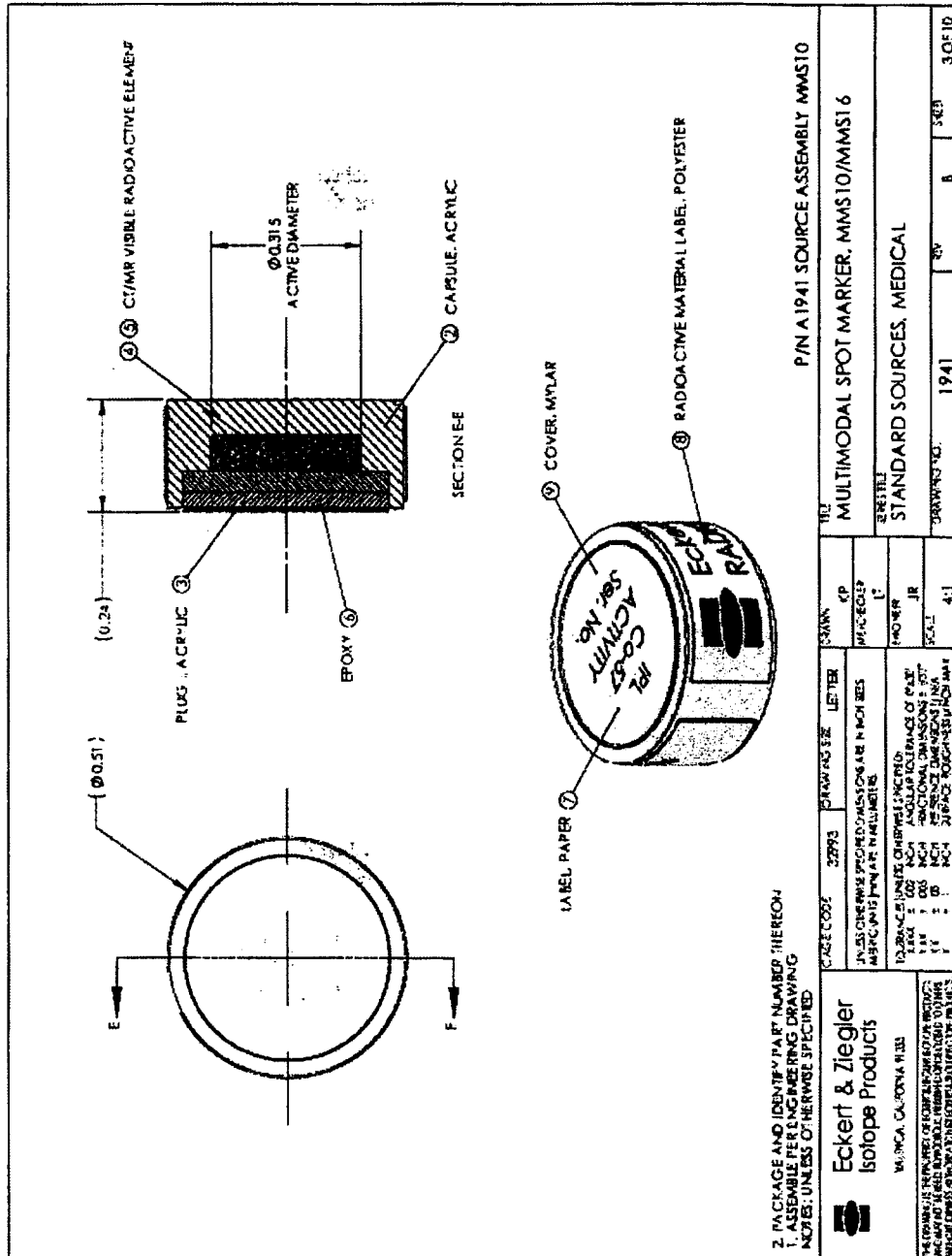
# REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

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ATTACHMENT: 6a

## Model MMS10 Multimodal Spot Marker





The drawing consists of two views of a capsule. The top view is a circle with a diameter of 1.97. Inside the circle is a stylized 'R' logo. A dimension line indicates a width of 0.74 for the top part of the 'R'. Another dimension line indicates a height of 0.19 TYP for the vertical stem of the 'R'. A callout '6' points to the top of the 'R'. The bottom view is a side profile of the capsule, showing a rectangular body with a width of 1.18 and a height of 0.25. A callout '5' points to the top surface of the capsule body.

ENGRAVE 'R' - HOLD 0.039in (1mm) THICKNESS FROM BOTTOM SURFACE

SQUARE LABEL 8040-2 OR 8040-6 ON BACK SIDE

4. PACKAGE AND IDENTIFY PART NUMBER THEREON

3. SURFACE ROUGHNESS: 32 RM RMS

2. REMOVE BURRS AND BREAK EDGES 0.005 MAX

1. MATERIAL: CAST ACRYLIC, WHITE

NOTES: UNLESS OTHERWISE SPECIFIED

**Eckert & Ziegler**

Isotope Products

VALDECA, CALIFORNIA 91355

THE DRAWING IS THE PROPERTY OF ECKERT & ZIEGLER. IT IS TO BE USED FOR THE MANUFACTURE OF THE PRODUCT ONLY. IT IS NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, WITHOUT PERMISSION IN WRITING FROM ECKERT & ZIEGLER.

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES.  
DIMENSIONS ARE TO BE MAINTAINED UNLESS OTHERWISE SPECIFIED.

TOLERANCES	FRACTIONS	DECIMALS	ANGLES	OTHER
± 0.005	± 0.005	± 0.005	± 0.005	± 0.005
± 0.010	± 0.010	± 0.010	± 0.010	± 0.010
± 0.020	± 0.020	± 0.020	± 0.020	± 0.020
± 0.050	± 0.050	± 0.050	± 0.050	± 0.050
± 0.100	± 0.100	± 0.100	± 0.100	± 0.100

ALL DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED.

THIRD ANGLE PROJECTION

DRAWN THICK

MEASUREMENT BY

ENGINEER

SCALE

NONE

TITLE

R-L-CAPSULE

SERIES TITLE

STANDARD SOURCES, MEDICAL

CAGE CODE

32993

DRAWING NO

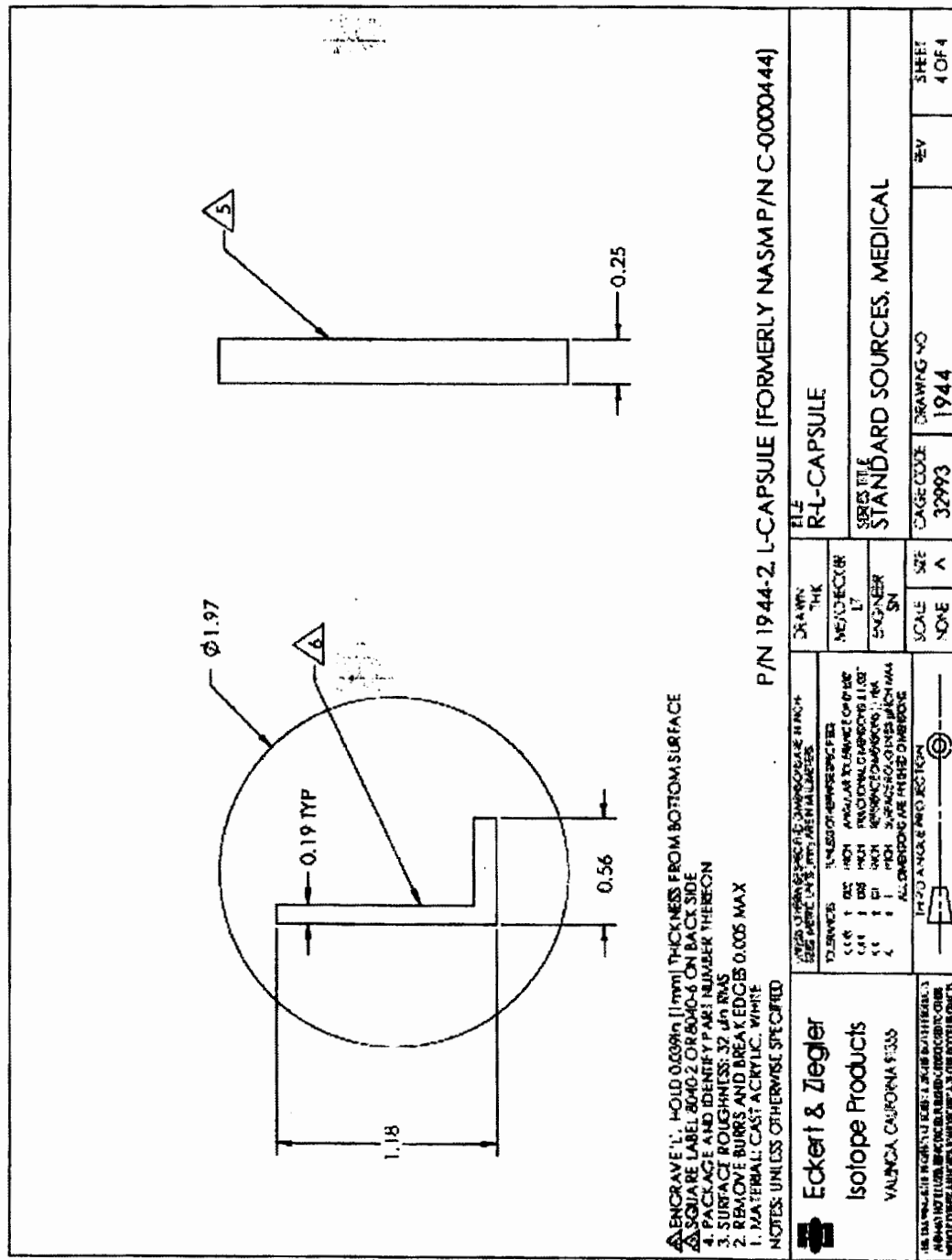
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SHEET

3 OF 4



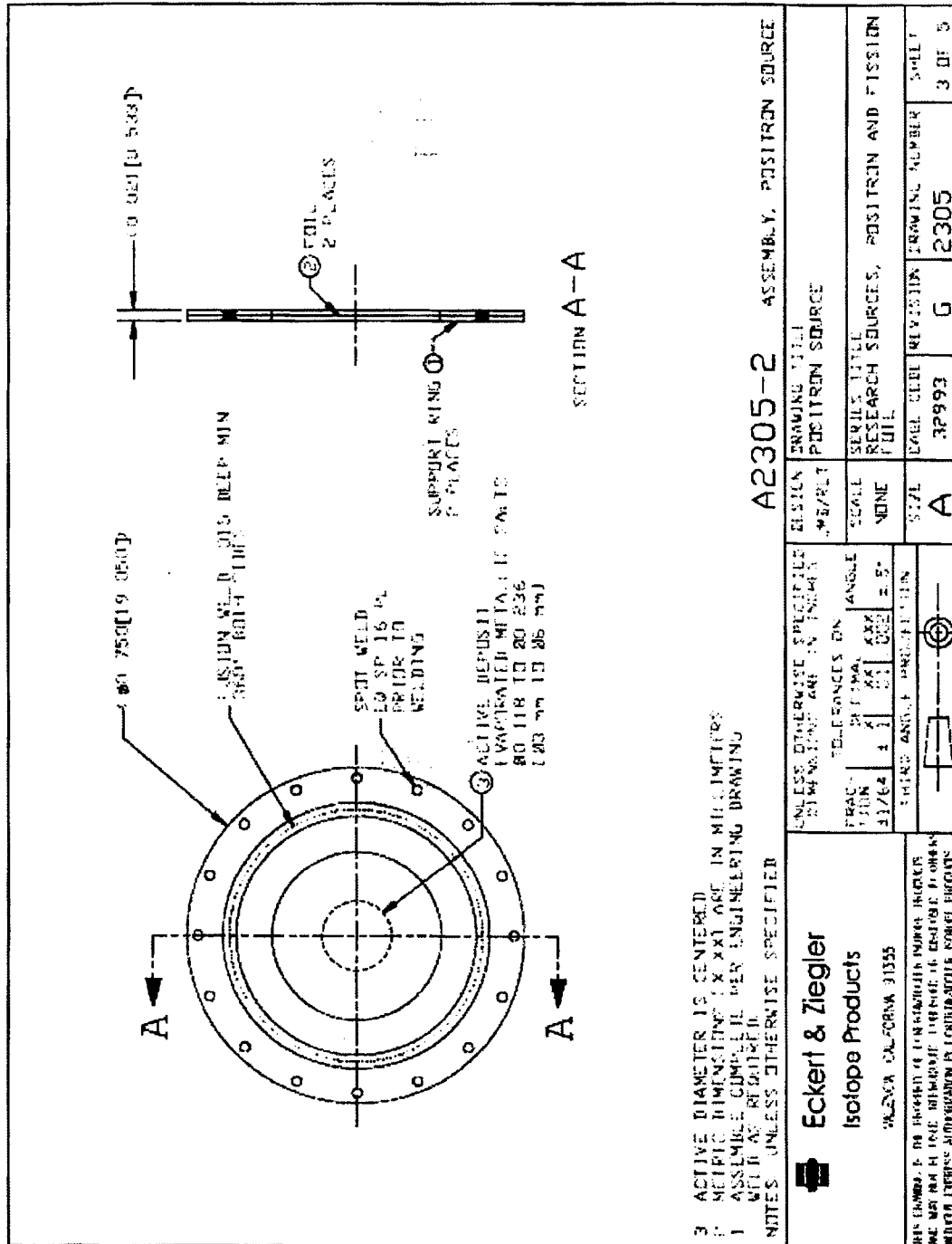
**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
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**ATTACHMENT:** 8

Model POSN Positron Source



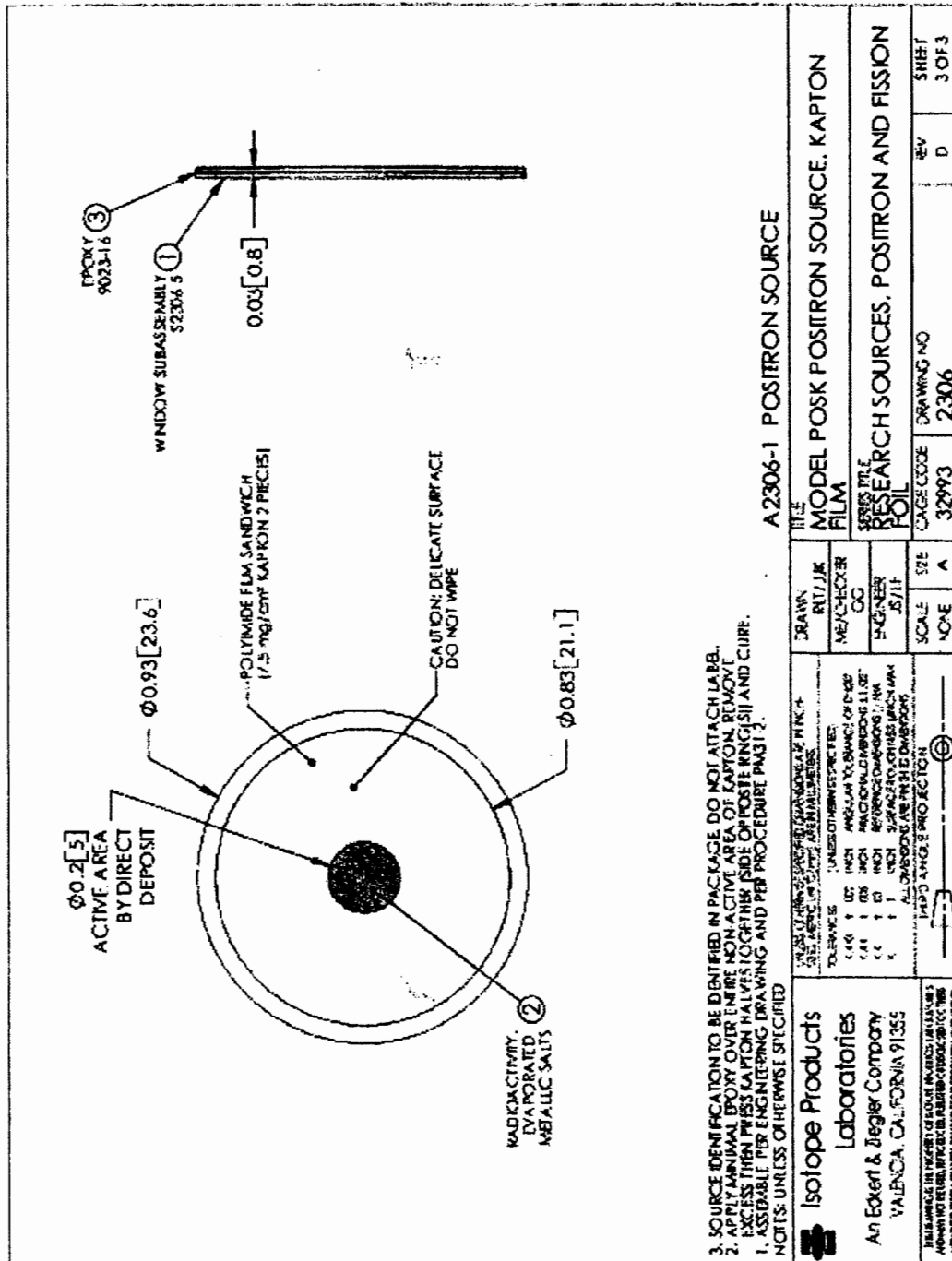
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ATTACHMENT: 9

## Model POSK Positron Source



3. SOURCE IDENTIFICATION TO BE IDENTIFIED IN PACKAGE, DO NOT ATTACH LABEL.  
 2. APPLY MINIMAL EPOXY OVER ENTIRE NON-ACTIVE AREA OF KAPTON, REMOVE EXCESS THEN PRESS KAPTON HALVES TOGETHER (SIDE OF PROXY RING) AND CURE.  
 1. ASSEMBLE PER ENGINEERING DRAWING AND PER PROCEDURE PAGE 12.

NOTES: UNLESS OTHERWISE SPECIFIED

**Isotope Products**  
**Laboratories**  
 An Eckert & Ziegler Company  
 VALLEJO, CA 94590-9135

THIS SOURCE IS TO BE USED IN ACCORDANCE WITH THE  
 AMERICAN SOCIETY OF MECHANICAL ENGINEERS (ASME)



**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES**  
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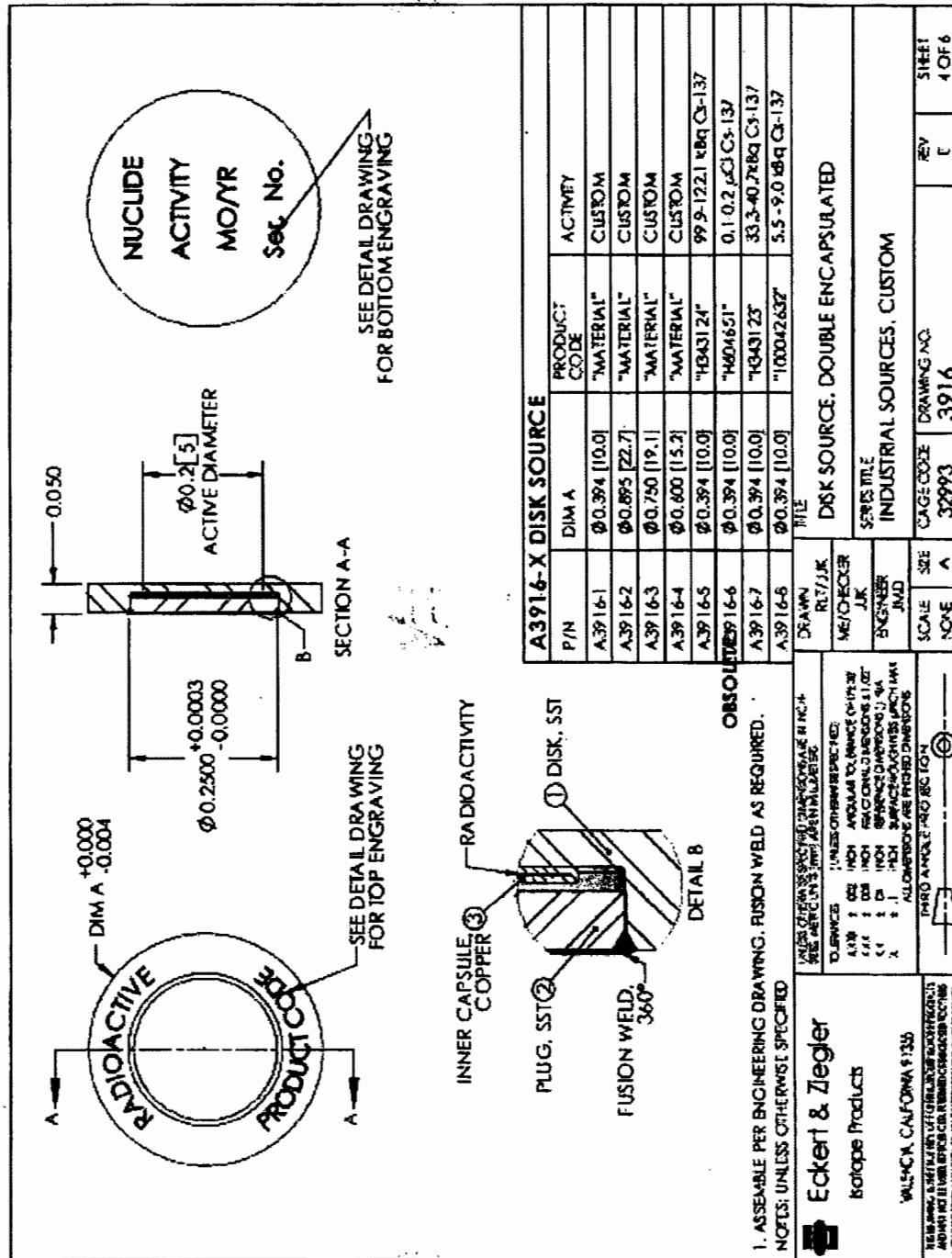
**NO.:** CA0406S106S

**DATE:** September 10, 2015

**ATTACHMENT:** 10

**Model 3888 Gamma Calibration Disk Source**

	<b>A3888</b> <b>ASSEMBLY</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center;">DRAWING TITLE GAMMA CALIBRATION DISK SOURCE</td> </tr> <tr> <td style="text-align: center;">REGION IND/ST</td> <td style="text-align: center;">SCALE NINE</td> </tr> <tr> <td colspan="2" style="text-align: center;">SERIALS TITLE INDUSTRIAL SOURCES, CUSTOM</td> </tr> <tr> <td style="text-align: center;">SIZE A</td> <td style="text-align: center;">PAGE CODE 38993</td> </tr> <tr> <td style="text-align: center;">REVISION E</td> <td style="text-align: center;">DRAWING NUMBER 3888</td> </tr> <tr> <td colspan="2" style="text-align: center;">SHEET 3 OF 4</td> </tr> </table>	DRAWING TITLE GAMMA CALIBRATION DISK SOURCE		REGION IND/ST	SCALE NINE	SERIALS TITLE INDUSTRIAL SOURCES, CUSTOM		SIZE A	PAGE CODE 38993	REVISION E	DRAWING NUMBER 3888	SHEET 3 OF 4	
DRAWING TITLE GAMMA CALIBRATION DISK SOURCE														
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SERIALS TITLE INDUSTRIAL SOURCES, CUSTOM														
SIZE A	PAGE CODE 38993													
REVISION E	DRAWING NUMBER 3888													
SHEET 3 OF 4														
<p><b>Eckert &amp; Ziegler</b>  <b>ISOTOPE PRODUCTS</b>          BURBANK, CALIFORNIA 91504</p>														
<p><small>ALL DIMENSIONS UNLESS OTHERWISE SPECIFIED          UNLESS OTHERWISE SPECIFIED          DIMENSIONS ARE IN INCHES          TOLERANCES ON ANGLES          1/16" 0.0015" 0.002" 0.003" 0.004" 0.005" 0.006" 0.007" 0.008" 0.009" 0.010" 0.012" 0.015" 0.020" 0.025" 0.030" 0.035" 0.040" 0.045" 0.050" 0.055" 0.060" 0.065" 0.070" 0.075" 0.080" 0.085" 0.090" 0.095" 0.100" 0.125" 0.150" 0.175" 0.200" 0.250" 0.300" 0.375" 0.500" 0.625" 0.750" 0.875" 1.000" 1.250" 1.500" 1.750" 2.000" 2.500" 3.000" 3.500" 4.000" 4.500" 5.000" 5.500" 6.000" 6.500" 7.000" 7.500" 8.000" 8.500" 9.000" 9.500" 10.000"</small></p>														



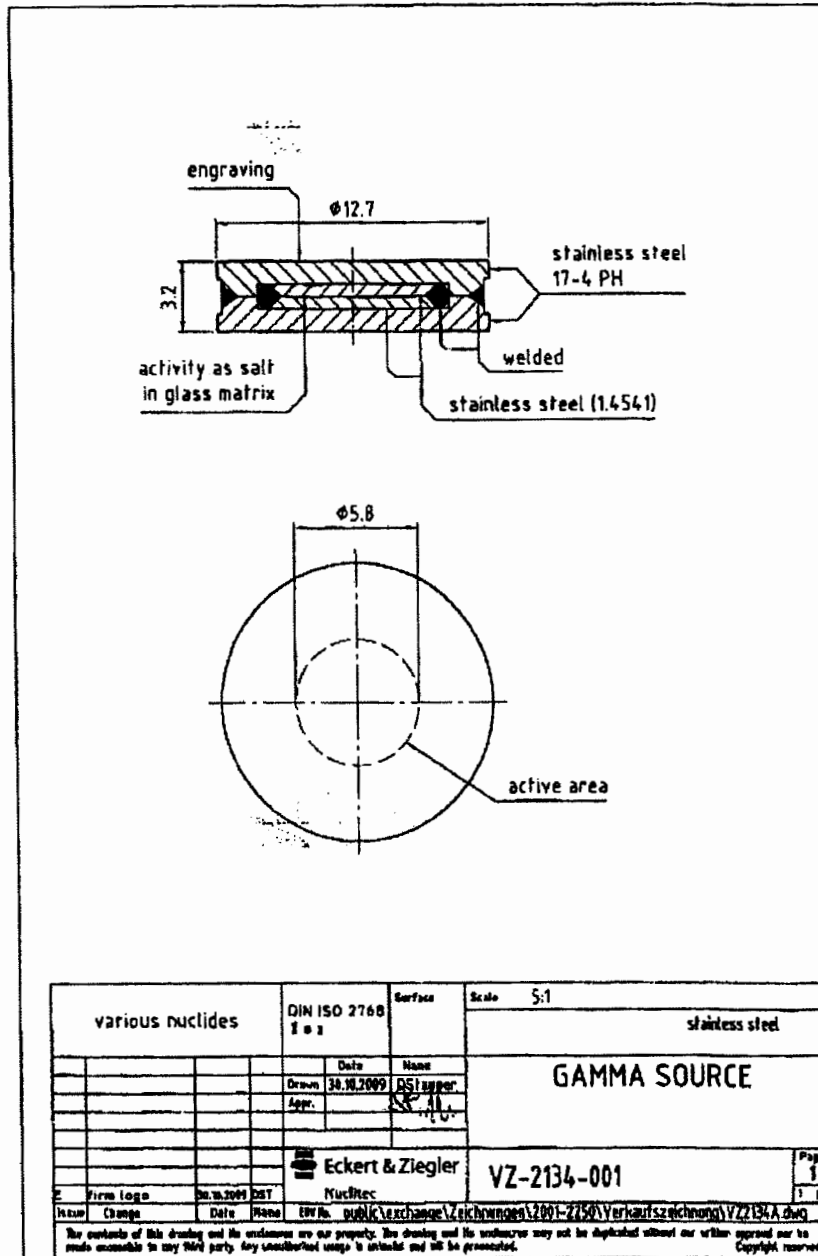
# REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCES (AMENDED IN ITS ENTIRETY)

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ATTACHMENT: 12

## Model CDC.PLS Gamma Source





**ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE**

<b>Name and Address of Applicant and/or Licensee</b>  Siemens Medical Solutions USA, Inc. ATTN: Mike Guin, Vice President of Service 221 Gregson Drive Cary, NC 27511	<b>Date</b> December 5, 2017
	<b>License Number(s)</b> 32-35165-01
	<b>Mail Control Number(s)</b> 601827
	<b>Licensing and/or Technical Reviewer or Branch</b> Commercial, Industrial, R&D, & Academic Branch (Branch 2)

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 11/27/2017

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>  
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

**Region I**  
**U. S. Nuclear Regulatory Commission**  
**Division of Nuclear Materials Safety**  
**2100 Renaissance Boulevard, Suite 100**  
**King of Prussia, PA 19406-2713**  
**(610) 337-5260, (610) 337-5313,**  
**(610) 337-5398, or (610) 337-5239**