

From: David T. Tang (DTT), NMSS
To: SLB S. L. Baggett, NMSS
Date: Tuesday, March 21, 1995 7:31 am
Subject: Picker Actions

Steve, Martone called yesterday on progress in all questions we raised. Formal response will be forthcoming in about two weeks. Briefly, item by item: (1) Will reconstruct radiation profiles; some deltas will be added; (2) are conducting tests with phantoms for extremities in different orientations; TLD readings are being sent out for processing; field trials data as collected in handling TC-99m for 3 months are being analyzed; (3) will supply Dwg. # 101881. (4) will conduct life tests for shutter operation; (5) is reviewing bend test approach and will work with source vendors to develop the data, if not already available; (6) will provide warning in the manual on asking for help in case source will not come out; (7) will provide labels as appropriate; and (8) will state that manufacturing is per FDA GMP program. Dave



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 23, 1995

Mr. James M. Fulton
Picker International
Picker - Ohio Imaging
23060 Miles Road
Bedford Heights, OH 44128

Dear Mr. Fulton:

This is in reference to your letter and affidavit dated February 14, 1995, in which you requested that Addendum 2, "Engineering Drawings," and Addendum 5, "Quality Control," of the February 14, 1995, Picker report "Application for Radiation Safety Evaluation and Registration of a Device Designed to Contain Byproduct Material," for the Model STEP transmission line-source holding device be withheld from public disclosure pursuant to 10 CFR 2.790.

You stated that the submitted information should be considered exempt from mandatory public disclosure since the information in these addenda is:

- o considered proprietary by the company and held in confidence with release only on a need to know basis;
- o held in confidence and early release would deny Ohio-Imaging a competitive advantage that took considerable time and expense to achieve;
- o transmitted to the Commission in confidence and not available in public sources; and
- o to cause substantial harm to Ohio-Imaging's competitive position as the development expenditure could be avoided by a competitor.

We have reviewed your application and the material in accordance with the requirements of 10 CFR 2.790 and, on the basis of your statements, have determined that the information in these addenda constitutes trade secrets or proprietary commercial information. Therefore, these addenda will be withheld from public disclosure pursuant to 10 CFR 2.790(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned to inspect the documents. If the need arises, we may send copies of this information to our consultants working in this area. We will, of course, ensure that the consultants have signed the appropriate agreements for handling proprietary information.

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J. Fulton

-2-

If the basis for withholding this information from public inspection should change in the future, such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC needs additional information from you or makes a determination adverse to the above, you will be notified in advance of any public disclosure.

Sincerely,

Original Signed By:
Steven L. Baggett

Steven L. Baggett, Section Chief
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

Distribution:

SSSS Staff

SCDB r/f

NE01

SSD-95-13

DOCUMENT NAME: PICKER2.790

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	OGC	<input checked="" type="checkbox"/>	SCDB	<input checked="" type="checkbox"/>					
NAME	MPSiemien		SBaggett						
DATE	03/11/95		03/15/95						

OFFICIAL RECORD COPY



Ohio Imaging
Nuclear Medicine Division
23060 Miles Road
Bedford Heights, Ohio 44128
Telephone: (216) 473-3000

February 14, 1995

Steven L. Baggett, Section Chief
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Source Containment and Device Branch
Division of Industrial and Medical Nuclear Safety, NMSS
Washington, D.C. 20555-0001

Dear Sir:

Attached in duplicate, please find a device review application prepared in the format described in USNRC Regulatory Guide 10.10 dated March, 1987.

It is the intention of Picker-Ohio Imaging to manufacture and distribute an accessory device not containing radioactive material, but designed to hold a sealed source manufactured by others. The device is designated by the model name STEP and is designed to be an image clarity accessory to Picker's various models of scintillation camera systems.

The sealed sources to be used with STEP are presently manufactured and distributed direct to specific licensees by Isotope Product Laboratories of Burbank, California. Isotope Product Laboratories has submitted to the California Department of Health a sealed source(s) safety evaluation request and has received registry number CA 406S165S in reply. Other manufacturers may in the future receive similar authorization to distribute sealed sources suitable for use in the STEP system.

In addition to sealed sources supplied to specific licensees by authorized vendors, the STEP system is designed to be used with Tc99m as supplied by the STEP user himself in accordance with a specific license and per the provisions of 10CFR 35.57 or 10CFR 35.200, or equivalent state regulations.

Picker-Ohio Imaging has received permission to distribute STEP for medical imaging purposes from the U.S. Department of Health and Human Services. A copy of an F.D.A. letter to this effect dated May 13, 1994 is included in the application as Addendum #9.

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Duke
11/10

who handled under 32-74

In accordance with 10CFR 2.790 (a) (4), it is requested that a portion of this application be withheld from public disclosure on the grounds that release of certain proprietary information regarding the design and fabrication of STEP devices would do irreparable commercial harm to Picker-Ohio Imaging by providing competitors access to designs and fabrication procedures developed by Ohio Imaging at considerable cost.

In accordance with 10CFR 2.790 (b) (1), the following portions of the application are requested to be withheld from public disclosure:

Addendum #2	-	Engineering Drawings
Addendum #5	-	Quality Control

An affidavit is hereby submitted over my signature below. As Vice President and General Manager of Picker-Ohio Imaging, I am on behalf of the company specifically delegated to review the attached application and select that portion for which withholding is requested.

In accordance with 10CFR 2.790 (b) (4), the following information is supplied:

10CFR 2.790 (b) (4) (i) - the engineering drawings and quality control procedures are considered proprietary by the company and held in confidence with release only on a need to know basis.

10CFR 2.790 (b) (4) (ii) - the engineering drawings and quality control procedures for all new products such as STEP are normally held in confidence until such time that competitor's products reaching the marketplace negate the need. Early release would deny Ohio Imaging a competitive advantage that took considerable time and expense to achieve.

10CFR 2.790 (b) (4) (iii) - the information contained in Addenda #2 and #5 of the application is hereby transmitted to the Commission in confidence.

10CFR 2.790 (b) (4) (iv) - the information contained in Addenda #2 and #5 is not available in public sources.

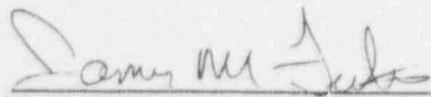
10CFR 2.790 (b) (4) (v) - public disclosure of the information found in Addenda #2 and #5 would cause substantial harm to our competitive position in as much as it represents an expenditure of 4.5 years in development at a cost approximating one million dollars that could be avoided by a competitor in developing his own product.

In closing, it is requested that consideration be given to prompt review of this application. We have already received firm orders for several STEP systems and anticipate many more. The medical imaging community is very enthusiastic over the potential improved cardiac studies made possible by STEP. NRC device approval remains the sole impediment to full market accessibility.

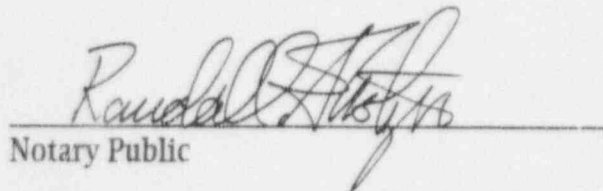
Appended are two (2) drafts totalling \$3,700.00 to be applied to review fees as prescribed in 10CFR 170.31 category 9A.

Thank you for your attention to this matter. If there is any way I or my Manager of Regulatory Affairs, Mr. Ron Martone, can do to assist you in your review, please do not hesitate to call. His direct telephone number is (216) 473-7651.

Sincerely,



James M. Fulton
Vice President and General Manager


Notary Public

RANDALL A. NOTZEN, Esq.
Notary Public, State of Ohio
County of Summit
My Commission Does Not Expire

E-mail Message on the PICKER STEP Imaging Device
and the ADAC VANTAGE Imaging Device

Contacts: Larry Camper, Josie Piccone, Steve Baggett

ALERT: *This message is to alert you to current action by Headquarters staff and request that the regions do not authorize the use of the STEP or VANTAGE devices discussed below until a sealed source device review has been performed of each device, and favorable results have been communicated to the regions.*

This issue was discussed by Janet Schlueter of this staff during the Monthly Regional Conference Call conducted on April 4, 1995.

Devices: STEP (Transmission Line Source Holding Device) by Ohio Imaging
CA registered and FDA approved

VANTAGE by ADAC, Inc. Undergoing a CA and FDA device review.

Sources: Tc-99m (14-20 mCi);
Gd-153 (75 mCi); or
Co-57 (25 mCi)

Issue: As some of you are aware, Ohio Imaging (Picker) recently requested a sealed source and device review of a device used with SPECT imaging systems that contains either a Gd-153, Tc-99m or Co-57 sealed source. The request was submitted in a letter dated February 14, 1995, and is currently under review by David Tang of the Sealed Source Safety Section (SSSS). The completion of the device review will depend on the timely submission of information by Ohio Imaging.

Additionally, since this issue surfaced, the SSSS learned of a similar device referred to as VANTAGE, manufactured by ADAC, Inc. This device is currently undergoing a sealed source device review by the State of California and is under FDA review for a 501(K) approval.

It is our understanding through conversations with regional staff that at least one medical licensee has been authorized for the STEP device prior to the required regulatory review. In conversation with ADAC, they indicated that "NRC had approved" the use of the VANTAGE device. Headquarters is not aware of such authorization or approval.

We have received guidance from OGC on this issue. As a result, *No action* is needed at this time for either device if currently in use by medical licensees when identified through licensing and/or inspection. However, if identified, licensees should be informed of the need for an amendment request, which in turn, will entail a sealed source device review.

Device Description for STEP: (Information on VANTAGE is not available at this time). Basically, the source holding device is a shutter shield affixed to the rotating gantry of a triple headed scintillation camera patient imaging system. Its purpose is to provide, during image acquisition, a photon beam of differing energy from that of the radiopharmaceutical administered to the patient that can be used to improve resolution losses normally experienced in

radionuclide tomography studies due to the non-uniform absorption characteristics of tissues and structures surrounding the organ of interest.

The STEP device is manufactured by Ohio ~~Nuclear~~ ^{Imaging} but the sources must be obtained by the licensee from some other manufacturer. As a result, Ohio Imaging is not a 10 CFR 32.74 licensee and does not intend to become one. According to Steve Baggett, there are approximately 10 other manufacturers that are in the process of manufacturing or marketing a similar device, and FDA currently has ~4 under review.

Based on a preliminary review of the information by IMAB and SSSS, the device does not appear to fit either the "reference/calibration source" (10 CFR 35.57) or "sealed source for diagnosis" (10 CFR 35.500) categories. Rather, it should probably be licensed as a "line item" on the medical use license.

What is the basis for safety evaluation?

*wrong
it's not
35-57*

REQUEST FOR A SEALED SOURCE OR
DEVICE EVALUATION

MLB

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.
NOTE: Retain a copy of this request with the application and background files.

REQUESTER <i>Pickard, Ohio Imaging</i>		REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB	
TELEPHONE NUMBER	DATE	TYPE OF ACTION REQUESTED (Check as appropriate)	
APPLICANT'S NAME		<input type="checkbox"/> SOURCE REVIEW <input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S)	
MAIL CONTROL NUMBER(S)		<input checked="" type="checkbox"/> DEVICE REVIEW	
LETTER/APPLICATION DATE <i>2/17/95</i>		<input type="checkbox"/> CUSTOM REVIEW	
LICENSE NUMBER(S) <i>NA</i>			

COMMENTS: *22-8 23060 Nth Road
Bedford Heights, Ohio 44120* *5 2-780 STAFF Continued*

FOR SSSS USE ONLY		
REVIEWER <i>David Tany</i>	MODEL NUMBERS <i>STEP</i>	NUMBER ASSIGNED <i>95-13</i>
DATE RECEIVED <i>2/21/95</i>	DATE ASSIGNED <i>02/28/95</i>	DATE TO FEES <i>2/27/95</i>

TYPE OF ACTION (Indicate the number of each type)			
<input checked="" type="checkbox"/> COMMERCIAL DISTRIBUTION (FORMAL)		USE BY A SINGLE APPLICANT (CUSTOM)	
SOURCE (9C)	DEVICE (9A)	SOURCE (9D)	DEVICE (9B)
<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input checked="" type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT	<input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT
<input type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED		<input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN	
<input type="checkbox"/> OTHER (Specify)		<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	

	TOTAL NUMBER OF REVIEW HOURS	NOTES <i>Coordinate with INRS</i>
	NUMBER OF DEFICIENCY LETTERS	
	NUMBER OF DEFICIENCY CALLS	

FOR BILLING PURPOSES ONLY			
<input type="checkbox"/> NAME CHANGE	<input type="checkbox"/> ADDRESS CHANGE	<input checked="" type="checkbox"/> NEW REGISTRATION - ADD TO BILLING	<input type="checkbox"/> PRODUCT INACTIVE - REMOVE FROM BILLING

FOR FEE USE ONLY	
TYPE OF FEE	FEE CATEGORY
AMOUNT RECEIVED	<input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D
DATE OF CHECK	CHECK NUMBER
APPROVED BY	LOG
DATE RETURN	MATANN UPDATED AS REQUIRED
	MATSYS UPDATED AS REQUIRED
COMMENTS	DATE



Recd
2/21/95

Ohio Imaging
Nuclear Medicine Division
23060 Miles Road
Bedford Heights, Ohio 44128
Telephone: (216) 473-3000

February 14, 1995

Steven L. Baggett, Section Chief
U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Source Containment and Device Branch
Division of Industrial and Medical Nuclear Safety, NMSS
Washington, D.C. 20555-0001

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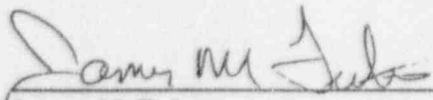
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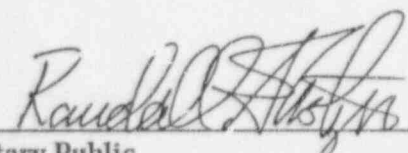
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Thank you for your attention to this matter. If there is any way I or my Manager of Regulatory Affairs, Mr. Ron Martone, can do to assist you in your review, please do not hesitate to call. His direct telephone number is (216) 473-7651.

Sincerely,


James M. Fison
Vice President and General Manager


Notary Public
RANDALL A. NOTZER, Esq.
Notary Public, State of Ohio
County of Summit
My Commission Does Not Expire

OHIO IMAGING23060 MILES ROAD
BEDFORD HTS., OHIO 44128-544355-389
412CHECK
NO. **96002444**

CHECK DATE

2/7/95

PAY EXACTLY One-Thousand, Seven-
Hundred DOLLARS AND 00 CENTS


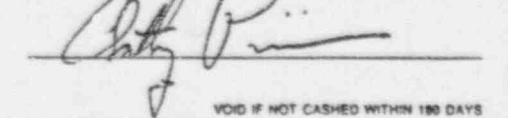
CHECK AMOUNT

1,700.00

PAY TO THE

ORDER OF U.S. Nuclear Regulatory Commission

OHIO IMAGING

FIRST NATIONAL BANK OF ASHLANDAN AFFILIATE OF
NATIONAL CITY BANK
CLEVELAND, OHIO 44101


VOID IF NOT CASHED WITHIN 180 DAYS

⑈96002444⑈ ⑆04⑆203895⑆ 0082755⑈

OHIO IMAGING23060 MILES ROAD
BEDFORD HTS., OHIO 44128-544355-389
412CHECK
NO. **96002443**

CHECK DATE

2/7/95

PAY EXACTLY Two-Thousand
DOLLARS AND 00 CENTS


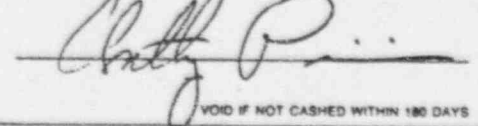
CHECK AMOUNT

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OHIO IMAGING

FIRST NATIONAL BANK OF ASHLANDAN AFFILIATE OF
NATIONAL CITY BANK
CLEVELAND, OHIO 44101


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PICKER INTERNATIONAL OI DIV.



Ohio Imaging
Nuclear Medicine Division
23060 Miles Road
Bedford Heights, Ohio 44128
Telephone: (216) 473-3000
Fax (216) 475-2975

Purchase Order
PURCHASE ORDER NO: N21799

PAGE: 1
PO REV DATE: 02/07/95

THIS PURCHASE ORDER NUMBER MUST BE SHOWN ON ALL INVOICES,
SHIPPING DOCUMENTS, CARTONS AND CORRESPONDENCE RELATED TO THIS ORDER.

PO REV:
ORIGINAL PO DATE: 02/07/95
CONTRACT NUMBER:
CONTACT:

VENDOR ID: 07467
U.S. NUCLEAR REGULATORY COMM.
DIV. OF FUEL CYCLE & MAT'L
SAFETY MATERIAL LICENSING BRA.
WASHINGTON DC
20555 USA

SHIP TO:
PICKER INTERNATIONAL
OHIO IMAGING
23130 MILES RD.
BEDFORD HTS. OHIO
44128 USA

TAX EXEMPT NUMBER:

LN#	ITEM/DESCRIPTION	UM	REV	ORDER QUANTITY	BALANCE DUE	PROMISED DOCK	UNIT PRICE	EXTENDED PRICE	T X
001	APPLICATION FEE FOR STEP REGISTRAT.	EA		1	1	02/15/95	3700.00	3700.00	N
ACCOUNT 1002-440-83-78017 REQ NU 06352 STEP DEVICE REGISTRA-TION APPLICATION FEE									

For purchase order number and part number must appear on all invoices, packing
s. shipping cartons, and correspondence.
use sign and return acknowledgement with shipping promises within 10 days of
receipt of order. Clearly express any deviations
or shipments, early shipments, and unauthorized substitutions are not acceptable.
s order from Buyer is subject to the general terms and conditions printed on the

reverse side of this form. By accepting this order, seller agrees to be bound by these
general terms and conditions.
5. Render invoices in Duplicate to Picker International, Attn: Accounts Payable
Department.
6. All material subject to Picker inspection and acceptance.
7. All merchandise must be packaged properly to insure safe arrival

EQUAL OPPORTUNITY: The seller (unless exempt) agrees that during the performance of this contract, it will comply
Executive Orders 11246 and 11375 and will comply with
other Federal and state laws and regulations prohibiting
discriminatory practices as are effective and in force on the
of this agreement

AUTHORIZED BY:
BUYER: GK =

[Signature]
2/7/95

TOTAL EXTENDED AMOUNT
THIS PURCHASE ORDER: 3700.00

ORIGINAL PURCHASE ORDER