REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(Amendment in Entirety)

NO.: TX-1153-S-103-S DATE: August 6, 2004

SOURCE TYPE: Positron emission tomography line source

MODEL: BM68-XX-YY **Where XX is an identification number assigned to a specific epuipment manufacturer and YY denotes nominal activity in mCi**

MANUFACTURER/DISTRIBUTOR: International Isotopes Idaho, Inc.
4137 Commerce Circle
Idaho Falls, ID 83401

ISOTOPE: Ge-68 MAXIMUM ACTIVITY: 24 mCi (888 MBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (X) Medical reference source For use in accordance with Title 25 Texas Administrative Code 289.256(cc)(1) [10 CFR 35.500] or equivalent state regulations

CUSTOM SOURCE: ____ YES __X__ NO

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DESCRIPTION:

These sources are designed by RadQual, L.L.C. and consist of a Ge-68 source matrix doubly encapsulated in stainless steel tubing sealed with a friction fit stainless steel plug or screw using a structural epoxy or metal weld. Structural components of the source (i.e. inner and outer capsules and seal plugs or screws) are constructed of Type 304 or comparable stainless steel.

Two methods of constructing the active source matrix have been tested. The preferred method involves homogenously mixing Ge-68 with a two part epoxy and then remotely injecting this mixture into an inner centering tube that has had one end sealed. The epoxy is then cured in accordance with the manufacturer's instructions.

An alternate method of the constructing the active source matrix is by evenly distributing the Ge-68 onto a metal wire, rod or foil via an electroless or electrolytic process and then placing this source matrix into the inner centering tube. This method would be used when the inside diameter of inner centering tube would restrict the flow of the two part epoxy.

After the source matrix is contained within the inner centering capsule, the open end is sealed and the inner capsule is then placed into an outer capsule which has one end sealed. The remaining open end of the outer capsule is then sealed. Source specifications are summarized in the table below:

Model	Nominal Outside Diameter	Minimum Wall Thickness	Active Length	Overall Length	Maximum Activity
BM68-XX-YY	0.15-0.23 in. +/- 0.002 in. (3.9- 6.5 mm +/- 0.05 mm)	0.039 in. (1.0 mm)	0.04 - 7.95 in. +/- 0.02 in. (1.0 - 202 mm +/-0.5 mm)	0.28 - 8.19 in. +/- 0.02 in. (7.0 - 208 mm +/- 0.5 mm)	24.0 mCi (888 Mbq) Loaded to a maximum of 100 uCi/mm of active length

The majority of these sources will be affixed to a custom source holder for attachment to a specific imaging device. These source holders and attachment mechanisms are not considered a part of the encapsulation of the source matrix.

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LABELING:

The outer capsule of each source is engraved, as a minimum, with the source model number and the radiation trefoil. This minimum identification is reserved to the smallest sources. In larger sources the serial number, nominal activity, isotope, and reference date for each source will be included as space on the capsule permits.

Each shielded storage container has a laminated adhesive label that complies with Title 25 Texas Administrative Code (TAC) §289.202(cc)(1) [10 CFR 20.1901] by containing the radiation symbol (in magenta on a yellow background), isotope present, nominal activity, month and year of assay, designer's name and logo, serial number and the words, "CAUTION: RADIOACTIVE MATERIAL." Refer to Attachment 1.

A second laminated adhesive label will be provided to the customer to be affixed to the permanent source holder or will be affixed directly by the source manufacturer if the permanent source holder is provided. Refer to Attachment 2.

DIAGRAM:

Refer to Attachment 3.

CONDITIONS OF NORMAL USE:

These sources are designed and manufacturered for use as transmission sources during diagnostic imaging of patients undergoing positron emission tomography (PET). Sources may also be used as calibration or reference sources for the PET scanning system detector array. These sources are designed for use in a hospital or clinic environment and are not expected to experience extreme environmental factors. These sources are not to be subjected to abrasion, corrosion, impact, puncture or temperature/pressure cycling or extremes. The expected useful life of these sources is approximately two years.

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PROTOTYPE TESTING:

Prototype sources have been subjected to tests described in American National Standards Institute, Inc. (ANSI) publication "Sealed Radioactive Sources - Classification" (ANSI/HPS N43.6-1997) and have been found to meet the classification of 97C32312. A bend test (10.2 kg applied static force for four hours) was performed on a prototype model BM68-11 as a part of the original evaluation of theses sources and was found to have maintained its integrity. The test was not repeated as a part of this amendment due to similarity of materials and construction.

EXTERNAL RADIATION LEVELS:

Maximum dose rates were extrapolated for sources with nominal activities of 0.1 mCi (3.7 MBq) and 20.2 mCi (747.4 MBq) to represent a maximum source loading of 100 uCi/mm of active length. Dose rates were modeled using data from measurements of similar sources produced by this manufacturer. All dose rates are mRem/hr unless otherwise indicated.

Position	0.1 mCi (3.7 MBq)	20.2 mCi (747.4 MBq)
5 cm off axis on ⊥ bisector	21 (0.21 mSv)	2385 (23.85 mSv)
30 cm off axis on ⊥ bisector	0.60 (6 uSv)	117 (1.17 mSv)
100 cm off axis on ⊥ bisector	0.05 (0.5 uSv)	11 (0.11 mSv)

QUALITY ASSURANCE AND CONTROL:

International Isotopes Idaho, Inc. maintains a quality assurance program which has been deemed acceptable for licensing purposes by the U. S. Nuclear Regulatory Commission. Periodic audits by International Isotopes Idaho, Inc. Quality Assurance staff, as well as periodic audits performed by external vendors, ensure that the program continues to perform at an acceptable level. A copy of the quality assurance program is on file with the Texas Department of Health, Bureau of Radiation Control.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed to persons specifically licensed by the NRC, an Agreement State or a Licensing State.

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SOURCE TYPE: Positron emission tomography line source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (continued)

- 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.
- The sources shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- The sources shall not be subjected to conditions that exceed their ANSI/HPS N43.6-1997 classification of 97C32312 or bend test parameters (applied static force greater than 10.2 kg for longer than four hours).
- This registration sheet and the information contained within the references shall not be changed without the written consent of the Texas Department of Health, Bureau of Radiation Control.
- Licensees in possession of sources that have decayed below their useful range of activities may contact International Isotopes Idaho, Inc. for instructions regarding return to the manufacturer.

SAFETY ANALYSIS SUMMARY:

Based on a review of the information and test data submitted for this source and the references cited below, we conclude the these sources are acceptable for licensing purposes.

Furthermore, we conclude that this source would be expected to maintain containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate. The probable effect of severe environmental conditions, such as accidents and fire, would be minimal release of radioactivity in most cases since the preferred method of construction incorporates the radioactive material into a cured epoxy matrix which is contained within a stainless steel housing.

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REFERENCES:

The following supporting documents for the Model BM68-XX-YY source is hereby incorporated by reference and made a part of this registry document.

- International Isotopes Idaho, Inc. application dated January 20, 2003, with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated March 28, 2003 with enclosures thereto.
- International Isotopes Idaho, Inc. electronic mail dated May 9, 2003 with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated January 5,2004 with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated April 19, 2004 with enclosures thereto.
- International Isotopes Idaho, Inc. letter dated May 24, 2004 with enclosures thereto.

ISSUING AGENCY: Texas Department of Health
Bureau of Radiation Control

Date: August 6, 2004 Reviewer: J. Scott Kee
J. Scott Kee

Date: August 6, 2004 Concurrence:
William Stringfellow

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
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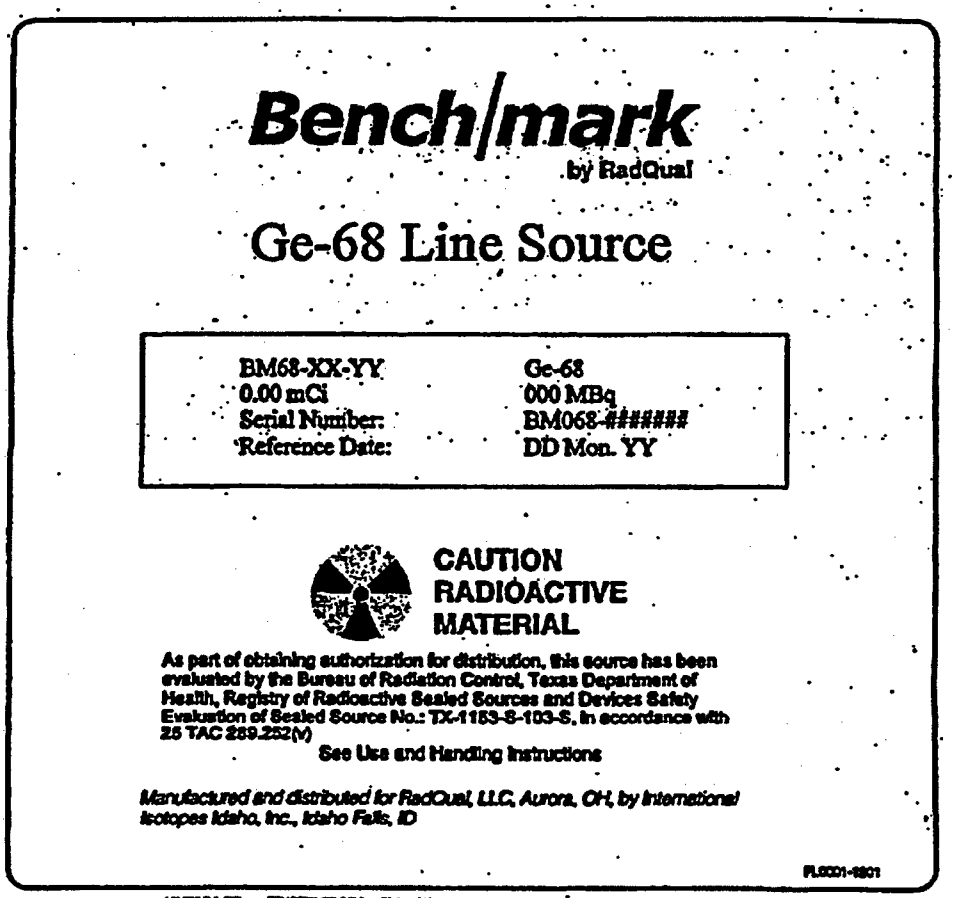
NO.: TX-1153-S-103-S DATE: August 6, 2004 ATTACHMENT 1



Storage Container Label

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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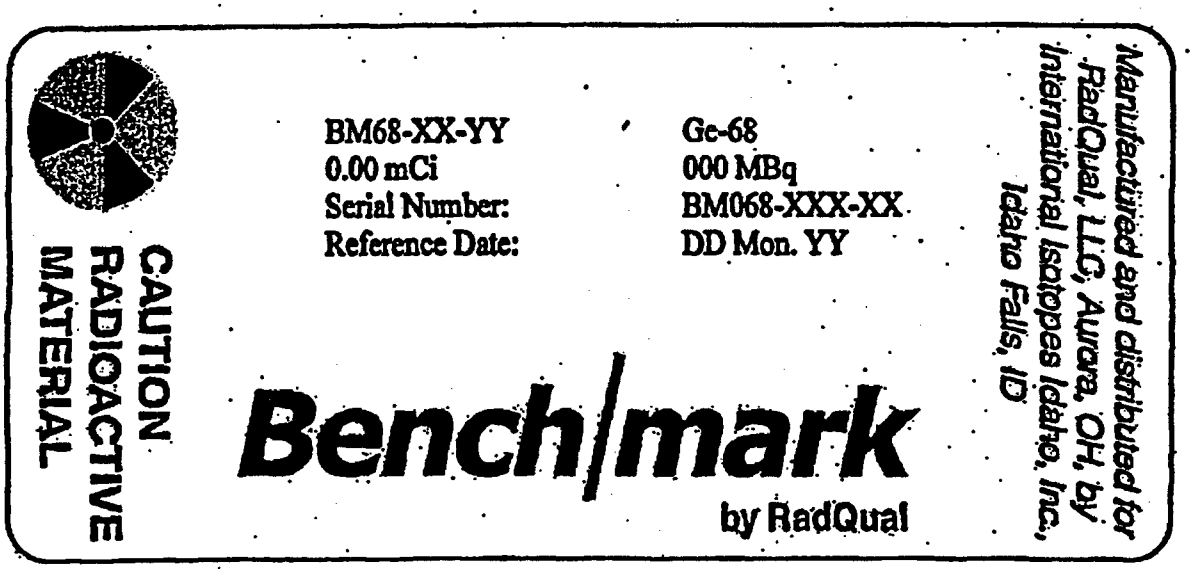
NO.: TX-1153-S-103-S DATE: August 6, 2004 ATTACHMENT 2



Source Holder Label

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SAFETY EVALUATION OF DEVICE
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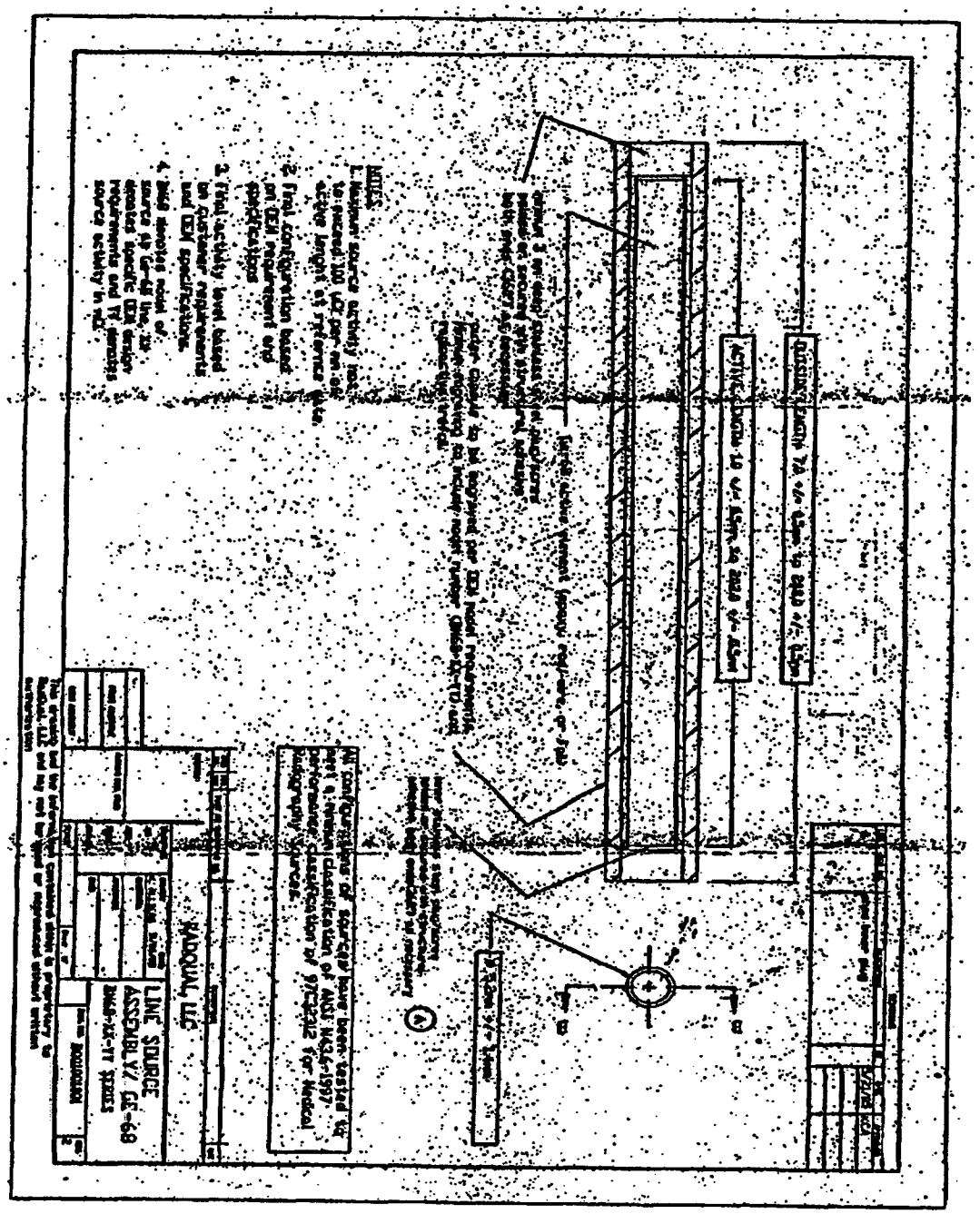
NO.: TX-1153-S-103-S DATE: August 6, 2004 ATTACHMENT 3



Model BM68-XX-YY Line Source