Texas Department of Health

Charles E. Bell, M.D.
Executive Deputy Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Radiation Control
(512) 834-6688

September 20, 2001

U.S. Nuclear Regulatory Commission
Attn: Ms. Tracy Kime
Source Containment and Devices Branch
Office of Nuclear Material Safety
and Safeguards
Document Control Desk
P1-37
Washington, D.C. 20555

RE: Registry Sheet TX-1141-D-101-S

Dear Ms. Kime,

Enclosed is the Safety Evaluation of Device sheet TX-1141-D-101-S for Positron. This sheet is issued to document the completed evaluation of this new device. We would appreciate you distributing copies of this sheet to the other State Programs and NRC Regions, as appropriate.

Thank you for your cooperation and efforts.

Sincerely,

D. Ray Jisha, Chief
Medical and Academic Licensing
Division of Licensing, Registration
and Standards
Bureau of Radiation Control

Enclosure: a/s

NMSS17

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX1141D101S DATE: September 20, 2001

DEVICE TYPE: Positron Emission Tomography (PET) Medical Diagnostic Scanner

MODEL: POSICAM HZ/HZL and mPower series

MANUFACTURER/DISTRIBUTOR: Positron Corporation
1304 Langham Creek Drive, Suite 300
Houston, Texas 77084

SEALED SOURCE MODEL DESIGNATION: DuPont (NEN) Model NER 8410

Isotope Products Laboratories
301 Series (formerly Model A-3402)

Sanders Medical Products
PET-XXX/YY Series (Variables indicate source length and activity)

ISOTOPE:	MAXIMUM ACTIVITY:
Ge/Ga-68 (NER 8410)	5 millicuries/source - 2 sources per scanner
Ge/Ga-68 (301 Series)	5 millicuries/source - 2 sources per scanner
Ge/Ga-68 (PET-XXX/YY Series)	5 millicuries/source - 2 sources per scanner

LEAK TEST FREQUENCY: 6 months - NER 8410 and 301 Series

12 months - PET- XXX/YY Series

PRINCIPAL USE: (B) Medical Radiography/Imaging

CUSTOM DEVICE: _____ YES __X__ NO

DEVICE TYPE: Positron Emission Tomography (PET) Medical Diagnostic Scanner

CUSTOM USER: NO

DESCRIPTION:

The POSICAM HZ/HZL and mPower series PET scanners are whole-body PET imaging systems. The device is an integral part of the system which is comprised of a medical imagining scanner and a host computer.

The POSICAM HZ/HZL and mPower series PET scanners utilize two (2) rod sources with nominal activities of 4 mCi and 1 mCi each for performing patient transmission scans and system calibration respectively. In use, theses sources are extended into the scanner's field of view from a pig on the back side of the scanner in order to perform system calibration and patient transmission scans. Transmission scan data is used for attenuation correction of patient emission scan data, which is necessary to perform quantitative diagnostic studies of body organs and other anatomical structures.

POSICAM HZ/HZL and mPower series PET scanners are equipped with a rod auto park (RAP) and rotating rod mechanisms that are responsible for inserting the rod source into the rotating ring located in the gantry field of view. The system has a "Rod Present" warning light which activates any time that the rod source is in the scanner field of view.

The RAP provides automated storage and loading of the rod source. At the beginning of an attenuation scan the source is moved from the shielded storage pig into the scanner field of view where it rotates around the table at approximately 10 revolutions per minute. The photons are attenuated to varying degrees depending upon the location of the source with respect to the subject being scanned and the density variation within the subject. Upon completion of a scan the source automatically stops rotating and is returned to the pig. The duration of patient exposure is controlled by the operator and varies for different procedures.

Two sources are required for calibration of the Positron HZ/HZL and mPower series PET scanners. These are placed in color coded red and blue source holders for quick and easy identification by operating personnel prior to use. The red source holder is intended for use with the 4 mCi activity source to be used for attenuation scans. The blue source holder is intended for use with the 1 mCi activity source to be used for scanner calibration. There may be some variation in the individual activities of the sources but the total activity will not exceed 10 mCi. After 18 months to 2 years the 3 - 4 mCi source may be utilized in the capacity of scanner calibration.

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Access to the inside of the gantry is restricted to qualified nuclear medicine technologists. The source pig has a built in lock mechanism to prevent access to the sources by unauthorized personnel. The source pig has three positions into which sources may be placed. The center position is "active" as it is from this position that the source is moved into the scanner field of view. The other two positions are storage only. User personnel are authorized to perform source exchanges and to exchange the sources between the active and storage positions within the device for scanner calibration activities upon successful completion of the Positron Operator Training course.

Mobile Units:

The POSICAM HZ/HZL and mPower are authorized for mobile use [510(k) K894998/A] and may be transported and used in specialized motor coaches and trailers. When this occurs a mobile upgrade package will be employed consisting of the modifications listed below. These modifications are in addition to the device which is now the manufactuerer's standard for production. The device is bolted to the backside of the scanner gantry which is bolted to the floor in both the fixed and mobile configurations. The modifications referenced above include:

1. Additional bracing for the electronics cabinet to provide reinforcement for rack-mounted power supplies.
2. Shock mounting for the electronics cabinet.
3. Bolts to secure the electronics cabinet to the floor of the coach/trailer.
4. Clamps to provide restraints for circuit boards in the electronics cabinet and for electronics housed under the patient bed.
5. Heavy-duty ties to secure signal cables to the backplane.
6. Rub-resistant covering for signal cables.
7. Locking devices on the scanner frame to provide additional stability.

LABELING:

The source pig is permanently labeled with Mylar labels placed on the right and left sides. These are provided by Positron and contain the words "Radioactive Material" as well as the trefoil radiation symbol, the source model number, serial number, recommended manufacturer, isotope, activity and assay date. Note that the actual source manufacturer must be identified on the labels by the device user.

The scanner gantry is labeled on the right and left sides with permanent Mylar labels which state "Caution: Radioactive Material" and have the trefoil radiation symbol. The labels also identify that the sources are to be handled only by authorized personnel and that the sources are licensed for distribution only to persons specifically licensed by the NRC, an Agreement State, or a Licensing State.

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DIAGRAM:

Attachment 1: 3-hole Lead Pig Showing the Locking Cover

Attachment 2: Rod AutoPark Mechanism

Attachment 3: Positron HZL Rod Holder

Attachments 4 & 5: Sample labels (2 pages)

Attachment 6: Positron PET Scanner

CONDITIONS OF NORMAL USE:

The POSICAM HZ/HZL and mPower series PET scanners are designed and intended for use in either a fixed medical facility or in a mobile scanning coach/trailer and are intended to be operated under conditions normally associated with a medical facility environment. Mobile units will not be operated during transit and will routinely be subject to normal transportation conditions of vibration, shock, and some temperature variation. The estimated working life of the device is 5 to 7 years.

PROTOTYPE TESTING:

The basic design of the source has been in existence since 1994 and has undergone extensive testing. There is no history of any sealed source leaking or being damaged as the result of a source transport mechanism failure or by failure of any other system.

Department of Transportation (DOT) Type 7A package certification tests have been conducted on prototypes of the lead pig that houses the sources and this item meets the requirements for certification as a DOT type 7A container.

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EXTERNAL RADIATION LEVELS:

Radiation survey of a 1.5 mCi source rod were conducted with the rod in the attenuation scanning position and calculations performed to show dose rates from nominal 3 mCi and 4 mCi sources for the POSICAM HZ/HZL scanners and results are as described below.

3 mCi source	Contact	14 mR/hr
	5 cm	12 mR/hr
	30 cm	4.0 mR/hr
	100 cm	1.0 mR/hr
4 mCi source	Contact	18.7 mR/hr
	5 cm	16 mR/hr
	30 cm	5.3 mR/hr
	100 cm	1.3 mR/hr

QUALITY ASSURANCE AND CONTROL:

Positron POSICAM HZ/HZL and mPower PET scanner are manufactured at Positron corporation's facility in Houston, Texas. Construction and testing of each device is consistent with the manufacturer's quality assurance program. Each finished device complies with all applicable standards of the Department of Health and Human Services Code of Federal Regulations Part 21.

Positron Corporation's vendor qualification process and quality control procedures comply with FDA Good Manufacturing Practices (GMP). Positron drawings specify to the vendor the raw materials to be used, and incoming inspection procedures assure that the purchased product meets Positron's specifications.

The sealed sources utilized with this system have been evaluated separately and are described under the Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Device #TX-0476-S-167-S, Safety Evaluation of Source #CA-0406-S-154-S and Safety Evaluation of Sealed Source #TN-0241-S-101-S.

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LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- POSICAM HZ/HZL and mPower scanners will be distributed only to persons licensed for the use of Ge-68 sealed sources in the healing arts by an Agreement State, the USNRC, or a Licensing State.
- Positron PET scanners are shipped from the factory to the customer without sealed sources. The customer must obtain all sources directly from the manufacturer.
- Source installation, and calibration testing shall be performed only by personnel trained by Positron Corporation. This will normally be the equipment users.
- Scanner installation, relocation, maintenance, or repair of the scanner shall be by Positron personnel or other persons authorized in a specific license issued by the NRC, and Agreement State, or a Licensing State to perform these services.
- The sealed sources used in these devices shall be leak tested at intervals not to exceed 6 months (DuPont NER 8410 and IPL 301 Series) or 12 months (Sanders PET-XXX/YY Series) using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- Handling, storage, use, transfer, and disposal of the sources associated with this device shall be determined by the licensing authority.
- The sources shall not be subjected to conditions that would exceed their ANSI N542 classifications of 77C33322 (DuPont NER 8410), 77C33222X (IPL 301 Series) or 77C32312 (Sanders PET-XXX/YY Series).

SAFETY ANALYSIS SUMMARY:

The sealed sources associated with the POSICAM HZ/HZL and mPower PET scanners have been subjected to testing by their respective manufacturer's as provided in ANSI N542 and have achieved the classifications 77C33322 (DuPont NER 8410), 77C33222X (IPL 301 Series) and 77C32312 (Sanders PET-XXX/YY Series). These sources should maintain their integrity under ordinary conditions of use, handling, and storage and should not release radioactive material to the environment.

Maximum external radiation levels for a nominal 4 mCi source are as previously identified in this certificate.

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REFERENCES:

The following supporting documents for TX1141D101S are hereby incorporated by reference and are made a part of this registry document.

- Positron Corporation application dated November 22, 2000, signed by Ross K. Hartz,Director of PET Technology, with enclosures thereto.
- Positron Corporation letter dated April 13, 2001, signed by Ross K. Hartz, Director of PET Technology, with enclosures thereto.
- Positron Corporation letter dated May 25, 2001, signed by Ross K. Hartz, Director of PET Technology, with enclosures thereto.
- Positron Corporation letter dated August 9, 2001, signed by Ross K. Hartz, Director of PET Technology, with enclosures thereto.
- Positron Corporation letter dated September 10, 2001, signed by Ross K. Hartz, Director of PET Technology, with enclosures thereto.

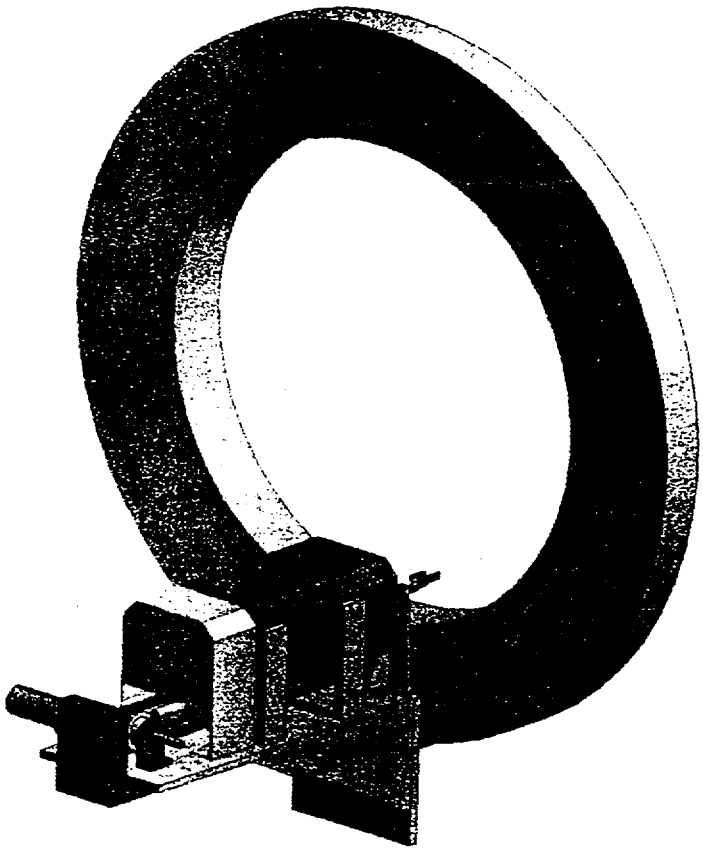
ISSUING AGENCY: Texas Department of Health
Bureau of Radiation Control

Date: September 20, 2001 Reviewer: James Scott Kee
James Scott Kee

Date: September 20, 2001 Concurrence: D. Ray Jisha
D. Ray Jisha

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

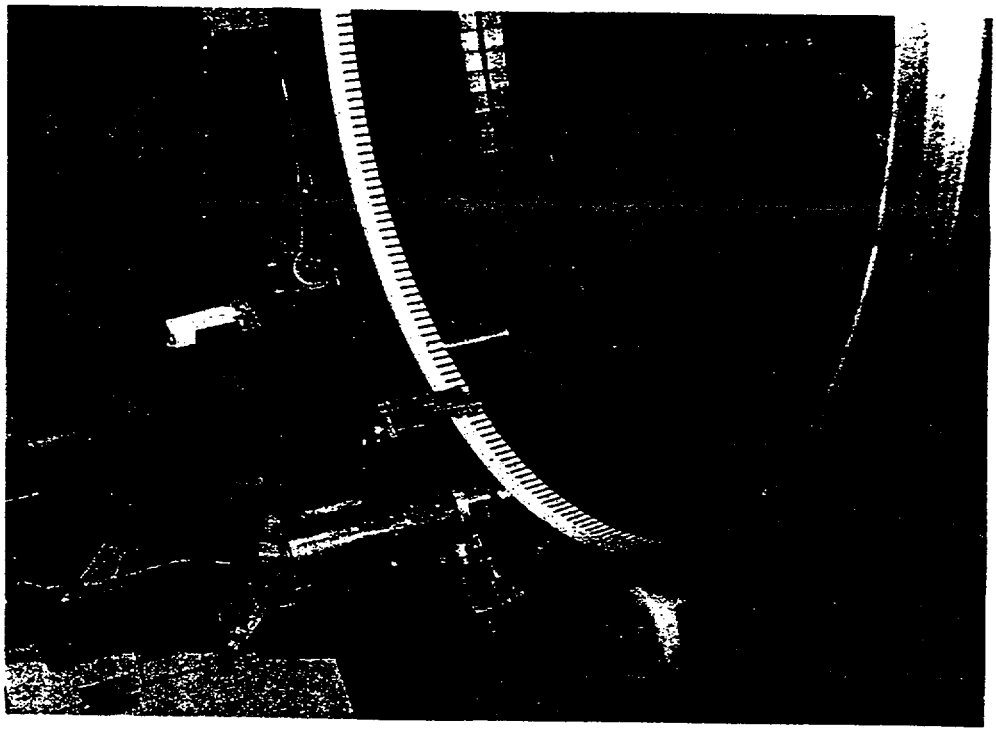
NO.: TX1141D101S DATE: September 20, 2001 ATTACHMENT 1



3-hole Lead Pig Showing the Locking Cover

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX1141D101S DATE: September 20, 2001 ATTACHMENT 2



Rod AutoPark Mechanism

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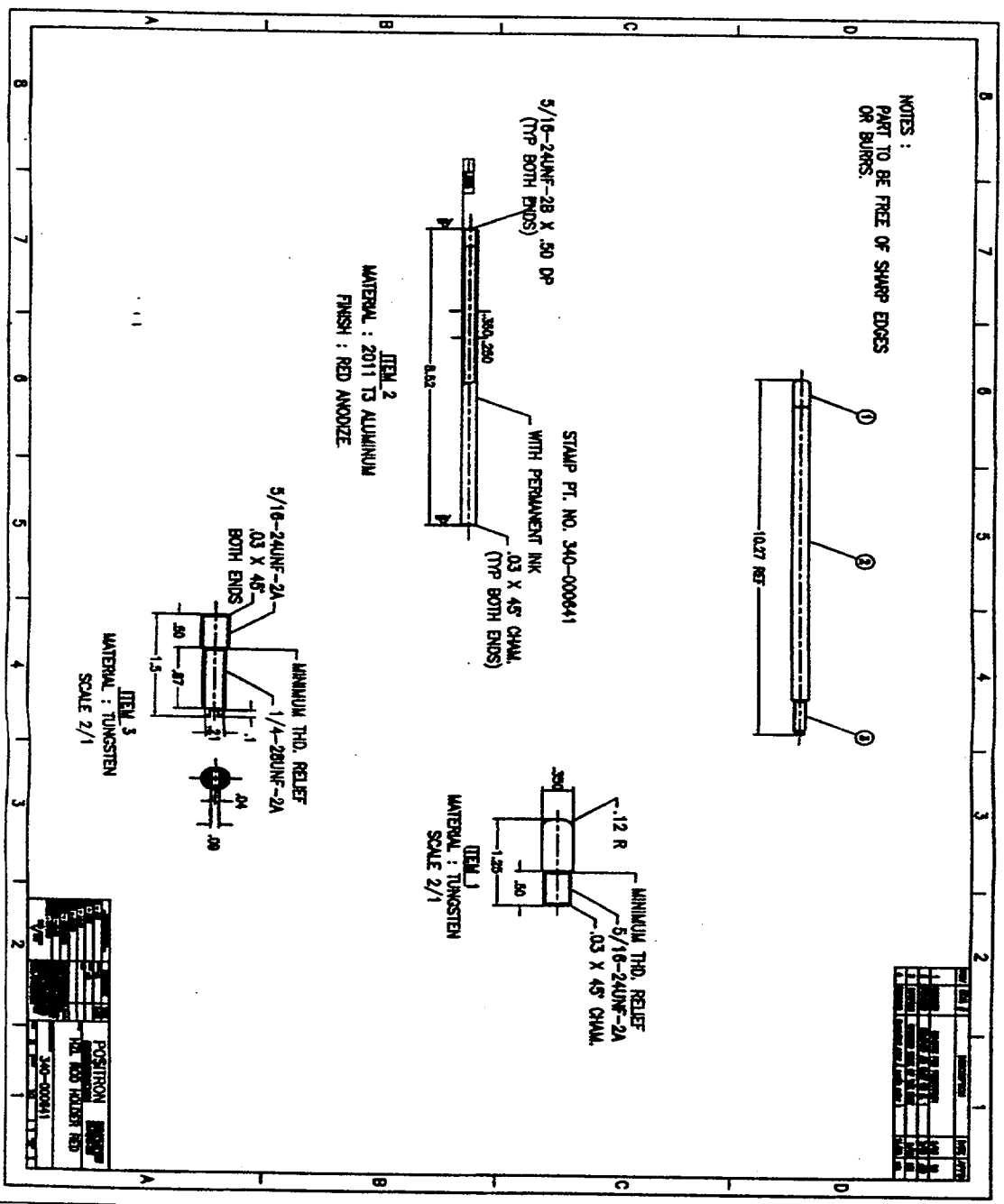
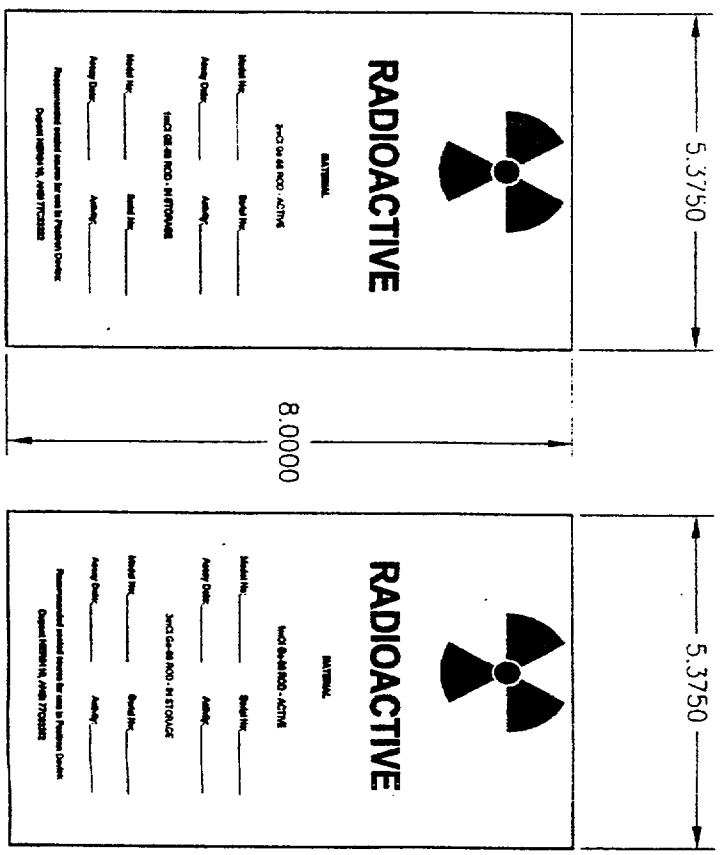
Positron HZL Rod Holder



REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

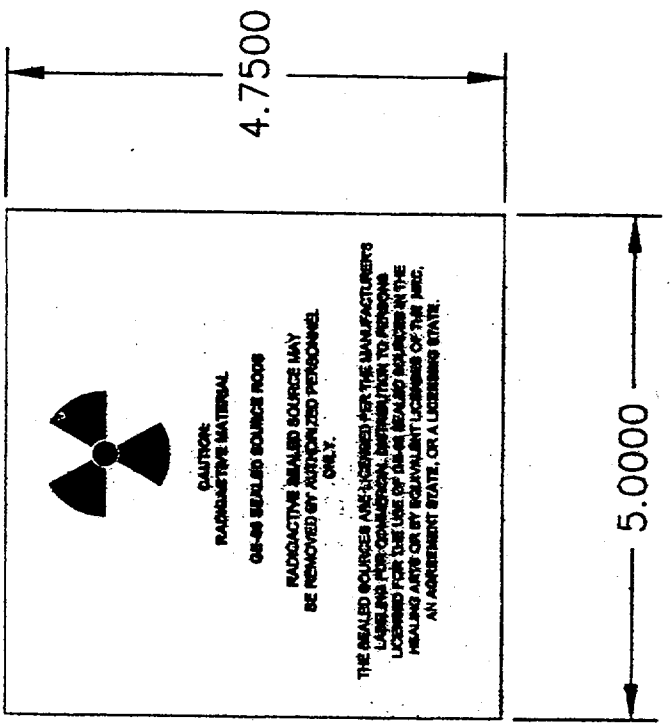
NO.: TX1141D101S DATE: September 20, 2001 ATTACHMENT 4



Sample Labels

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

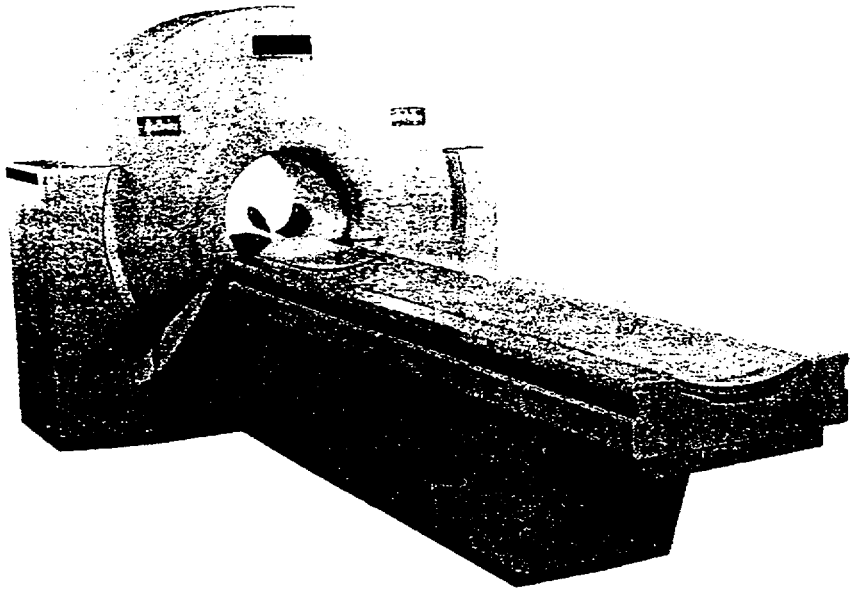
NO.: TX1141D101S DATE: September 20, 2001 ATTACHMENT 5



Sample Label

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: TX1141D101S DATE: September 20, 2001 ATTACHMENT 6



Positron PET Scanner