



West Virginia University Hospitals

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

October 12, 2010

Attn: Penny Lanzisera
Senior Health Physicist
Medical Branch
Division of Nuclear Material Safety

Subject: Delay Time for Medical Event Report "Sirtex"
License No. 47-23066-02 Docket No. 03-020233

Dear Ms. Lanzisera,

This is in response to the request for additional information, in regards to justification of the delay in reporting the medical event associated with Sirtex. On the afternoon of June 21, 2010, the Radiation Safety Department (RSD) received a report from the manufacturer, Sirtex, indicating that the vial did leak, but they could not determine if it was because of manufactures defect or user error.

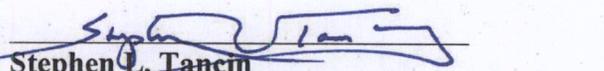
Since the report was not clear, the RSD wanted the Interventional Radiologist and the licensed Authorized User (AU) to preview the report before the declaration was made. This was determined to be the appropriate actions because of the amount of time between the actual treatment and the discovery of the event. The week the RSD received the report, from Sirtex, the AU was not available to review the information. The following week the RSO was at the Health Physics Society meetings and discussed the issue with the NRC inspector who was associated with our last inspection, when the discovery was made.

The information was given to the AU to review the following week, it was determined to declare the incident a medical event and not faulty equipment. The declaration of the medical event was then made to the USNRC call center on July 7, 2010.

In conclusion, this time period was needed to investigate the medical event and come to a justifiable conclusion.

Sincerely yours,


Nasser Razmianfar
Director and Radiation Safety Officer


Stephen L. Tancin
Vice President for Ancillary & Support Services

Hospital Administration
Ruby Memorial Hospital
West Virginia University Children's Hospital
Jon Michael Moore Trauma Center
Chestnut Ridge Hospital

PO Box 8059
Morgantown, WV 26506-8059