STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH
L&C ANNEX – THIRD FLOOR
401 CHURCH STREET
NASHVILLE, TENNESSEE 37243-1532

May 25, 2006

U. S. Nuclear Regulatory Commission
Sealed Source Safety Section
Mail Stop T-8 F5
Washington, D.C. 20555

Attention: Traci Kime

Dear Ms. Kime:

Enclosed is Safety Evaluation TN-1067-D-101-S amended in its entirety. It is issued to Siemens Medical Solutions USA, Inc., Molecular Imaging, formerly CTI Molecular Imaging, Inc.

Please contact us at 615-532-0412, if you have any questions.

Sincerely,

Sasi Krishnasarma

Sasi Krishnasarma
Health Physicist
Division of Radiological Health

MMSS12

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

NO.: TN-1067-D-101-S DATE: May 25, 2006 PAGE: 1 OF 7

DEVICE TYPE: Source holder for Positron Emission Tomograph (PET) Medical Diagnostic Scanner

MODEL: ECAT EXACT SERIES (ECAT EXACT, ECAT EXACT HR, ECAT EXACT HR+)

ECAT REVEAL XL SERIES (ECAT ACCEL, ECAT REVEAL) - formerly ECAT ACCEL Series

SEALED SOURCE MODEL: **Siemens Medical Imaging Solutions USA, Inc.**
Molecular Imaging
810 Innovation Dr.
Knoxville, TN 37932
Model LS series (with suffix added to indicate scanner model)

MANUFACTURER/DISTRIBUTOR: **Siemens Medical Imaging Solutions USA, Inc.**
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932

ISOTOPE:	MAXIMUM ACTIVITY:
Ge/Ga 68	10.0 millicuries per source (370 MBq) 3 each used in the device

LEAK TEST FREQUENCY: 1 year

PRINCIPAL USE: (B) Medical Radiography

CUSTOM DEVICE: YES ____ NO __X__

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DEVICE TYPE: Source holder for Positron Emission Tomograph (PET) Medical Diagnostic Scanner

DESCRIPTION:

The ECAT EXACT SERIES and ECAT REVEAL XL SERIES PET scanners are whole body positron emission tomography imaging systems. The two systems differ in their detector assemblies. This product is a permanently installed system equipped with a scanner, an integrated work station, the Advanced Computational System (ACS), and a patient couch. These scanners are equipped with 3 rod source holders, in which are inserted sealed radiation sources containing Ge/Ga 68 (See Attachment 1). In use, these positron emitting rod sources are extended into the scanner's field of view in order to perform blank reference scans, as well as patient transmission scans. Transmission scan data is used for attenuation correction of patient emission scan data, necessary to performing quantitative diagnostic studies of body organs and other anatomical structures. The scanner is equipped with a gantry mounted to a steel baseplate which is permanently bolted to the facility's (concrete) floor (See Attachment 2). The gantry contains the 3 Ge/Ga sealed rod sources, each of which are installed into a bronze tubular source holder (See Attachment 3). The 3 source holders are mounted axially and equally spaced around the scanner gantry patient port on an assembly that rotates around the patient port (See **Attachment 4**). These 3 sources will vary in activity but will not exceed 1110 MBq (30.0 mCi) in total. In their shielded position, the rod sources are retracted into individual lead shields or "pigs". To extend the sources, a ring gear at the end of the assembly, which engages a pinion gear on each of the 3 rod sources holders, is electro-mechanically rotated which drives the rod sources linearly into the scanner's field of view via a jack screw mechanism on each source holder. Sensor switches at each source holder control the source position travel limits. These source holders are enclosed in the gantry and the gantry front, back and patient port are fully enclosed by covers that are secured by screws. Access to the inside of the gantry is restricted to the distributor's qualified service personnel.

Extension of the sealed sources into the field of view and retraction of the sources back into their shields is controlled by the operator, either manually by pushing the gantry front panel switch with the extend/retract sources command, or automatically, by the system computer during a scan procedure. The sources position/status (retracted, extending, extended, retracting) is displayed on the gantry front panels, located on either side of the patient port. This source position/status is also displayed on the control console monitor screen. When the sources are fully extended into the scanner's field of view, the displayed source position message flashes on and off to alert the system operator.

DEVICE TYPE: Source holder for Positron Emission Tomograph (PET) Medical Diagnostic Scanner

DESCRIPTION(continued):

The ECAT EXACT and ECAT REVEAL XL systems may also be transported and used in a mobile environment by adapting the systems for use in specialized motor coaches and trailers. In this mobile environment a mobile upgrade kit will be used with modifications to the scanner gantry. Special shielded containers, which have been securely latched and permanently secured to the floor of the coach or trailer have been designed for the universal phantom source and for the sealed calibration rod source, to enable safe transport of these sealed sources.

LABELING:

The distributor does not apply labels applicable to devices containing sealed sources on the PET scanners prior to shipment of those scanners because PET scanners are sold and shipped without sources installed. The system purchaser must procure the sealed sources separately from the scanner. The appropriate label is applied to the scanner by the distributor's representative at the time that the sealed sources are installed in the scanner.

Labeling for the model LS series sealed sources supplied by the distributor for the ECAT EXACT and ECAT REVEAL XL SERIES is described in the Registry of Sealed Sources and Devices Safety Evaluation of Sealed Sources, registration No. TN-237-S-103-S.

DIAGRAMS:

See **Attachments 1 through 5.**

CONDITIONS OF NORMAL USE:

The device is designed and intended for use in a fixed or mobile medical facility and operated under specific environmental conditions. As such, these devices are not expected to be subjected to environmental stresses which a patient could not reasonably endure. Since these PET scanners are shipped without the sources installed, there is no risk of exposure from accidental device or source damage during transport of the scanner.

DEVICE TYPE: Source holder for Positron Emission Tomograph (PET) Medical Diagnostic Scanner

CONDITIONS OF NORMAL USE (continued):

Sources are normally installed in the scanner at the site by technicians trained by the distributor. Because of the approximate 271 day half-life of the sealed Ge/Ga 68 rod sources, useful life of the sources is about one year. The sealed source manufacturer offers a source replacement service. After being replaced, depleted sources are generally returned to the distributor for eventual disposal. In mobile PET Systems, sealed sources are stored/shipped in special shielded lead containers which were tested per D.O.T. Specification 7A, Type A and found to be compliant.

The estimated working life of the device is 5 years.

PROTOTYPE TESTING:

The basic design of the sealed source holders as well as the mechanisms that move the rod sources into and out of the scanner field of view and rotate the sources around the patient port were incorporated into these PET scanners in 1990. Initial prototype testing was performed during this time and several incremental design improvements have since been implemented. An assessment of the overall reliability of these mechanisms can be made by looking at the device's performance history.

Since 1990 there have been very few reported complaints relating to failure of the rod source transport mechanism as compared to the number of studies conducted. The majority of the reported failures were subsequently found to be caused by maintenance problems, such as lubrication, mechanical adjustments, and component failures such as switches and sensors. Furthermore, there is no history of a sealed source ever leaking or being damaged as the result of a rod source transport mechanism failure or by any other system failure.

An occurring system failure or a power failure that prevents the rod sources from retracting into the shields is easily detectable by system operating personnel monitoring the scan procedure, who would then immediately remove the patient from the scanner if one is present. In this situation, a qualified service person must remove the scanner covers and manually retract the sources or, alternately, remove the sources from the source holders and place them in their lead storage containers.

DEVICE TYPE: Source holder for Positron Emission Tomograph (PET)
Medical Diagnostic Scanner

PROTOTYPE TESTING (continued):

Given the controlled hospital environment in which these PET scanners are installed and operated, the probability of the device being subjected to any extreme conditions or potential accident situations that would compromise the integrity of the device of the sealed sources is considered remote.

D.O.T. Specification 7A, Type A packaging tests were conducted on the shielding container for the phantom source, shielding container for the sealed calibration rod source, and on the mechanism containing the three rod source holders in the scanner gantry with all containers passing. Vibration tests were conducted by an independent third party on an ECAT EXACT system in a typical mobile environment, installed in a motorized coach. These tests indicated acceptable vibration levels for the system under various transport conditions.

Also a risk assessment was performed on the mobile ECAT EXACT system. All potential hazards were identified, assessed and found to be adequately addressed to the extent that any residual risks associated with the system during its use in a mobile environment were determined to be acceptable.

EXTERNAL RADIATION LEVELS:

Measurements were made around the gantry which houses the radiation sources. The levels in mrem/hr were 0.5 and 0.05 at 1 meter from the patient port with the rods retracted. The levels were 20.0 and 0.8 at 1 meter from the patient port with the rods extended. Calculated levels for all models were equal to or less than 6.0 mrem/hr at 25 cm and 1.1 mrem/hr at 1 meter. These measurements were taken with total activity of the Ge-68 sources at 15.0 mCi.

A survey of the new ECAT REVEAL XL matched the existing survey of the ECAT EXACT HR+. The radiation profiles were exactly the same. See **Attachment 5.**

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LIMITATIONS AND OTHER CONSIDERATIONS OF USE:

Devices may be distributed to specific licensees of the U. S. Nuclear Regulatory Commission or an Agreement State. Installation, relocation, maintenance, or repair of the device shall be performed by the distributor's personnel, or other persons authorized in a specific license issued by the NRC or an Agreement State to perform these services.

The handling, storage, use, transfer or disposal of devices used under a specific license shall be determined by the licensing authority.

The expected useful life of the device is 5 years. At the end of its useful life the device is returned to the manufacturer.

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

The device shall be leak tested at intervals not to exceed 1 year using techniques capable of detecting 0.005 microcurie of removable contamination. Specifically licensed persons shall perform the test.

SAFETY ANALYSIS SUMMARY:

Based on our review of the manufacturer's information and test data, our conclusion regarding the safety of the ECAT EXACT and ECAT REVEAL XL scanner source holder is as follows:

Under ordinary conditions of handling, storage, and use, these scanners and their source holders should maintain their integrity. Furthermore, it is unlikely that any person will receive a radiation dose in any calendar quarter exceeding 10 percent of the limits specified in 1200-2-5-.50(1) of the 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 device that any person would receive a radiation dose exceeding the limits specified in 1200-2-5-.50(1) of the Tennessee "State Regulations for Protection Against Radiation."

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DEVICE TYPE: Source holder for Positron Emission Tomograph (PET) Medical Diagnostic Scanner

REFERENCES:

The following supporting documents for the ECAT EXACT SERIES and ECAT REVEAL XL SERIES scanners are hereby incorporated by reference and are made a part of this registration document:

- Fax received October 8, 1998, with attachments, from Bill Skremsky
- Letters dated October 29, 1998, with attachments, November 23, 1998, with attachments, December 8, 1998, with attachment, September 9, 1999, with attachments, October 29, 2001, with attachments, March 1, 2002, February 20, 2004, with attachments, March 2, 2004, March 24, 2004, with attachments, **April 24, 2006, with attachments**

DATE: 5/25/06 REVIEWED BY: Sasi Krishnasarma
Sasi B. Krishnasarma

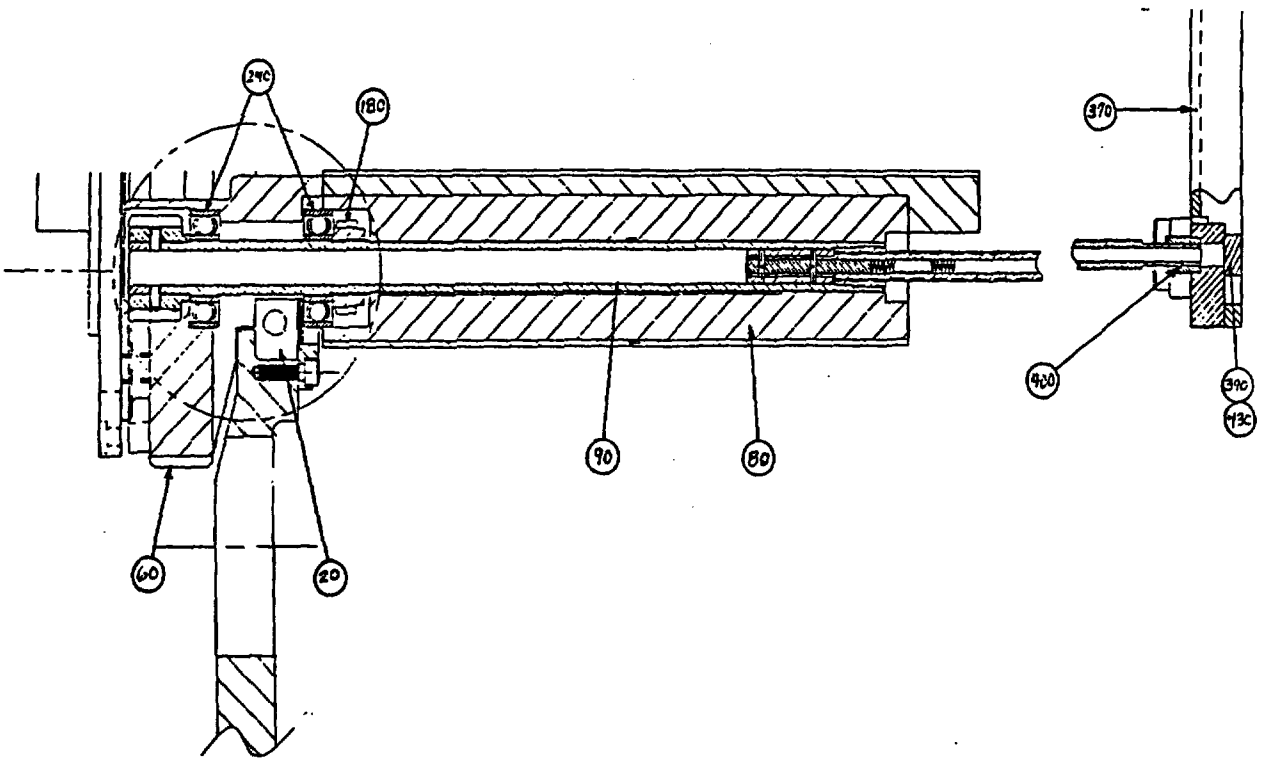
DATE: 5/25/06 CONCURRENCE: Ronald J. Parsons
Ronald J. Parsons

ISSUING AGENCY:

State of Tennessee

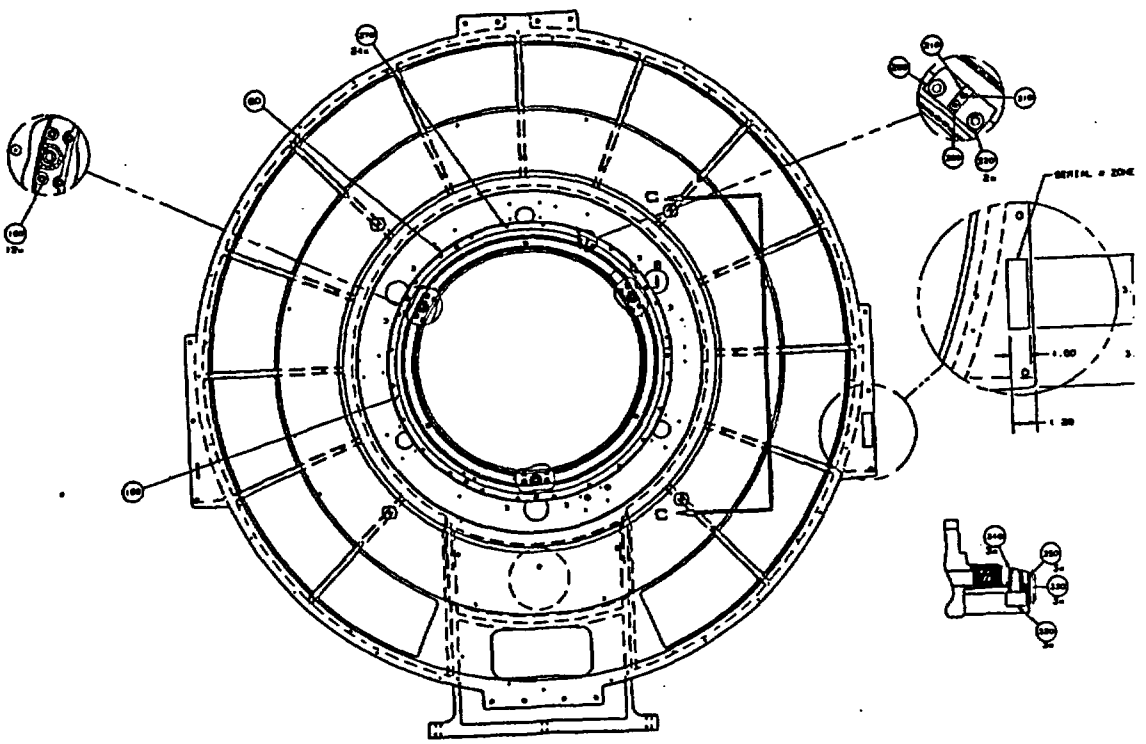
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: TN-1067-D-101-S DATE: May 25, 2006 Attachment 1



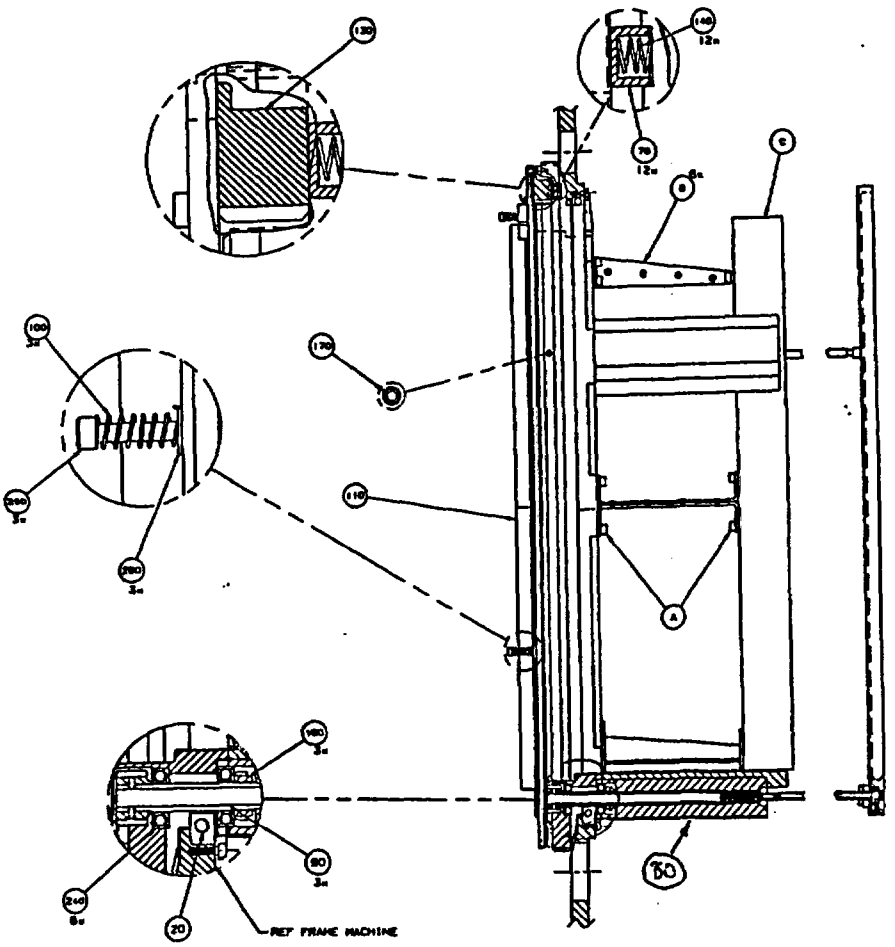
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: TN-1067-D-101-S DATE: May 25, 2006 Attachment 2



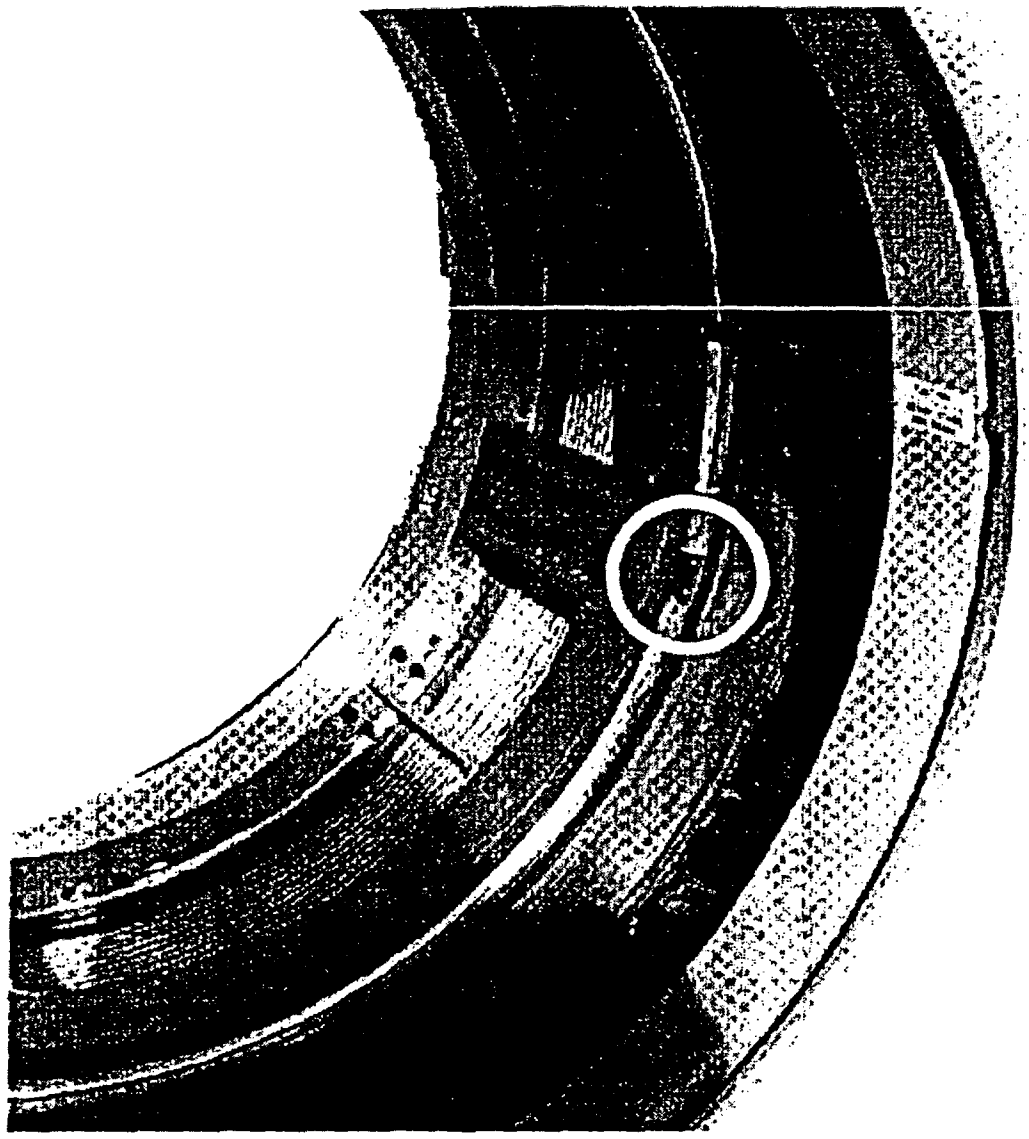
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: TN-1067-D-101-S DATE: May 25, 2006 Attachment 3



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

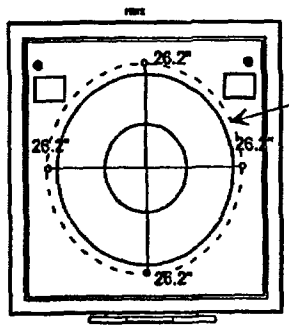
NO.: TN-1067-D-101-S DATE: May 25, 2006 Attachment 4



The circle shows the rod source end cap

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

NO.: TN-1067-D-101-S DATE: May 25, 2006 Attachment 5



Location	distance from the center of source mm (inches)	Angle (degree)
1	1400 (55.1")	0
2	1400 (55.1")	30
3	1217 (47.9")	60
4	665 (26.2")	90
5	1623 (63.9")	120
6	1542 (60.7")	150
7	1542 (60.7")	180
8	1542 (60.7")	210
9	1623 (63.9")	240
10	665 (26.2")	270
11	1217 (47.9")	300
12	1400 (55.1")	330