

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 99990003/89-008(DRSS)

Docket No. 99990003

License No. - Not Applicable

Facility: Picker International, Inc.
595 Miner Road
Highland Heights, OH 44143

Inspection Conducted: October 26 and November 9, 1989

Conducted At: St. Mary's Hospital
830 South Jefferson Avenue
Saginaw, MI 48601

Picker International, Inc.
870 Lively Boulevard
Wood Dale, IL 60191

Inspectors:

Evelyn R. Matson
Evelyn R. Matson
Radiation Specialist

November 30, 1989
Date

Roy J. Lambert
Kenneth J. Lambert
Radiation Specialist

November 30, 1989
Date

Roy J. Caniano
Roy J. Caniano, Chief
Nuclear Materials Safety
Section 2

November 30, 1989
Date

William P. Reichhold
William P. Reichhold
Radiation Specialist

November 30, 1989
Date

Approved By:

Bruce S. Mallett
Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch

December 5, 1989
Date

Inspection Summary

Special, announced inspection conducted on October 26, 1989 at St. Mary's Hospital, Saginaw, Michigan and on November 9, 1989 at Picker International, Inc., Wood Dale, Illinois (Report No. 99990003/89-008(DRSS))

Areas Inspected: This inspection was performed as a followup to a routine inspection of St. Mary's Hospital in which it appeared that Picker International, Inc. performed service on the hospital's Picker C/9 cobalt-60 teletherapy unit. This inspection included a review of service work performed on March 24 and 30, 1988 at St. Mary's Hospital, and included an inspection of service records at the Wood Dale, Illinois branch office to determine if Picker service engineers performed licensed service work on teletherapy units at any other locations.

Results: One violation was identified: a Picker International, Inc. service engineer performed licensed service of a teletherapy unit at St. Mary's Hospital and Picker is not authorized by an NRC Byproduct Materials License to perform such service (Section 3).

DETAILS

1. Persons Contacted

*William Gerber, Manager Industrial Relations & Standards, Picker International, Inc., Highland Heights, OH (telephone contact)
Mr. Dragman, Assistant Manager Industrial Relations & Standards, Picker International, Inc., Highland Heights, OH (telephone contact)
Gary Wierenga, Service Manager, Picker International, Novi, MI
Ron Powrozek, Field Engineer, Picker International, Inc., Novi, MI
Herman Idler, District Service Manager, Picker International, Inc. Wood Dale, IL
Joyce Summers, Secretary, Picker International, Inc., Wood Dale, IL
Karen McMenamin, Administrative Director Cancer Treatment Center, St. Mary's Hospital, Saginaw, MI
Debra Berton, Radiation Therapy Technician, St. Mary's Hospital, Saginaw, MI

*Participated in exit meeting conducted via telephone on November 17, 1989.

2. Background Information

The routine inspection of St. Mary's Hospital conducted on October 17, 1989 included interviews and review of records to determine compliance with 10 CFR Part 35.605, a regulation that states only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

During that inspection, an inspector determined that a Picker International, Inc. service engineer performed repairs on the teletherapy unit on March 24, 1988 and March 30, 1988. Records of the field service reports are enclosed as Attachment 1.

Picker Corporation (now Picker International Inc.) possessed an NRC Byproduct Material License that authorized the repair, servicing and installation of Picker teletherapy units until the license was terminated on August 23, 1986 by request of the licensee. Authorized service engineers during the time that Picker serviced teletherapy units included Mr. Ron Powrozek, who is the engineer who performed the servicing of the unit at St. Mary's Hospital.

3. Teletherapy Servicing

To determine whether or not the repairs performed by the Picker service engineer involved licensed service work pursuant to 10 CFR 35.605, two inspectors met the Picker International, Inc., Novi, Michigan service

manager and the service engineer at St. Mary's Hospital on October 26, 1989. The engineer demonstrated the actual work involved in these repairs. Based on this demonstration, explanations, and a review of the teletherapy unit wiring diagrams, the inspectors determined the following:

- A. In March 1988 the licensee noted that the head of the teletherapy unit would not tilt out. On March 24, 1988, the service engineer removed the cover on the left side of yoke to expose the head tilt wiring terminal. He then ran a continuity check on the two wires that control head tilt and determined that one wire was broken as there was no continuity. He ran a new wire from the back slip ring connection 24 through the C-arm to yoke connection TB4-17. He tested the head tilt by operating the hand controls on the side of the unit. He did not expose the source at any time. The head tilt function operated correctly. He replaced the covers and that completed his service call.

Placing a new wire from the back of the stand to the yoke involves a circuit that controls the head tilt only and is not related mechanically or electrically to the source drawer, shutter, or other mechanism that could expose the source. This did not appear to be licensed service work as defined by Part 35.605.

- B. On March 30, 1988, the licensee noted that the source would not expose. The service engineer saw that the Number 1 contact spring (which is part of the circuitry that controls the source on-off movement) was bent away from the center slip ring (a metal ring that allows electrical contacts to be made between the fixed stand and the moving C-arm). Apparently, a plastic tie wrap that he had installed on March 24, 1988, to hold a new wire in place, had moved enough to bend the spring contact. Refer to Attachment 2 for photographs. He rebent the spring. A teletherapy technician from the hospital then tested the unit by operating and exposing the source. The unit operated correctly and the covers were then replaced. This concluded the repair.

The inspectors concluded that the March 30, 1988 repair did involve licensed service work as defined by 35.605. Specifically, contact No. 1 on the center slip ring is part of the circuitry that directly involves control of the source exposure mechanism.

Therefore, it appears that the Picker service engineer, who was not specifically licensed by the Commission or an Agreement State, during March, 1988 performed a repair on a mechanism of a teletherapy unit that directly controls exposure of the source.

10 CFR 30.3 states that except for persons exempt as provided in this part and Part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulation in this chapter. Repair work on a teletherapy unit involving the source drawer, the shutter or other mechanism which could expose the source by an individual who is not licensed to use byproduct material is an apparent violation of 10 CFR Part 30.3.

From discussions with St. Mary's and Picker International representatives it was determined that the service engineer who conducted the work was an authorized user on the Picker Corporation service License No. 34-07225-15 before it was terminated on August 23, 1986. The hospital's medical physicist/radiation safety officer stated that this service engineer routinely repaired their teletherapy unit prior to 1986 and still services their other Picker x-ray equipment. He stated he was not aware that the service engineer was no longer permitted to service the unit.

One apparent violation was identified.

4. NRC Followup

On October 30, 1989 a telephone conversation was held between Mr. William Gerber and members of his staff and Dr. Bruce Mallett and members of the NRC staff. The purpose was to discuss NRC's findings at St. Mary's Hospital, obtain additional information, and to obtain commitments for corrective and preventative action to be taken by Picker. As a result of the conversation, Picker agreed to the following:

- a. To instruct all district office managers within the next several days not to perform service on teletherapy units that involves service work described by 10 CFR 35.605.
- b. To send a followup memorandum to all district office managers within the next 30 days to remind service engineers and managers that they are not authorized to perform certain teletherapy unit repairs. The memorandum should include a discussion of the Part 35.605 regulation.
- c. To perform a record search for indication of service work on any other teletherapy units.
- d. To send a letter to the NRC acknowledging the above agreement.

The letter of acknowledgement was received by Region III on November 13, 1989 and is enclosed as Attachment 3. In that letter Picker stated that an electronic mail message was sent to all District Service Managers reinforcing that no service is to be performed on anything related to cobalt teletherapy heads or controls. Picker also stated that a hard copy of the above mentioned message would also be sent to the District Managers. The letter also stated that Picker was going to conduct a research on service records to try and discover any other areas of unauthorized cobalt service. A report of their findings would be documented and forward to the NRC.

5. Service Record Review

On November 9, 1989 an inspector performed a sampling review of service records at the Picker International, Inc., Wood Dale, Illinois district office to determine if Picker service engineers have performed licensed service work on other teletherapy units.

The Wood Dale district office services the upper peninsula of Michigan, northern Indiana, Illinois, and Wisconsin. The District Service Manager assisted in compiling a list of 11 Picker clients in these areas that currently have cobalt-60 teletherapy units. The inspector then reviewed all service records for these 11 clients from January 1989 to October 1989. He found no records that indicated any servicing of teletherapy units.

No violations were identified

6. Exit Meeting

During a telephone conversation on November 17, 1989, an exit interview was conducted with Mr. Gerber to discuss the scope of the inspection, the findings, and subsequent NRC actions. Mr. Gerber also stated that Picker is continuing its search of records to determine whether any other licensable service work had been conducted on teletherapy units after Picker's service license was terminated. As of November 17, 1989, Picker had not found any other indications of licensable service work. According to Mr. Gerber, a final report will be submitted to the NRC Region III office following Picker's search of their record files. This report should be forthcoming within 30 days of the exit meeting. Mr. Gerber also stated that if Picker encounters any record which indicates that licensable service work was conducted after Picker's license termination, the NRC Region III office would be informed immediately.

Attachments:

1. Field Service Report
2. Photographs
3. Ltr dtd 11/06/89,
Picker to NRC



FIELD SERVICE REPORT

HEALTH CARE SERVICE EQUIPMENT SERVICE

page 1
FSR NO. 943139

CUSTOMER NAME ST. MARY'S MED CNTR.				CONTACT NAME		INCIDENT NO. 1 361057	
CITY, STATE, ZIP CODE SAGINAW, MI 48601				CONTACT PHONE NO.		INCIDENT NO. 2	
SERVICE AREA 32T1	CUSTOMER NO.	CUSTOMER P.O. NO. 68476-7-3-30A	SITE I.D. NO. 22709	F.E. NO. 12821	SERV. MGR. NO. 12005	JOB/CONTRACT	

PRODUCT SERVICE INFORMATION

ACTIVITY	OEM PIC 1385F	MODEL NO.	SERIAL NO. 166	MODEL DESCRIPTION COBALT STAND				
	ARRIVE DATE 3/30/88	ARRIVE TIME 09:45	COMPLETE DATE 3/30/88	COMPLETE TIME 10:45	SERVICE DEEFF	TRBLE R.P.	REPAIR	MANAGEMENT REVIEW BILL CODE
ACTIVITY	OEM	MODEL NO.	SERIAL NO.	MODEL DESCRIPTION				
	ARRIVE DATE	ARRIVE TIME	COMPLETE DATE	COMPLETE TIME	SERVICE	TRBLE	REPAIR	MANAGEMENT REVIEW BILL CODE

TRAVEL AND LABOR TIME

ACTIVITY	STRAIGHT TIME			OVERTIME												TOTAL HOURS	AMOUNT	
	CODE	HOURS	PPM	5			10			15			20					
1	TRAVEL		1:00	Y														
1	LABOR		1:00	Y														
1	WAIT			Y														
2	LABOR			Y														
2	WAIT			Y														

FSR 943139	MILES	SUNDAY/HOLIDAY <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	CALL COMPLETED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	INCOMP. CODE	TRVL CHARGE	BILLING CAT. NO.	BILLING AMT.	TAX C.D.
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PARTS USAGE SECTION

ACTIVITY	PART NUMBER	QTY.	BILL CODE	DESCRIPTION	SERIAL NO. IN	SERIAL NO. OUT	UNIT PRICE	OFFICE	TAX / C.D.

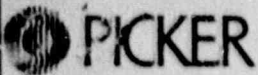
ACT. EXPENSE	BILL CODE	TYPE	DESCRIPTION	ACT. EXPENSE	BILL CODE	TYPE	DESCRIPTION
AMT.				AMT.			

PROBLEM REPORTED **SOURCE WON'T OPEN.**

REPAIR TEXT **FOUND OPEN SLIP RING (#1) IN HALO SWITCH CRIST. RE-FORMED SPRING CONTACT & TESTED.**

PRODUCT TYPE	X-RAY	VAS <input checked="" type="checkbox"/>	C.T.	M.R.I.	NUCL.	ULT.	CLIN.	PROC.	SOLUT.			
LABOR CODES	DEMAND SERVICE 520 <input checked="" type="checkbox"/>	CONTRACT SERVICE 521	PX / LABOR 522	INSTALLATION 530	WARRANTY 531 / 530	RECALL 533	FIELD CORRECTION 540	SAFETY SERVICE 541	SERVICE CONC. 542	SALES CONC. 543	HCP REFURB 522	CAD / SUPPORT 544

ACCEPTANCE OF WORK PERFORMED
A. J. Pourzech FIELD ENGINEER
H. Bryan CUSTOMER/DATE



FIELD SERVICE REPORT

HEALTH CARE SERVICE EQUIPMENT SERVICE

FSR NO. 943130

CUSTOMER NAME ST. MARY'S MED CNTR		CONTACT NAME 1	INCIDENT NO. 1
CITY, STATE, ZIP CODE SAGINAW MI 48601		CONTACT PHONE NO. 2	INCIDENT NO. 2

SERVICE AREA 32 T1	CUSTOMER NO.	CUSTOMER P.O. NO. 68476-7-3-24A	SITE I.D. NO. 22709	F.E. NO. 12821	SERV. MGR. NO. 12005	JOB/CONTRACT
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PRODUCT SERVICE INFORMATION										
ACTIVITY 1	OEM PIC 1385F	MODEL NO.	SERIAL NO. 166	MODEL DESCRIPTION COBALT STAND						
	ARRIVE DATE 3/24/88	ARRIVE TIME 09:30	COMPLETE DATE 3/24/88	COMPLETE TIME 14:00	SERVICE DE	TRBLE EF	REPAIR R	MANAGEMENT REVIEW BILL CODE	EXPOSURE COUNT	
ACTIVITY 2	OEM	MODEL NO.	SERIAL NO.	MODEL DESCRIPTION						
	ARRIVE DATE	ARRIVE TIME	COMPLETE DATE	COMPLETE TIME	SERVICE	TRBLE	REPAIR	MANAGEMENT REVIEW BILL CODE	EXPOSURE COUNT	

TRAVEL AND LABOR TIME																	
ACTIVITY	STRAIGHT TIME			OVERTIME												TOTAL HOURS	AMOUNT
	CODE	HOURS	PPM	5			1.0			1.5			2.0				
1	TRAVEL		1:00	Y													
	LABOR		4:00	Y													
	WAIT			Y													
2	LABOR			Y													
	WAIT			Y													

FBR 943130	MILES	SUNDAY/HOLIDAY <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	CALL COMPLETED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	INCOMP. CODE	TRVL CHARGE	BILLING CAT NO	BILLING AMT	TAX C/D
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PARTS USAGE SECTION									
ACTIVITY	PART NUMBER	QTY.	BILL CODE	DESCRIPTION	SERIAL NO. IN	SERIAL NO. OUT	UNIT PRICE	OFFICE	TAX / C/D

ACT. EXPENSE	BILL CODE	TYPE	DESCRIPTION	ACT. EXPENSE	BILL CODE	TYPE	DESCRIPTION
AMT.				AMT.			

PROBLEM REPORTED: **HEAD WON'T TILT OUT.**

REPAIR TEXT: **FOUND BROKEN WIRE BETWEEN SLIP-RING 24 AND YOKE TB4-17. RAN REPLACEMENT WIRE + TESTED.**

PRODUCT TYPE	X-RAY	VAS.	C.T.	M.R.I.	NUCL.	ULT.	CLIN.	PROC.	SOLUT.			
LABOR CODES	DEMAND SERVICE 520	CONTRACT SERVICE 521	PX / LABOR 522	INSTALLATION 530	WARRANTY 531 / 536	RECALL 533	FIELD CORRECTION 540	SAFETY SERVICE 541	SERVICE CONC. 542	SALES CONC. 543	HCP REPAIR 522	CADI / SUPPORT 544

ACCEPTANCE OF WORK PERFORMED

R. J. Powrozek FIELD ENGINEER

Terry Diller CUSTOMER/DATE

Attachment 2



Center Slip
Ring

plastic tie



end view of
a slip ring

spring contacts
(copper)