UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

September 19, 2008

MEMORANDUM TO: Lawrence Donovan, Health Physicist, DNMS, RIV
Rachel Browder, Health Physicist, DNMS, RIV
Latisha Hanson, Health Physicist, DNMS, RIV

FROM: Arthur T. Howell, Director ***/RA/***
Division of Nuclear Materials Safety

SUBJECT: SPECIAL INSPECTION CHARTER TO EVALUATE THE UNINTENDED EXPOSURE TO AN EMBRYO/FETUS AT THE USAF WILFORD HALL MEDICAL CENTER, LACKLAND AIR FORCE BASE, TEXAS

A Special Inspection is being chartered in response to an unintended exposure of an embryo/fetus that occurred at the USAF Wilford Hall Medical Center, Lackland Air Force Base, Texas, on June 4, 2008. Mr. Lawrence Donovan will be the lead for this Special Inspection, assisted by Ms. Rachel Browder and Ms. Latisha Hanson as needed.

BACKGROUND AND BASIS

NRC inspectors first learned of this incident on September 5, 2008, while conducting a routine, unannounced inspection of the 59th Medical Wing (MW) located at the USAF Wilford Hall Medical Center on Lackland Air Force Base (a permit holder with the US Air Force Master Materials License). The incident occurred on June 4, 2008, and involved a female patient that underwent a therapeutic administration of radioiodine-131 for thyroid ablation therapy. Two days prior to administration of the radioiodine, a pregnancy test had been given which yielded a negative result. The hospital's radiation safety staff became aware of the pregnancy on August 13, 2008, when the patient contacted the radiation safety staff and wanted to know the consequences of the ablation therapy on her embryo/fetus.

The hospital staff immediately conducted an investigation utilizing third-party experts (DOE REAC/TS) to assist in the evaluation. The hospital, in consultation with DOE REAC/TS, determined that the fetus (in the zygote phase of development) would have been 7 days old (postconception) at the time of treatment of the patient and concluded that there would be no immediate health effects; however, it is possible there could be latent health effects. The patient and her physician were consulted regarding the hospital's conclusions. The NRC is obtaining the services of a medical consultant to assist in its ongoing review and has initiated this Special Inspection.

The permittee (59th MW) notified by telephone the USAF Radioisotope Committee (RIC) on August 13, 2008. The RIC requested a written report in 14 days. By memorandum dated August 27, 2008, the permittee provided the USAF RIC a written report regarding the incident. The USAF RIC did not notify NRC until September 5, 2008, after NRC inspectors, onsite at the USAF Wilford Hall Medical Facility, questioned the RIC about its basis for not reporting the

incident. The USAF RIC then reported the event to the NRC Headquarters Operations Center on September 5, 2008 (Event Notice 44468), and the NRC issued a Preliminary Notification (PNO-IV-2008-009) on September 9, 2008.

The NRC is chartering this Special Inspection pursuant to NRC Manual Chapter 1301, "Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Response Plan." The basis for this response is described in Section 1301-06.03 of the Manual Chapter which refers to an occurrence that meets the threshold for an abnormal occurrence pursuant to MD 8.1, "Abnormal Occurrence Reporting Procedure." Region IV inspectors reviewed this incident with the Wilford Hall radiation safety staff when they were onsite on September 5, 2008, and, as a result, there is no need for immediate dispatch to Wilford Hall. As part of the Special Inspection, you may decide to conduct additional onsite reviews.

SCOPE

The inspection should seek to address the following items as a minimum:

1. Develop a sequence of events associated with the incident (i.e., a chronology leading up to and including the incident, the initial response by the permittee and licensee, and the follow-up response by the permittee and licensee). This should also include the internal reporting within the licensee's organization leading up to the USAF Master Materials Licensee's notification to the NRC on September 5, 2008.

2. Assess the level of compliance with the USAF permit, the USAF Master Materials License, and other NRC requirements (as applicable) with respect to the protocols followed for the radioiodine treatment at the medical center and USAF RIC reporting procedures.

3. Assess the information contained in the licensee's 15-day report required by 10 CFR 35.3047.

4. Assess the licensee's/permittee's overall investigation, including root cause and contributing factors.

5. Review the licensee's corrective actions for consistency with the regulations, license requirements, permit conditions, and approved procedures regarding the nature of the radioiodine treatment incident and reporting to the NRC. Assess the adequacy of the licensee's/permittee's immediate and long-term corrective actions to prevent similar events.

6. Based on the medical consultant's report, provide an assessment of the exposures and the potential radiological consequences to the embryo/fetus exposures.

7. Notify and discuss with the region, program office and USAF officials, as necessary, any new developments or significant changes.

9. Assess whether there are any generic implications associated with this incident.

GUIDANCE

NRC Manual Chapter 1301, “Response to Radioactive Material Incidents that Do Not Require Activation of the NRC Incident Response Plan,” provides guidance on the level of response. This Manual Chapter identifies Inspection Procedure 87103, “Inspection of Material Licensee Involved in an Incident or Bankruptcy Filing,” for specific use by the team in reviewing the event.

The inspection should emphasize fact-finding in its review of the circumstances surrounding the incident. It is not the responsibility of the inspection to examine the regulatory process. Safety concerns identified that are not directly related to the event should be reported to the USAF RIC and to NRC management for appropriate action.

This charter may be modified should significant new information be identified that warrants review. Should you have any questions concerning this Charter, contact me at (817) 860-8106.

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SUNSI review completed: ADAMS: X Yes Initials: LD
X Publicly Available X Non Sensitive

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09/11/ 2008	09/12/2008	09/19/2008