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NRC TO DISCUSS APPARENT VIOLATIONS AT LANCASTER, PA., HOSPITAL

Nuclear Regulatory Commission staff will meet with representatives of a Lancaster, Pa., hospital on Friday, Sept. 16, to discuss three apparent violations of agency requirements. The apparent violations stem from the treatment of a patient with a medical device containing radioactive sources known as a gamma knife.

The predecisional enforcement conference is scheduled to begin at 10 a.m. at the NRC Region I Office, 475 Allendale Road in King of Prussia, Pa. It will be open to the public and there will be an opportunity for members of the public to ask questions of NRC staff before they adjourn the session.

During a review that began last Oct. 21 at Lancaster General Hospital, NRC inspectors examined activities at the facility on North Duke Street that are licensed by the agency. They also looked into the circumstances surrounding a medical event at the facility in September 2003. That event involved a gamma knife, or gamma stereotactic radiosurgery, treatment administered to a patient at a location on the body other than the intended site. This occurred for only a portion of the treatment. (A gamma knife uses a special helmet to focus radiation from numerous radioactive sources to a specific location deep within brain tissue.)

The NRC inspectors found that at the conclusion of the administration, one of the coordinates for the treatment site was 7 centimeters different from the initial setting, resulting in an estimated dose of 35 to 40 Gray to the wrong site. (A Gray is a measure of the amount of radiation absorbed by the body.) The event did not result in harm to the patient, a medical consultant retained by the NRC to review the incident determined.

Hospital personnel concluded the event was caused when the patient moved "vigorously" during the treatment. However, the treatment was not suspended to verify the setting coordinates following this movement. Further, hospital staff did not return a subsequently replaced portion of the focusing mechanism known as the "z-bars" to the manufacturer for analysis despite a recognition it was not properly functioning.

Based on the results of the inspection, the following apparent violations have been identified: (1) failure to implement adequate procedures to verify that the administration of the gamma knife dose

was in accordance with the treatment plan and written directive; (2) failure to report to the NRC the medical event involving a dose administered to the wrong treatment site; and (3) failure to report to the NRC an equipment malfunction of the device's z-bars.

The purpose of the meeting is to obtain information to enable the NRC to make an enforcement decision. This information can include a common understanding of the facts, root causes, missed opportunities to identify the apparent violations sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action.

No decision will be made during the meeting. Rather, the NRC will consider the facts and render a decision sometime following the conference.

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