Hospital Event # 42304

Rep Org:	WESTERN PENNSYLVANIA HOSPITAL	**Notification Date / Time:**	02/02/2006 17:19 (EST)
Licensee:	WESTERN PENNSYLVANIA HOSPITAL	**Event Date / Time:**	11/18/2005 (EST)
		Last Modification:	02/02/2006
Region:	1	**Docket #:**	
City:	Pittsburgh	**Agreement State:**	No
County:		**License #:**	37-02136-01
State:	PA		
NRC Notified by:	MARGARET BLACKWELL	**Notifications:**	GLENN MEYER R1
HQ Ops Officer:	BILL HUFFMAN		GARY JANOSKO NMSS
Emergency Class:	NON EMERGENCY		
10 CFR Section:			
30.50(b)(2)	SAFETY EQUIPMENT FAILURE		
21.21	UNSPECIFIED PARAGRAPH		

PROBLEM WITH A VARIAN HIGH DOSE RATE (HDR) AFTERLOADER

The licensee provided the following information via facsimile:

"On December 1, 2005, [an NRC Region 1 inspector] conducted an inspection of our facility. During the inspection [the inspector was told] about a problem [the hospital was] having with [its] HDR unit [Varian Model VS-200] . On November 18, 2005, during a patient treatment the unit reported a fault during source retraction which reported as a source path constriction. However, the source retracted fully and the error was cleared. The patient received the treatment as prescribed; there was no unintended radiation exposure to the patient. During the following treatment, on November 21, 2005, the error recurred and Varian was contacted to service the unit. The source again retracted fully; the patient received the treatment as prescribed. Varian arrived on November 26, 2005. The engineer repaired that fault, but after the repair, a new problem arose. During post-repair testing by Varian, the inactive wire failed to move from the shielded safe position. [The NRC inspector] requested [..] a report of the findings of the manufacturer after the repair was completed.

"Varian subsequently sent a new loaner HDR to [the] West Penn [hospital], and [the] HDR unit was returned to the [Varian] factory in England for repair. [The hospital] immediately forwarded the Varian Troubleshooting Report to [the NRC inspector] upon receipt on January 31, 2006. The report from the factory indicated that the cause of the wire not moving was a signal wire that had been improperly stripped at the time of assembly. Over time, this connection oxidized causing a loss of contact for that signal, which was for the drive mechanism. This caused the inactive source wire not to drive out of the safe.

"Although [the West Penn Hospital is] reporting this as requested, [it] respectfully disagree[s] with the NRC interpretation of the 10 CFR 30.50(b)(2) reporting requirement. 10 CFR 30.50(b)(2) states that a 24 hour report is required when 'An event in which equipment is disabled or fails to function as designed when: (i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to

IE20

Hospital Event # 42304

radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; (ii) The equipment is required to be available and operable when it is disabled or fails to function; and (iii) No redundant equipment is available and operable to perform the required safety function.' [The West Penn Hospital] believe[s] the safety systems of the HDR unit functioned appropriately by reporting the fault. [The hospital] notified the vendor and requested repair when the fault repeated and discontinued using the HDR unit until it was repaired and tested. No regulatory limits were exceeded; the source did not stick; the safety systems did not fail. [The hospital] also do[es] not believe this to be a manufacturing defect requiring reporting under 10 CFR 21.21 but defer[s] to the manufacturer and the NRC interpretation."

****