From: David T. Tang (DTT), NMSS
To: MLB5 M.L. Burgess, NMSS
Date: Wednesday, April 12, 1995 4:26 pm
Subject: Picker - Ohio Imaging

Michele, The SSDS Database registers only two manufacturers under the name Picker:

0692 - Picker Andrex, Denmark
0542 - Picker Corporation, 595 Minor Road, Cleveland, Oh 44143

The Model STEP (SSD-95-13) transmission line source holding device is being manufactured by Picker - Ohio Imaging located at 23060 Miles Road, Befford Heights, Ohio 44128.

Since this device appears to be the first for which registration is being applied by Picker - Ohio Imaging, please assign a new vendor code BBBB for this device so that the device can be registered under NR-BBBB-D-101-S. Thanks. Dave

CC: SLB

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ADDENDUM #6
Picker-Ohio Imaging
Date Prepared: 2/10/95
Revision: Initial

September 10, 1993

PRISM 3 STEP RADIATION MEASUREMENTS

1.0 INTRODUCTION:

Measurements were made of the absorbed dose and scatter radiation levels around the PICKER, PRISM 3000 System (SPECT Nuclear Imaging System) with a STEP Source Holder, source and collimator for transmission imaging. Radiation measurements were made with Al2O3 TLD's, Cutie Pie Survey Meter, and G-M Survey Meter.

The techniques measured were 1) the STEP Torso Mode with a non circular body scan, 16.5 cm short axis and 20 cm long axis with a fixed 65 cm Source to Image Receptor Distance (SID), and 2) the STEP Head Mode with a circular, 15.9 cm radius circle with a fixed 50 cm SID. The radiation sources used were 267 mm active length, 20 millicurie line sources with Tc-99m, Co-57 or Gd-153.

2.0 TEST SETUP:

Phantoms used in the study were standard CT dose phantoms as defined in the CDRH Standard. The head phantom was positioned using the standard head support and the body phantom was positioned on the table. The exposure measurements were made on the central axis and at 4 equidistant locations, 1 cm below the surface of the phantom. The TLD's were positioned on the central axis and at + and - 6 cm from the central axis.

3.0 Exposure measurements were made using Aluminum Oxide TLD's (5 mm dia., 1 mm thick) that have a sensitivity of less than 1 millirem. The uncertainty or the measurements were 0.55 mR or 17% of the reading, whichever is greater.

EXPOSURE TEST DATA
AVERAGE EXPOSURE READINGS FOR EACH TEST

Exp. #	Phantom	Source	Avg. mR	Exp. #	Phantom	Source	Avg. mR
1	Body	Gd-153	1.95	5	Head	Co-57	1.04
2	Body	Gd-153	1.65	6	Body	Co-57	1.19
3	Head	Gd-153	1.83	7	Body	Tc-99m	0.62
4	Head	Gd-153	1.54				

Leakage radiation was measured with the 20 millicurie Gd-153 source in the housing with the source in the "OFF" position, using the Model 470A survey meter. The maximum leakage measured was 2.0 mR/h at 5 centimeters from all external surfaces.

not corrected w/ latest counts

Scatter Radiation Measurements were made radially from the central axis of the STEP Radiation Field. Exposure to the patient outside the primary is calculated using the scatter measurements. These measurements are the maximum exposure at the distance of interest. Measurements were made using a VICTOREEN Model 470A Survey Meter and an Eberline Model E-120 Geiger Counter with a Pancake Probe.

SCATTER MEASUREMENTS (Gd-153)

RADIAL DISTANCE	BODY SCAN mR/h	HEAD SCAN mR/h
0.5 m	0.052	0.048
1 m	0.036	0.028
2 m	0.024	0.020
Aperture	0.024	0.024
Background	0.022	

The radiation field size was measured with a film. The size of the beam and penumbra is referenced to the useful field of view (UFOV) of 240 mm x 400 mm as specified in the PICKER, PRISM 3000 Detector, Product data sheet.

The radiation field size is defined as the full width at the half maximum density as measured on the films. The measured radiation field size was 1) for the 50 cm SID, 235 mm x 276 mm and 2) for the 65 cm SID, 235 mm x 357 mm. The radiation field is contained completely within the UFOV of the detector. The axial dimension for the field was the same for both SID's because in the axial direction the unique multileaf STEP design collimates the source so that at any point in the useful field of view (UFOV) only a few millimeters of the source are in the useful beam resulting in the field size and the length of the source being the same.

4.0 EXPOSURE COMPARISON:

The following is a comparison of exposures from typical studies using 1) STEP, 2) X-ray transmission CT, and nuclear medicine administrations. The doses are whole body and to specific organs. The exposure from a typical STEP study is 2 mrad/scan or less to the region of the body being imaged. The exposure from a typical X-ray transmission CT study is between 1000 and 5000 mrad/scan series. The Exposure to standard man for two typical nuclear medicine procedure is 1) Technetium-99m Pertechnetate (30 mCi), a whole body exposure of 420 mrad and Thyroid exposure of 3900 mrad, and 2) Thallous Chloride Tl-210 (2 mCi), a whole body exposure of 420 mrad and an exposure the heart wall of 1000 mrad. These comparisons do not include any image quality comparisons.

5.0 CONCLUSION:

In conclusion, the exposure to the patient and scatter radiation to the operator from a STEP scan with a 20 millicurie line source is extremely low, less than 0.5% of the typical CT or nuclear medicine study. The operator exposure is much less than background. Useful information determined from the STEP transmission procedure does not significantly increases exposure.

Robert A Jucius — September 16, 1993

Robert A. Jucius, Health Physicist — Date

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 15, 1995

Mr. Ronald Martone
Picker International
Picker - Ohio Imaging
23060 Miles Road
Bedford Heights, Ohio 44128

Dear Mr. Martone:

This letter responds to your application dated February 14, 1995, requesting a device evaluation for the registration of the Model STEP transmission line-source holding device to be used in medical radiography. We are in the process of evaluating the information submitted in your report, "Application for a Radiation Safety Evaluation and Registration of Device Designed to Contain Byproduct Material." We are also examining the mechanical and construction details of a STEP prototype and its gantry adopter assembly sent to us on March 7, 1995. However, we need the following additional information and clarification to complete our evaluation:

1. Please supplement the information in Section 3.2.1.5 of the report which provides, with the shutter closed, maximum observed radiation levels at 5.0 cm from the surface of the device for a .. mCi Gd-153 source. The radiation profile information is incomplete and it should address: (1) dose rates at a distance 5 cm, 30 cm, and 100 cm from the line source for all shutter operation modes - closed, open, and calibration and (2) maximum source activities with 25 mCi (+15%) for Co-57, 75 mCi (+15%) for Gd-153, and 20 mCi (+15%) for Tc-99m. Provide justification if radiation profiles are based on extrapolating limited measured data.

2. Please provide annual extremities dose estimates for STEP operators as their hands will be in close contact with the sealed source and the device in routine handling operation. How often will the device be attached to and removed from the gantry? How often will the Gd-153 or Co-57 sealed source be replaced? How much elapsed time required to prepare the Tc-99m source in a glass tube? How will the above operations be factored into dose estimate?

3. Addendum 2 to the report contains only six engineering drawings. To support discussion of the "inner cylinder," in Section 3.2.1.6 of the report, please also provide, as a minimum, Drawing No. 101881, "Source Holder," for record and review.

4. The prototype testing discussed in Section 3.3.4.2 and Addendum 4 of the report appear to have addressed only the functionality field trials for the STEP/SPECT. Although Addendum 4 provides engineering analysis, it is not clear how the analysis can be related to the field trials results to demonstrate integrity of the radiation safety features under stresses, wear, and fatigue for the design useful life of 10 years.

Picker should test STEP prototype by cyclically operating the STEP for the total estimated number of steps that the shutter mechanism is likely to operate for the design life. Alternatively, if engineering analysis is used to supplement limited amount of prototype testing to demonstrate integrity of the device for the design useful life, additional justification must be provided.

5. The large length-to-diameter slenderness ratio (greater than 40) of the sealed sources is prone to permanent bending deformation, which, in turn, may impede source insertion into or removal from the "inner cylinder" of the device. Was this feature considered in determining the diameter of the inner cylinder to provide sufficient tolerance? Was the "bend test" such as that of ANSI N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators," ever conducted?

6. Page 5-5 of Operator's Guide warns: "Do not force the source into the lead source holder..." This statement needs to be supplemented with additional cautionary statement to remind the operator to call for help if the source will not come out its installed position.

7. The labeling discussed in Section 3.3.3.2 of the report could not be found with the prototype send to us. Considering frequent installation and removal of the device by the operator, Picker should submit for review the design of a durable label(s) to be attached to the device to describe radioactive content of the source and provide instructions for handling and storing of the device and sources. The content labeling should clearly indicate the isotope and its maximum activity at the time the device is in use. The source and device handling instructions should provide relevant information but do not have to be as detailed as those of Operator's Guide of Addendum 7 of the report. Also, instructions should be provided in Operator's Guide on labeling source storage containers.

8. Section 3.3.5 of the report states that the quality control procedures and records are summarized in Addendum 5. Our review shows that the addendum addressed only the setup, test, and verification of a STEP unit on a Prism 3000 gantry. Picker should submit for review quality control procedures to assure that production devices meet the standards of the design and prototype tests. As an alternative, Picker should so state if it is manufacturing the device under the Food and Drug Administration's Good Manufacturing Practices program.

Please provide the requested information as soon as possible. If you have any questions, please contact me at (301) 415-5799 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,

David T. Tang, Mechanical Engineer
Sealed Source Safety Section
Source Containment and Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc: SKimberly