

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

NO.: CA-0406-S-184-S

DATE: March 6, 2003

PAGE: 1 OF 5

SEALED SOURCE TYPE: Cylinder Source

MODEL: A1911

MANUFACTURER/DISTRIBUTOR:

Isotope Products Laboratories
24937 Avenue Tibbitts
Valencia, CA 91355
Phone: (818) 843-7000
Fax: (818) 843-6168

ISOTOPE:

Ge/Ga-68

MAXIMUM ACTIVITY:

10 mCi

LEAK TEST FREQUENCY:

Six (6) Months

PRINCIPAL USE:

Medical Reference Source (x)

CUSTOM SOURCE:

YES NO

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DESCRIPTION:

The source consists of an open-top cylinder shell 7.87 inches diameter by 8.87 inches in length, made of high density polyethylene which contains the solid active element in an organic complex of Germanium/Gallium-68 in a resin matrix. The outer shell's open top is enclosed by a circular high density polyethylene plug/cap that is secured with screws and epoxy resin. **A carrying handle is provided fixed to the top of the source's plug/cap.** Source contains a maximum of 10 millicuries total of Germanium-68 and Gallium-68 in equilibrium.

LABELING:

The source is labeled with a "Caution-Radioactive Material" label that contains IPL's logo, the radionuclide, model and serial number, assay date, activity and the radiation tre-foil symbol. The label will be durable material and firmly adhered to one face of the source.

DIAGRAM:

Attachment 1. Cylinder source.

CONDITIONS OF NORMAL USE:

The sources are intended to be used by trained personnel in a laboratory or clinical environment to provide necessary calibration and correction factors for positron emission tomography (PET) systems. The source may be mounted on a source holder in the scanner or placed directly on the patient couch.

PROTOTYPE TESTING:

The A1911 cylinder source has been tested and has achieved a classification of 77C22314 per ANSI N542-1977.

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EXTERNAL RADIATION LEVELS:

The exposure rate measurements from the side of a 10 millicurie Ge-68 source are determined to be approximately 70 mR/hr at 5 cm, 20 mR/hr at 30 cm and 3 mR/hr at 100 cm and exposure rates from the top are determined to be approximately 47 mR/hr at 5 cm, 14 mR/hr at 30 cm and 2 mR/hr at 100 cm. (The measurements were performed using a "RO-2" type ion chamber.)

QUALITY ASSURANCE AND CONTROL:

The source is 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:

- a. Distribution: These sources shall be distributed only to specific licensees of the NRC, Agreement States, or a Licensing State.
- b. Leak Test: Sources containing radioactive material in excess of 100 microcuries shall be leak tested at intervals not greater than six months. Such tests must be capable of detecting 0.005 microcuries of removable radioactivity, and be performed by specific licensees of the U. S. NRC, Agreement States, or Licensing State.
- c. Use: The A1911 sources are intended to be used by trained personnel in a laboratory or clinical environment to provide necessary calibration and correction factors for positron emission tomography (PET) systems. They should not be subjected to conditions exceeding their ANSI N542-1977 classification of 77C22314.
- d. Handling: Remote handling tools and localized shielding are generally not required.
- e. Storage: Store in shielded storage container.
- f. Cleaning: Sources may be cleaned with alcohol or water with a mild detergent.

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- g. Disposal: Disposal of decayed or otherwise unusable sources must be made via the user's authorized radioactivity disposal method.
- h. This registration sheet and the information contained within the references shall not be changed without the written consent of the California Department of Health Services.

REVIEWERS NOTE: The Model A1911 source is manufactured and distributed by Isotope Products Laboratories from two locations in California. However, only one address is listed on PAGE 1, since mail service is no longer available to the second location. The second address that is not listed is:

Isotope Products Laboratories
1800 North Keystone Street
Burbank, CA 91504

SAFETY ANALYSIS SUMMARY:

Based on review of the Model A1911 Cylinder Source, its 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 Model A1911 Cylinder 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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REFERENCES:

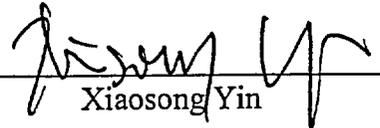
The following documents for the Model A1911 source are hereby incorporated by reference and are made a part of this registry document.

1. IPL letters dated October 24, 1995, May 24, 1996 and September 29, 1997, with attachments thereto.
2. IPL letter dated July 13, 2001.

ISSUING AGENCY: California Department of Health Services

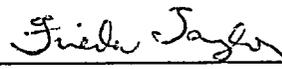
DATE: March 6, 2003

AMENDED BY:


Xiaosong Yin

DATE: March 6, 2003

CONCURRED BY:



Frieda Taylor

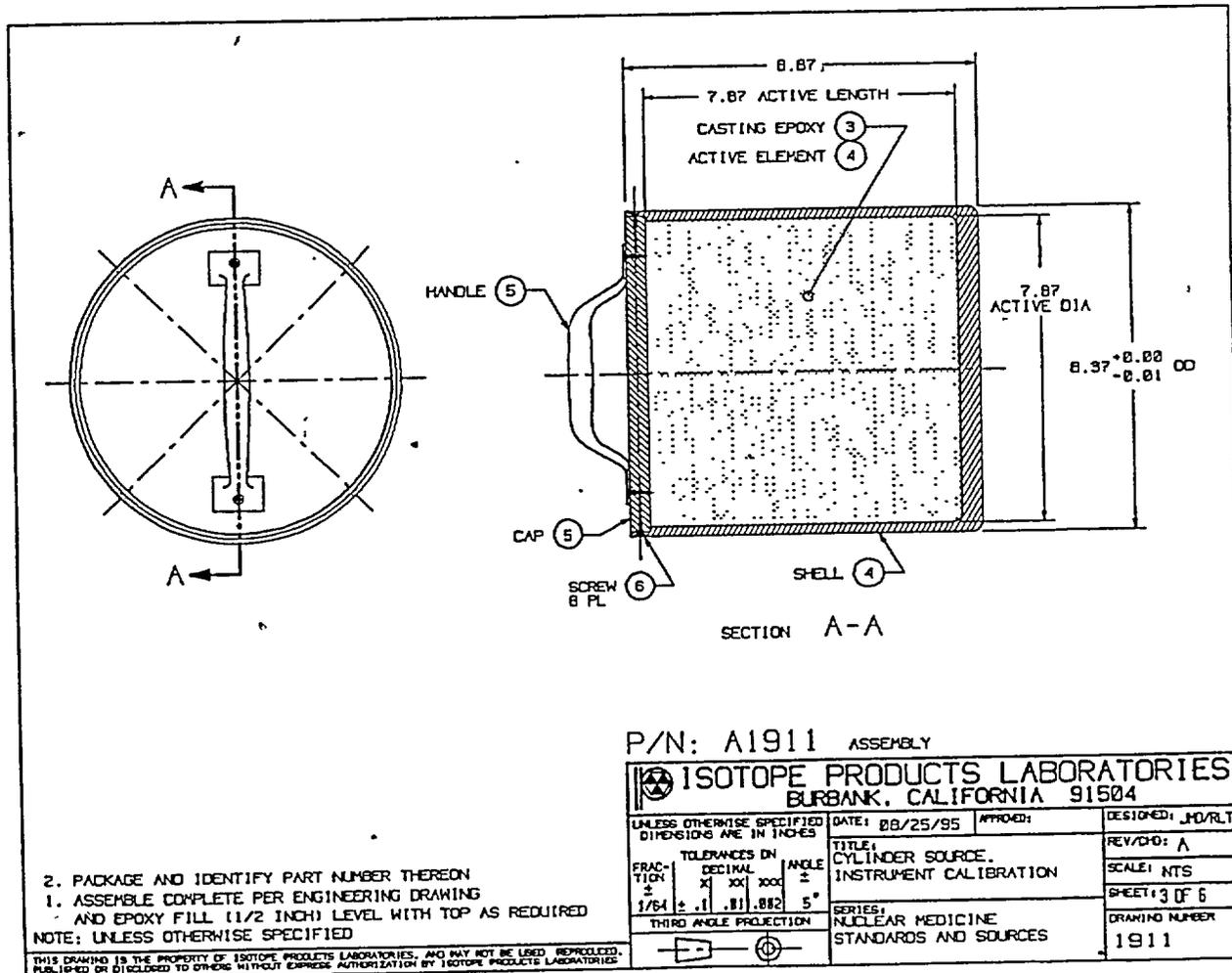
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ATTACHMENT: 1

CYLINDER SOURCE



2. PACKAGE AND IDENTIFY PART NUMBER THEREON
 1. ASSEMBLE COMPLETE PER ENGINEERING DRAWING
 AND EPOXY FILL (1/2 INCH) LEVEL WITH TOP AS REQUIRED
 NOTE: UNLESS OTHERWISE SPECIFIED