



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 24, 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-102-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

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

NO: TN-1067-D-102-S

DATE: May 24, 2006

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

MODEL: ECAT ART SERIES (ECAT ART)
ECAT REVEAL QS SERIES (ECAT REVEAL QS)

SEALED SOURCE MODEL: Isotope Products Laboratories
800 North Keystone Street
Burbank, CA 91504
Model PHI-0089

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

ISOTOPE:

Cesium 137

MAXIMUM ACTIVITY:

15 millicuries per source (555 MBq)
two each used in the device

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (B) Medical Radiography

CUSTOM SOURCE: YES: _____ NO: X

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DESCRIPTION:

The ECAT ART SERIES and ECAT REVEAL QS SERIES PET scanners are whole body positron emission tomography imaging systems. This product is a permanently installed system equipped with a scanner, operator's console, and a patient bed. These PET scanners are equipped with two source holders into each of which is inserted a sealed radiation source containing Cesium 137 (See Attachment 1). In use, these gamma emitting 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. The gantry contains the two Cesium sealed sources, each of which are installed into collimated lead holders mounted in their source mechanisms. The two source holders are mounted on one of the two detector array assemblies which in turn are mounted to the rotating carriage assembly within the scanner gantry (See Attachment 2). These two sources will vary in activity but will not exceed 1110 MBq (30mCi) in total. In their shielded position the point sources are positioned behind individual lead shields. When an "extend sources" command is given the collimated source holders are stepped by a motor driven conveyor chain out from behind the shield across the scanner's field of view for a user programmed period of time, and upon completion of the transmission scan are cycled around and back behind the shields (See Attachment 3).

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. 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.

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DESCRIPTION (continued):

The ECAT ART and the ECAT REVEAL QS 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.

LABELING:

The distributor does not apply labels applicable to devices containing sealed sources on these 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 at the time that the sealed sources are installed in the scanner.

Labeling for the model PHI-0089 series sealed sources supplied by the distributor is described in the Registry of Sealed Sources and Devices Safety Evaluation of Sealed Sources, registration No. CA-406-S-118-S.

DIAGRAMS:

See Attachments 1-3.

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.

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CONDITIONS OF NORMAL USE (continued):

The intended users of the device are licensed medical technologists, physicians and other qualified users having the necessary training in radiation safety for handling radioactive materials and using sealed sources. System operating personnel may be in close proximity to the scanner when the point sources are extended, and therefore may be exposed to low levels of radiation for short time periods. However, even this low level exposure from the sealed sources is generally avoided by operating the scanner from the system's control console, which is always located some distance away (3 meters or further) from the system gantry containing the sources. System operating instructions contain warnings to device users, describing how to avoid unnecessary radiation exposure.

Sources are normally installed in the scanner at the site by the distributor's trained technicians. Because of the approximate 30 year half-life of the sealed Cesium 137 sources, the useful life of the sources is at least as long as the life of the scanner. At the end of its working life, or at any other time the scanner is to be transported to another location, the sealed point sources are required to be removed from the scanner and either stored in their lead containers at the site, shipped back to the source distributor, or otherwise disposed of in a manner that conforms with local laws and regulations applicable to the disposal of radioactive materials.

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 point sources into and out of the scanner field of view and rotate the sources around the patient port were tested during its development. The sealed source mechanism was extensively tested for a simulated scanner use time over two years without a failure of the mechanism.

An occurring system failure or a power failure that prevents the sources from returning 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

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PROTOTYPE TESTING (continued):

manually retract the sources, or alternately, remove the sources from the source holders and place them in their lead storage containers.

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 or the sealed sources is considered remote.

D.O.T. Specification 7A, Type A packaging tests were conducted on the devices and it was determined that the devices meet the D.O.T. standards and are acceptable as Radioactive Shipping Containers.

EXTERNAL RADIATION LEVELS:

Measurements of an ECAT ART scanner were made in and around the gantry which houses the radiation sources. The levels from the source area with the sources retracted were <8 mR/hr at 5 centimeters and <0.1 mR/hr at 1 meter. The level was <30 mR/hr in the center of the patient port with the sources extended. These measurements were taken with 30 mCi total activity of Cesium 137.

QUALITY ASSURANCE AND CONTROL:

The distributor has an established quality assurance system for the design, manufacture and testing of PET systems which has been deemed acceptable for licensing purposes by TUV, Essen, an independent certification body, and found to be in conformance with the requirements of ISO 9001 / EN ISO 9001 / EN 46001, enabling the distributor to be registered as ISO 9001 compliant.

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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 trained 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 6 months 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 ART SERIES and ECAT REVEAL QS SERIES 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 year exceeding 10 percent of the limits specified in 1200-2-5-.50 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 of the Tennessee "State Regulations for Protection Against Radiation."

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REFERENCES:

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

- Letters dated March 29, 1999, with attachments, April 30, 1999, with attachment, March 5, 2002, with attachments, March 14, 2002, with attachment, December 26, 2002, with attachments, January 31, 2003, with attachments, February 20, 2004, with attachments, and April 24, 2006, with attachments

DATE: 5/26/06

REVIEWED BY: Sasi Krishnasarma
Sasi B. Krishnasarma

DATE: 5/26/06

CONCURRENCE: Ronald J. Parsons
Ronald J. Parsons

ISSUING AGENCY:

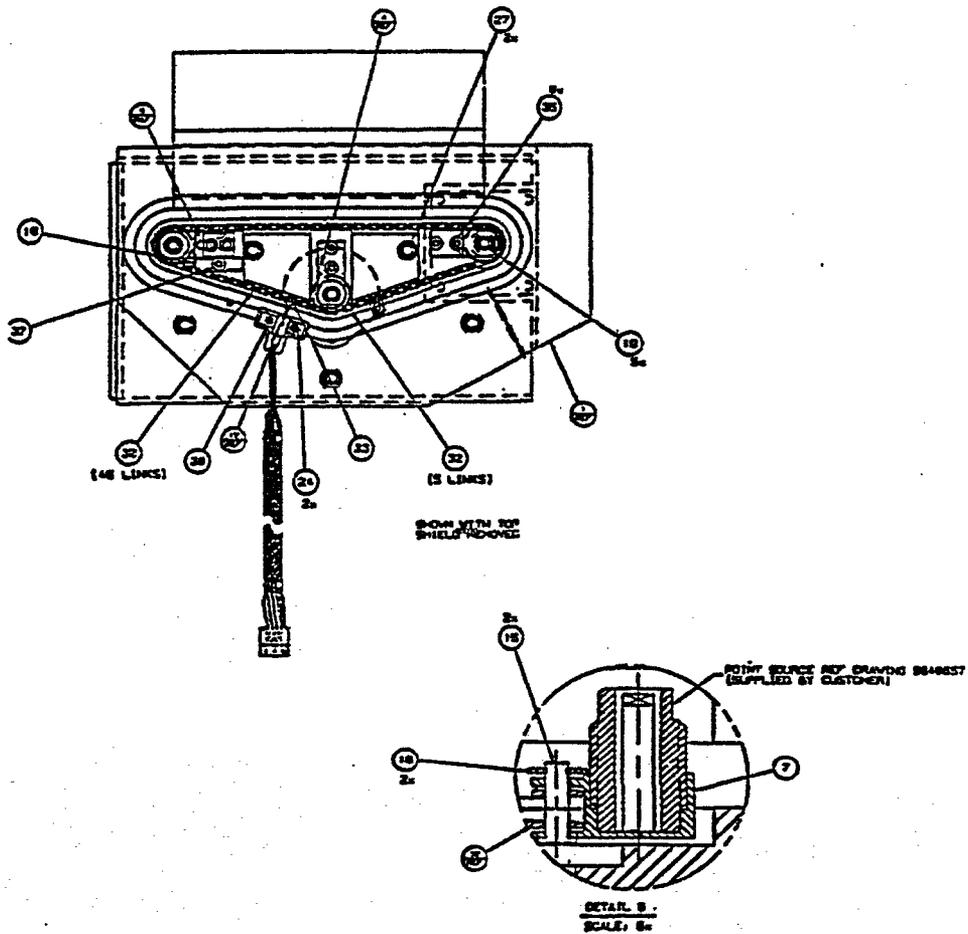
State of Tennessee

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SAFETY EVALUATION OF SEALED SOURCE
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Attachment 1

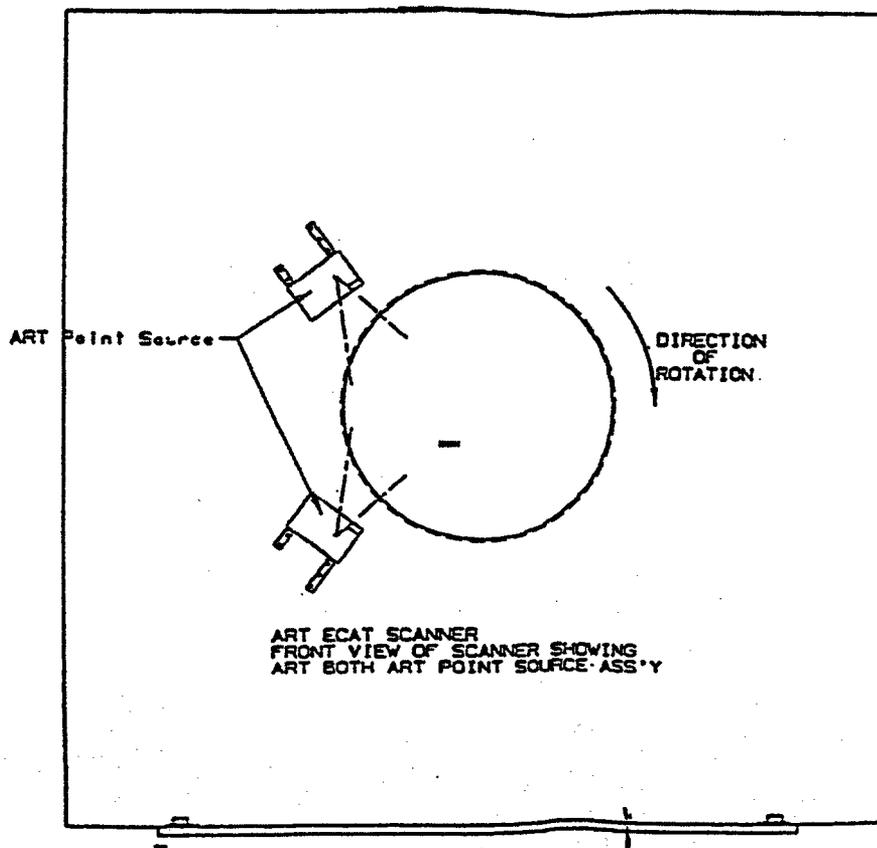


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Attachment 2



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Attachment 3

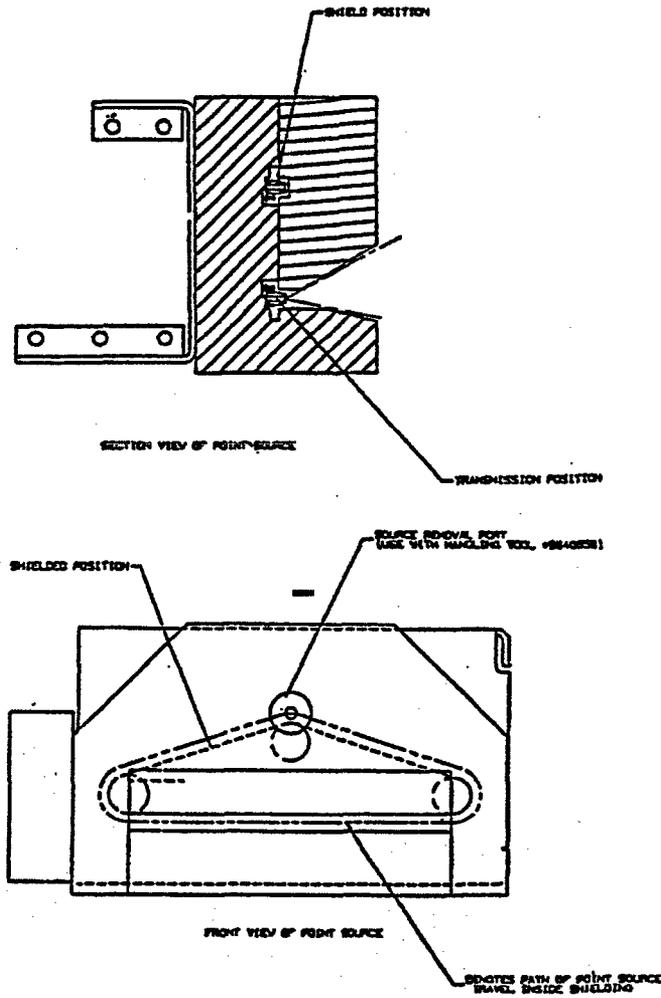


FIG. 1
ART POINT SOURCE MECHANISM