August 6, 2007

NMED No. 070339

Bruce Backus, M.S., PE
Assistant Vice Chancellor for Environmental Health & Safety
Washington University in St. Louis
Campus Box 8229
660 South Euclid Ave.
St. Louis, MO 63110

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-02271/07-01(DNMS) - WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Backus:

This refers to the special inspection conducted on June 5, 2007, with continued in-office review through July 16, 2007, of an unintended dose to an embryo/fetus from an iodine-131 therapy that occurred on May 29, 2007, at Washington University in St. Louis. The purpose of the inspection was to review the circumstances, causes, and corrective actions related to this event. The in-office review included a review of your written report of the event dated June 11, 2007, and the NRC medical consultant's report dated July 13, 2007. At the conclusion of the on-site inspection, the preliminary inspection findings were discussed with selected members of your staff, and the inspection results were subsequently discussed with Susan Langhorst of your staff on July 16, 2007. The enclosed report presents the results of this inspection.

The inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel. Based upon the inspection, no violations of NRC regulatory requirements were identified.

The NRC contracted with a medical consultant, Ronald Goans, Ph.D., M.D., to review the medical significance of the event. Dr. Goans' report indicated that the most likely outcome of the event would be delivery of a normal infant with regard to thyroid function; however, there may be a slightly increased risk of childhood cancer. A copy of Dr. Goans' report is enclosed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-02271
License No. 24-00167-11

Enclosures:
1. Inspection Report No. 030-02271/07-01(DNMS)
2. NRC Medical Consultant's Report

cc w/encls: Susan Langhorst, Ph.D., CHP, Radiation Safety Officer

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REGION III

Docket No.:	030-02271
License No.:	24-00167-11
Report No.:	030-02271/07-01(DNMS)
Licensee:	Washington University in St. Louis
Location:	St. Louis, Missouri
Date:	June 5, 2007, with continued in-office review through July 16, 2007
Inspector:	Geoffrey M. Warren, Health Physicist
Approved by:	John R. Madera, Chief Materials Inspection Branch Division of Nuclear Materials Safety

NMED No. 070339

Enclosure 1

EXECUTIVE SUMMARY

Washington University in St. Louis
St. Louis, Missouri

NRC Inspection Report 030-02271/07-01(DNMS)

This was a special, announced inspection to review the circumstances, root and contributing causes, and corrective actions associated with a reported event that occurred at Washington University in St. Louis on May 29, 2007, and was reported to the NRC by the licensee on June 1, 2007. The reported event involved an administration of a 125.5 millicurie iodine-131 (I-131) sodium iodide therapy dosage to a patient that resulted in an unintentional dose to an embryo/fetus. At the time of the dosage administration, the patient was unaware that she was four to five weeks pregnant. On May 30, 2007, the patient notified the hospital that she was pregnant when she received the dosage.

The event was isolated. The root cause was a false negative pregnancy test that was performed by the licensee before the dosage administration and the patient's belief that she was not pregnant. Prior to the dose administration, the patient stated that to the best of her knowledge, she was not pregnant, and she also signed a confirmation statement to that effect.

Licensee staff estimated the dose to the embryo/fetus to be approximately 25 to 34 rem. Licensee staff stated that loss of the embryo/fetus was highly unlikely. The licensee staff also stated that the embryo/fetus had a greater risk of cancer because of the dose. The NRC medical consultant confirmed the licensee's estimate of the dose to the embryo/fetus, and stated in his report that the most likely outcome would be delivery of a normal infant with regard to thyroid function, though there might be a slight increase in the risk of childhood cancer. He recommended that a complete thyroid evaluation of the infant be made after delivery.

Licensee personnel stated that they did not intend to take any corrective actions to prevent a similar event because the root cause was beyond their control.

Report Details

1.0 Program Scope and Inspection History

NRC Byproduct Materials License No. 24-00167-11 authorized Washington University in St. Louis (licensee) as a broad-scope medical facility to use a variety of byproduct materials for medical and research purposes, including therapeutic nuclear medicine. The licensee performed approximately 130 therapeutic treatments annually using iodine-131 (I-131). The licensee was authorized to conduct licensed activities at several facilities in the St. Louis, Missouri, area.

No violations of NRC regulatory requirements were identified during the two previous NRC inspections of the licensee's activities, conducted from October 30 through November 3, 2006, and from September 13 through 16, 2004.

2.0 Sequence of Events

2.1. Inspection Scope

The inspector interviewed the physician authorized user, nurse, and radiation therapist involved with the administration of the I-131 dose to determine the sequence of events that resulted in the unintentional dose to an embryo/fetus. In addition, the inspector reviewed records, a selective number of procedures, and compliance with regulatory requirements relevant to the administration of the I-131 dose.

2.2. Observations and Findings

A 22-year-old patient was diagnosed with thyroid cancer at the licensee's hospital, and her thyroid was surgically removed on May 2, 2007. She was referred to the licensee for radiopharmaceutical therapy to treat any remaining thyroid tissue. On May 22, 2007, the patient had a blood test to check for pregnancy and met with the physician to discuss the therapy. The pregnancy test indicated that the patient was not pregnant. The physician briefed the patient about the therapy and provided her written instructions about it. The patient then signed an informed consent statement, stating that, to the best of her knowledge, she was not pregnant. The physician prepared and signed the written directive at this time, prescribing a dosage of 125 millicuries of I-131. Because of scheduling concerns, the patient asked that the therapy be delayed, and it was scheduled for May 29, 2007.

The patient returned to the oncology clinic on May 29 for the therapy. The therapist asked the patient again whether she had any reason to believe she was pregnant, and the patient stated that she did not. The therapist reviewed the result of the May 22 pregnancy test and asked about the patient's menstrual cycle. The licensee's procedure required that the patient have a recent pregnancy test, and guidance on the scheduling form suggested that the test be performed no more than seven days before the therapy. Because the test had been done seven days earlier, the therapist administered 125.5 millicuries of I-131 to the patient in accordance with the written directive, and the patient was released.

On May 30, the patient performed a home pregnancy test, which indicated that she was pregnant. She notified licensee staff about the pregnancy test result, and the nurse had the patient come in that afternoon for a blood test. The nurse requested a quantitative blood test to verify that the patient was pregnant and to determine how long she had been pregnant. The results of the blood test were available on May 31, indicating that the patient had been pregnant for approximately four to five weeks.

2.3. Conclusions

The inspector concluded that the licensee took reasonable precautions, including conducting a blood test for pregnancy and verifying that the patient did not believe she was pregnant, to prevent administration of a therapeutic dosage of I-131 to a pregnant patient.

3.0 Licensee Investigation

3.1 Inspection Scope

The inspector reviewed the licensee's investigation of the event, including a root cause assessment. The inspector also interviewed the RSO, the physician authorized user, the nurse, and the radiation therapist. In addition, the inspector reviewed the licensee's 15-day report dated June 11, 2007.

3.2 Observations and Findings

Upon notification of the patient's pregnancy, the physician authorized user immediately contacted the Radiation Safety Officer (RSO) and a nuclear medicine physician to begin an investigation of the event and the consequences of the dose to the embryo/fetus. The investigation indicated that the root cause of the event was the patient being unaware that she could potentially be pregnant and the false negative result of the pregnancy test. Licensee staff determined that the false negative result was due to the early stage of pregnancy at the time of the test. The investigation further indicated that licensee staff involved in the administration of the I-131 had followed procedures and guidance, conducted appropriate tests, and asked for appropriate verification from the patient to ensure that she was not pregnant.

Based on International Commission on Radiological Protection Report No. 84, "Pregnancy and Medical Radiation," the licensee calculated that the estimated dose to the patient's uterus, and thus the embryo, was 25 to 34 rem. After consultation with nuclear medicine physicians, the licensee staff estimated the embryo/fetus dose to be 25 rem. The licensee staff determined that loss of the embryo/fetus was highly unlikely and the embryo/fetus was at a greater risk of cancer because of the dose.

3.3 Conclusions

The inspector determined that the licensee conducted a thorough investigation of the event, including determination of the root cause. The root cause was attributed to the patient being unaware that she could potentially be pregnant and the false negative result of the pregnancy test. The false negative result was due to the early stage of pregnancy at the time of the test. The inspector agreed with the licensee's determination of the root cause.

4.0 Notifications and Reports

4.1 Inspection Scope

The inspector interviewed the RSO and selected radiation safety staff to determine what event notifications and reports had been made. The inspector also reviewed the licensee's event notification and its 15-day written report dated June 11, 2007.

4.2 Observations and Findings

On May 31, 2007, the licensee determined that an event requiring notification of the NRC per 10 Code of Federal Regulations (CFR) 35.3047(a) had occurred. The RSO notified the NRC Operations Center of the event at 3:56 pm EDT on June 1, 2007. The patient and the referring physician were notified of the event on May 31, 2007. The licensee's 15-day report, dated June 11, 2007, contained the information required by 10 CFR 35.3047(d) and it was received by the NRC on June 12, 2007.

4.3 Conclusions

The inspector determined that the licensee made the required event notification and report to the NRC. The telephonic notification to the NRC was made the next calendar day after discovery of the event. The licensee provided a timely 15-day report, and the report included all required information.

5.0 Corrective Actions

5.1 Inspection Scope

The inspector interviewed the RSO, selected members of the radiation safety staff, and the Radiation Safety Committee chair regarding any corrective actions they proposed for the event.

5.2 Observations and Findings

The RSO stated that the root cause of the event was a false negative pregnancy test and the patient being unaware that she could be pregnant. The licensee determined that the root cause was beyond their control. The authorized user stated that the blood test used in this case was the standard test for pregnancy. Licensee staff followed their procedures by performing a blood test for pregnancy within seven days before the therapy and asked the patient if she had any reason to believe she could be pregnant. Because the root cause was beyond the licensee's control, the licensee did not intend to implement any corrective actions for the event.

5.3 Conclusions

The inspector determined that, because the root cause of the event was beyond the control of the licensee, and because the licensee's actions to prevent administering a therapeutic dosage of I-131 to a pregnant patient were similar to actions taken by other licensees, the licensee's decision not to implement any corrective action was reasonable.

6.0 NRC Medical Consultant's Review

The NRC staff contracted with a medical consultant, Ronald Goans, Ph.D., M.D., to review the possible health effects associated with the dose to the embryo/fetus as a result of the event. Dr. Goans' report indicated that the most likely result of the event would be delivery of a normal infant with regard to thyroid function because of the age of the embryo at the time of the administration, though he stated that there may be a slight increased risk of childhood cancer. In addition, he confirmed the licensee's dose estimate of 25-34 rads to the embryo. He also recommended that a complete thyroid evaluation of the infant be made after delivery. The licensee is considering the NRC medical consultant's recommendations.

7.0 Exit Meeting Summary

The inspector discussed the conclusions described in this report with the licensee during a preliminary exit meeting conducted at the licensee's facility on June 5, 2007. The licensee did not identify any information reviewed during this inspection as proprietary in nature. A final exit meeting was conducted by telephone with the licensee's RSO on July 16, 2007.

LIST OF PERSONS CONTACTED

Perry Grigsby, M.D., Physician Authorized User, Radiation Oncology
#* Susan Langhorst, Ph.D., CHP, Radiation Safety Officer
Trudy Liss, Radiation Therapist, Radiation Oncology
Joan Martin, RN, Nurse Coordinator, Radiation Oncology
Barry Siegel, M.D., Radiation Safety Committee Chair (by telephone)
John Smith, Ph.D., Associate Radiation Safety Officer

Participated in preliminary exit meeting
* Contacted by telephone for final exit meeting