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

NO.: TN-0241-S-101-S DATE: June 29, 2015

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

MODEL: PET-XXX/YY (Variables indicate length and activity – XXX indicates length in millimeters, YY indicates activity in millicuries)

MANUFACTURER/DISTRIBUTER: Sanders Medical Products
10475 Dutchtown Road
Knoxville, Tennessee 37932

ISOTOPE: Germanium 68 **or**
Cobalt 57

MAXIMUM ACTIVITY: 20 millicuries

LEAK TEST FREQUENCY: 12 months

PRINCIPAL USE: Instrument calibration and patient transmission determinations

CUSTOM SOURCE: YES _____ NO __X__

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

DESCRIPTION:

This calibration source (Line source) consists of a ceramic or epoxy active element with Ge-68 or Cobalt 57 added and doubly encapsulated in stainless steel tubing. The inner tube is sealed using structural epoxy. Using a laser, a stainless steel plug is fusion welded into the ends of the outer tube. **A titanium source is available. It consists of a titanium tube with an inserted polyethylene tube containing epoxy with added Ge-68. Titanium end plugs are laser welded into each end of the outer tube.**

DIAGRAMS:

The **stainless steel** source is shown schematically in Attachment 1.

LABELING:

The source is labeled by engraving or etching. Information on the label includes company name, serial number, model number, activity, isotope, and calibration date if space permits. In the case of the smallest size only the serial number will be shown since space does not permit more legible information to be shown. When the source is installed in an instrument's shielded housing, an adhesive-backed identifying label provided by the source manufacturer will be attached to the instrument so that it will be visible to anyone removing the shielded housing. The labels are shown in Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The source is designed for use in controlled medical diagnostic facilities to adjust the response of nuclear medicine diagnostic imaging instruments. The source is either mounted inside source holders which are normally provided with the imaging instruments, or it is placed on the patient couch.

The amount of exposure received during the use of this source should be reviewed by the state licensing the source or other agency having jurisdiction over the possession and use of accelerator produced radioactive material. The useful life of the source is approximately 1.5 years.

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

PROTOTYPE TESTING:

The **stainless steel** source was tested by the manufacturer, Sanders Medical Products, Inc., according to American National Standard N542-1977. As a result of that testing, the manufacturer claims an ANSI rating of 77C32312 as specified in the standard for calibration sources with an activity greater than 30 microcuries. The source containment was not breached during testing. **Subsequent testing was conducted by the manufacturer for two stainless steel and two titanium prototype sources based on guidelines in ISO 2919-2012(E) and ISO 9978. Tests for the titanium sources included temperature, pressure, impact, puncture, bending, and leakage. The titanium line sources achieved a rating of ISO/12/C32312(7). The stainless steel sources were bend tested since this was not done at the time of the original device evaluation.**

EXTERNAL RADIATION LEVELS:

The radiation profile of the **stainless steel** PET source in a range of sizes is detailed in the chart below:

Source Length	Activity/Isotope	Radiation level at 5 cm	Radiation level at 30 cm	Radiation level at 100 cm
15 cm	10 mCi (370 MBq) Ge-68	850 mR/hr	65 mR/hr	6 mR/hr
207 cm (coiled)	1 mCi (37 MBq) Ge-68	90 mR/hr	6 mR/hr	1 mR/hr
15 cm	1 mCi (37 MBq) Co-57	17.5 mR/hr	1.3 mR/hr	0.12 mR/hr

QUALITY ASSURANCE AND CONTROL:

The Sanders Medical Products, Inc. "Source Manufacturing Quality Assurance Program" provides for quality checks and tests in the manufacturing process including design, material purchasing, storage, in-process steps, final testing, and certification. Handling instructions are provided for installers and users.

SEALED SOURCE TYPE: Nuclear Medicine Calibration Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

This source shall be distributed only to persons who are approved for its use in a specific license issued by this Department, another Agreement State, or other state or agency who maintains jurisdiction over the possession and use of accelerator produced radioactive material.

The source shall be installed, relocated, removed, initially surveyed, leak tested, serviced, and repaired by Sanders Medical Products, Inc. personnel or other persons specifically licensed by this Department, another Agreement State, or other state or agency who maintains jurisdiction over the possession and use of accelerator produced radioactive material. Special attention should be given to hand and extremity monitoring for those performing source installations.

The source shall be leak tested at least annually using techniques capable of detecting 0.005 microcuries of removable contamination. Specifically licensed persons shall perform the test.

This registration sheet and the information contained within the references shall not be changed without the written consent of the State of Tennessee.

SAFETY ANALYSIS SUMMARY:

Based on our review of the manufacturer's information and test data, our conclusion regarding the safety of the Line source is as follows:

Under ordinary conditions of handling, storage, and use, the radioactive material contained in the source will not be released or inadvertently removed from the source. Furthermore, it is unlikely that any person will receive an occupational annual dose exceeding the limits specified in Tennessee "State Regulations for Protection Against Radiation."

It is unlikely under accident conditions (such as fire or explosion) associated with handling, storage, and use of the source that any person would receive an occupational annual dose exceeding the limits specified in Tennessee "State Regulations for Protection Against Radiation."

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REFERENCES:

The following supporting documents for the source are hereby incorporated by reference and are made a part of this registry document:

- Application dated May 18, 1995, with attachments
- Letters dated June 5, 1995, with attachment, June 29, 1995, with attachments, June 27, 2000, with attachments, December 5, 2006, with attachments, **March 26, 2015, with attachments, and June 10, 2015, with attachments**
- Information received September 24, 2001, with attachments, and February 28, 2007

ISSUING AGENCY:

Tennessee Department of Environment and Conservation
Division of Radiological Health

DATE: 6/29/15 REVIEWED BY: Charles Arnott

DATE: 6/29/15 CONCURRENCE BY: Johnny C. Graves

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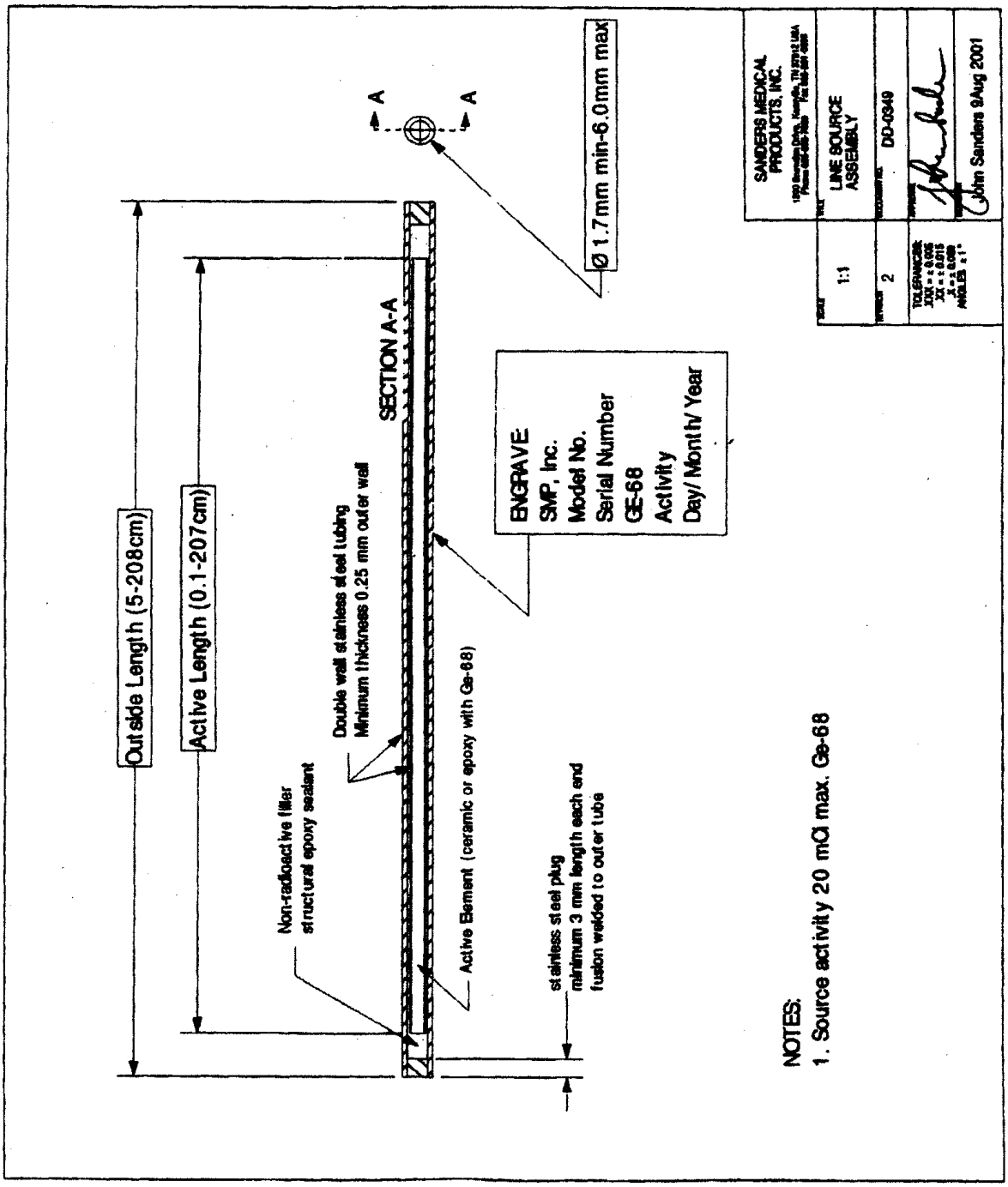
NO.: TN-0241-S-101-S DATE: June 29, 2015 Attachment 1



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Line Source Label