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

May 18, 2009

EA-09-047
NMED NO. 080514

Colonel Robert F. Todaro
Chairman, USAF Radioisotope Committee
Department of the Air Force
Office of the Surgeon General
AFMSA/SG3PB
ATTN: Radiation Protection Program
1400 Key Boulevard
Rosslyn, VA 22209-1559

SUBJECT: NRC SPECIAL INSPECTION REPORT 030-28641/08-003 AND NOTICE OF VIOLATION

Dear Colonel Todaro:

This refers to the special inspection initiated on September 19, 2008, in response to an embryo/fetus exposure event, which occurred at the USAF Wilford Hall Medical Center (WHMC), Lackland Air Force Base, Texas, on June 4, 2008. This inspection was chartered in response to an unintended exposure of approximately 31.5 rem to an embryo/fetus as a result of a therapeutic administration of sodium iodide iodine-131 (I-131) to a female patient. The NRC inspectors first learned of this incident on September 5, 2008, while conducting a routine, unannounced inspection of the 59th Medical Wing located at WHMC, a permit holder with the U.S. Air Force Master Materials License. The preliminary special inspection (henceforth identified as inspection) findings were discussed with Major General Travis, WHMC Commander; members of his senior staff; and Lt Col Adams, of your staff, at the conclusion of the onsite portion of the inspection. A final exit briefing on the inspection was conducted telephonically with you and members of your staff on April 3, 2009. The enclosed report presents the results of the inspection.

The focus of the inspection was to address the elements of the inspection charter dated September 19, 2008 (ML082630255). The inspection was a focused review of the circumstances surrounding the incident that occurred at WHMC on June 4, 2008, and the cause for the delay in the notification to the NRC. In addition, the inspection involved a review of aspects of WHMC's nuclear medicine department and its procedures.

In a telephone conversation on April 3, 2009, Mr. Jack E. Whitten, of my staff, informed you that the NRC was considering escalated enforcement for an apparent violation of NRC requirements. The violation involved the failure to notify the NRC no later than the next calendar day after discovery of an unintended dose to an embryo/fetus that is greater than 50 mSv (5 rem) as a result of an administration of byproduct material to a pregnant individual that was not specifically approved by the authorized user as required by 10 CFR 35.3047. The circumstances surrounding this violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit briefing. Additionally, you have initiated corrective actions, some of which are documented in this report to address the violations. Further, we provided you an opportunity to: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. Mr. Whitten also informed you that the NRC had sufficient information regarding the apparent violation and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from you. You agreed that a predecisional enforcement conference or written response was not needed.

Based on the information developed during the inspection and documents provided by the licensee dated September 22, 2008, and January 14, 2009, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation occurred on August 14, 2008, when the licensee failed to notify the NRC that it had discovered, on August 13, 2008, that as a result of the administration of a therapeutic dose of I-131 to a pregnant individual, an unintended dose of approximately 31.5 rem to an embryo/fetus occurred. Although a qualitative serum pregnancy test was performed prior to the procedure and yielded a negative result, the licensee later learned that the individual was in the very early stages of pregnancy during the I-131 procedure.

The NRC considers this violation significant because when a licensee fails to notify the NRC of an event in accordance with the Commission's regulations, the NRC's ability to meet its regulatory responsibility to ensure that licensed activities are conducted in a safe and secure manner is impacted. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The NRC Enforcement Policy may be found on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $6,500 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy." Based on your prompt and comprehensive corrective actions, the NRC has determined that *Corrective Action* credit is warranted. Your corrective actions included developing and implementing new standard operating procedures that provide the explicit NRC definition of an embryo/fetus, the establishment of an event review team, and the requirement for immediate

notification of the USAF Radioisotope Committee Chair of any potential reportable medical events.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in letters from the licensee dated September 22, 2008, and January 14, 2009. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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's Web site at http://www.nrc.gov/reading-rm/pdr.html or www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket No. 030-28641
License No. 42-23539-01AF

Enclosures:
1. Notice of Violation
2. Special Inspection Report 030-28641/2008-003
   (w/Attachment)
3. NRC Medical Consultant's Report

cc w/enclosures:
Lt. Col. Craig L. Adams
Secretariat, USAF Radioisotope Committee
Department of the Air Force
AF Medical Support Agency (AFMSA/SG3PB)
1400 Key Blvd, Ste 400
Rosslyn, VA 22209

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SUNSI Review Complete	☑ Yes ☐ No	ADAMS	☑ Yes ☐ No	Initials	MCM
Publicly Available	☑ Yes ☐ No	Sensitive	☐ Yes ☑ No	Initials	MCM
Category/Item #		Keywords	EA-09-047, NOV, USAF MML, Wilford Hall Medical Center		

RIV/ORA/ACES/ES	DNMS/NMSB-A	NMSB-B	NMSB-A/BC
MCMaier	LDonovan	RBrowder	VHCampbell
/RA/	***/RA/ E***	***/RA/ RJTorres for***	***/RA/***
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NMSB-B/BC	**RC**	**DIV DIR**	**RA/DRA**
JEWhitten	KSFuller	ATHowell	EECollins
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NOTICE OF VIOLATION

Department of the Air Force
USAF Radioisotope Committee
Brooks AFB, Texas

Docket No. 030-28641
License No. 42-23539-01AF
EA-09-047

During an NRC special inspection conducted from September 19, 2008, through April 3, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.3047(a) requires, in part, that a licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved by the authorized user.
>
> 10 CFR 35.3047(c) requires, in part, that a licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report in Paragraph (a) of this section.
>
> Contrary to the above, as of August 14, 2008, the licensee failed to notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved by the authorized user. Specifically, on August 13, 2008, the licensee discovered that an embryo/fetus had received a dose of approximately 31.5 rem, a dose greater than 5 rem, as a result of the administration of sodium iodide iodine-131 to a pregnant individual; however, notification was not made to the NRC Operations Center until September 5, 2008.

This is a Severity Level III violation (Supplement IV).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in letters from the licensee dated September 22, 2008, and January 14, 2009. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation (EA-09-047)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, 612 E. Lamar Blvd., Suite 400, Arlington, Texas 76011-4125 within 30 days of the date of the letter transmitting this Notice of Violation.

If you choose to respond, your response 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's Web site at www.nrc.gov/reading-rm/pdr.html or www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction."

Dated this 18th day of May 2009

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-28641
License No.:	42-23539-01AF
Report No.:	030-28641/08-003
EA No.:	EA-09-047
Licensee:	Department of the Air Force USAF Radioisotope Committee
Location:	Wilford Hall Medical Center (59th Medical Wing) Lackland Air Force Base, San Antonio, Texas
Dates:	September 5, 2008 through April 3, 2009
Inspectors:	Lawrence Donovan, Health Physicist Nuclear Materials Safety Branch A Rachel Browder, Health Physicist Nuclear Materials Safety Branch B Latischa Hanson, Health Physicist Nuclear Materials Safety Branch A
Approved By:	Jack E. Whitten, Chief Nuclear Materials Safety Branch B
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Department of the Air Force
NRC Inspection Report 030-28641/08-003

During a routine, unannounced inspection conducted on September 5, 2008, at Wilford Hall Medical Center (WHMC), 59th Medical Wing, Lackland Air Force Base, San Antonio, Texas, the NRC became aware of an incident involving the inadvertent exposure to an embryo/fetus that received a dose equivalent greater than 50 mSv (5 rem) as a result of a sodium iodide iodine-131 (I-131) treatment to a female patient. As a result of this incident, a special inspection was chartered to review the circumstances surrounding the inadvertent exposure that occurred at WHMC on June 4, 2008, and the cause for the delay in the notification to the NRC.

The charter for this special inspection included, a review of the chronology of events, an assessment of the licensee's investigation, reporting and corrective actions, an evaluation of the NRC medical consultant's report, and an assessment of any generic implications or extent of circumstances associated with the event. The inspectors reviewed permittee's records, the permittee's and the licensee's evaluation reports, and the NRC medical consultant's evaluation report, as well as conducted interviews with personnel at the permittee's WHMC facility and licensee personnel at the USAF Radioisotope Committee (RIC).

Based on the information developed during the special inspection and documents provided by the licensee, the NRC has determined that a violation of NRC requirements occurred. The violation occurred on August 14, 2008, when the licensee failed to notify the NRC that it had discovered, on August 13, 2008, that as a result of the administration of I-131 to a pregnant individual, an embryo/fetus received an unintended dose of approximately 31.5 rem. The licensee notified the NRC Operations Center of this incident on September 5, 2008.
10 CFR 35.3047 requires licensees to report to the NRC doses received by an embryo/fetus that are greater than 50 mSv (5 rem) dose equivalent, no later than the next calendar day after discovery. This violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III (escalated enforcement), no civil penalty.

The licensee implemented prompt and comprehensive corrective actions. Corrective actions completed by the licensee included developing and implementing new standard operating procedures that provide the explicit NRC definition of an embryo/fetus, establishing an event review team, and implementing the requirement for immediate notification of the USAF Radioisotope Committee Chair of any potential reportable medical event.

The licensee's investigation into the inadvertent exposure to an embryo/fetus determined that the occurrence was an isolated event. The NRC medical consultant and the licensee both concluded that there was not any deviation from policy or standard of care exhibited by the U.S. Air Force Master Material License permittee.

REPORT DETAILS

1. Program Overview (87103) and Inspection History

The U.S. Air Force (USAF) Radioisotope Committee (RIC) holds a multisite Master Material License (MML). The MML authorizes the USAF RIC to issue permits for the possession and use of byproduct, source and special nuclear material for a wide spectrum of applications under the license. The MML provides the framework for the licensee to conduct oversight, inspection and enforcement activities relative to its permittees. There are approximately 400 permits authorized by the MML. Wilford Hall Medical Center (WHMC), 59th Medical Wing, Lackland Air Force Base, San Antonio, Texas, is a large broad-scope medical permit authorized under the MML. The permittee typically performs an average of 20 patient procedures per year using I-131. The MML last inspected this permittee on April 1, 2008, and no violations were identified during that inspection.

The NRC performs a biennial inspection of the MML program which exams the activities conducted under the USAF RIC's MML license as the activities relate to safety and compliance with the Commission's rules and regulations and with the conditions of the MML. The last NRC inspection of the MML was conducted between October 20-24, 2008, and no violations were identified. During the biennial review period, three events were reported by the MML. Two of the events were reported in accordance with the applicable regulatory requirement. One event was reported on October 24, 2006, and the second event was reported on February 11, 2008. The third event was reported on September 5, 2008, which is the focus of this special inspection.

The NRC performs routine, unannounced inspections of selected permits during each calendar year as part of the NRC's oversight of the MML program. The previous NRC inspection of WHMC was conducted on November 18-19, 2003, and no violations of NRC requirements were identified during that inspection. The NRC conducted a routine, unannounced inspection of WHMC on September 5, 2008. During the inspection, the NRC became aware of an incident involving the inadvertent exposure to an embryo/fetus as a result of an I-131 treatment to a female patient. The permittee's estimated dose to the embryo/fetus was 31.5 rem; however, the permittee's final calculated dose to the embryo/fetus was 35 rem.

2. Sequence of Events

2.1 Inspection Scope

The inspection included a review of the sequence of events that resulted in an unintentional dose to an embryo/fetus and the reporting and notification requirements of the event pursuant to the provisions of 10 CFR 35.3047. The scope of the inspection included interviews of selected licensee and permittee staff, reviews of selected records and the NRC medical consultant's report.

2.2 Observations and Findings

A 20 year-old female patient was diagnosed with thyroid cancer and subsequently received a total thyroidectomy. The patient was referred to WHMC nuclear medicine clinic by WHMC endocrinologist for radiopharmaceutical therapy to treat any remaining thyroid tissue. On June 2, 2008, the patient received a qualitative serum pregnancy test as a prerequisite for the ablation therapy. The pregnancy test indicated that the patient was not pregnant. The patient was provided guidelines specific to the ablation therapy procedure and signed consent forms as part of the permittee's procedure. On June 4, 2008, the patient received the prescribed therapeutic administration of 149.2 millicuries (mCi) of sodium iodide iodine-131 (I-131) for remnant thyroid ablation therapy. The ablation therapy was conducted as planned and the patient was released.

On June 25, 2008, the patient contacted her endocrinologist and informed the physician that she believed she was pregnant. Additional quantitative serum pregnancy tests were conducted between June 28 and July 8, 2008, and an ultrasonography was performed on June 28, 2008, which confirmed the patient was pregnant and established the possible date of conception sometime between May 27 and 31, 2008.

The WHMC nuclear medicine clinic was not made aware of the pregnancy test results from the June through July, 2008 quantitative tests that were conducted by the referring endocrinologist. On August 13, 2008, the WHMC Radiation Safety Officer (RSO) became aware of the incident when the patient contacted the nuclear medicine clinic with concerns regarding any potential hazards or complications to the embryo/fetus as a result of the radiation therapy conducted on June 4, 2008. The RSO immediately initiated an investigation of the potential risks to the embryo/fetus, in consultation with the senior medical physicist and third-party experts from the Department of Energy Radiation Emergency Assistance Center/Training Site (DOE REAC/TS).

On August 13, 2008, the RSO briefed the executive management of the facility and notified the USAF RIC by telephone regarding the incident as required by Air Force procedure AFI 40-201, *Managing Radioactive Materials in the US Air Force*. The RIC Deputy Chief took the telephonic event report and after discussing it with the RIC Secretariat, requested that WHMC provide a written report in 2 weeks.

On August 27, 2008, the RIC received the written report from WHMC. The RIC decided the event would be discussed at the next quarterly RIC meeting scheduled for September 9, 2008.

As previously discussed, on September 5, 2008, the NRC conducted a routine, unannounced inspection at WHMC. During the inspection, the NRC became aware of the incident involving the inadvertent exposure to an embryo/fetus as a result of an I-131 treatment to a female patient.

On September 5, 2008, the RIC reported the event to the NRC Headquarters Operations Center (Event Notice 44468) as a result of further discussions with NRC Region IV regarding the required notification under 10 CR 35.3047.

On September 9, 2008, the NRC issued a Preliminary Notification (PNO-IV-2008-009) for the event.

On September 19, 2008, a Special Inspection Team was chartered by the NRC to investigate the event. The purpose of the NRC special inspection was to assess the licensee's investigation, root cause analysis and response to the event as well as to review the adequacy of the corrective actions to prevent a similar occurrence.

On September 22, 2008, the USAF RIC submitted the 15-day written report, as required by 10 CFR 35.3047(d).

On October 20, 2008, the NRC Region IV office issued a letter of agreement to a medical consultant to review the incident. On November 19, 2008, the NRC received the medical consultant's report.

On January 14, 2009, the RIC submitted the USAF RIC Special Inspection Report for their investigation. The USAF special inspection report discussed root causes, extent of circumstances, and provided an assessment of the event.

3. NRC Assessment of Licensee Investigation

3.1 Inspection Scope

The NRC inspection team evaluated the permittee's event report and supporting documentation that was submitted to the USAF RIC. In addition, the licensee's 15-day written report and the licensee's special inspection report were reviewed by the NRC inspection team. The licensee's special inspection report included a root cause assessment, event significance determination, extent of circumstances, and corrective actions. The NRC inspection team also interviewed the RIC staff, the permit RSO, the permit authorized medical physicist, and other selected permittee staff.

3.2 Observations and Findings

Upon notification by the patient of the pregnancy test results, the permittee staff immediately initiated an investigation of the event and obtained the resources of DOE REAC/TS to assist with the estimated dose to the embryo/fetus. The permittee staff conferred with the patient's referring physician and held a teleconference between the referring physician, the permittee staff, and three consultant physicians from DOE REAC/TS to discuss the estimated dose and the appropriate dose coefficient based on "Radiation Dose Estimates for Radiopharmaceuticals," which was published by the Radiation Internal Dose Information Center, on April 30, 1996. Within several hours, the permittee staff and the permittee's outside consultants determined that the treatment had occurred 7 days post conception and the initial dose estimate was calculated as 31.5 rem to the embryo/fetus. The calculation was based on: (1) the patient's rapid clearance rate, (2) the assumption that iodine transport does not occur in a fetus until 10 weeks gestational age, and (3) the zygote dose may be estimated based on the calculated dose

to the patient's uterus. The permittee obtained the required certification that the referring physician had discussed the event with the patient as required by the regulations in 10 CFR 35.3047.

The permittee's staff determined that the policy and procedures in-place for the thyroid ablation therapy procedure were followed when administering I-131 for therapeutic treatment of the patient's thyroid. The investigation also concluded that the staff had made reasonable attempts to ascertain the medical status of the patient, specifically her pregnancy status prior to the administration of the I-131 dosage. The permittee staff also determined there was not any deviation from policy or standard of care.

The USAF RIC submitted to the NRC the 15-day required written report and a subsequent special inspection report that was initiated by the licensee. The licensee's special inspection report evaluated the period between September 1, 2006, and September 18, 2008, and identified four permittees who had performed I-131 procedures with delivered dosages greater than 20 millicuries (mCi). The licensee stated that they had selected a 20 mCi threshold because this dosage could potentially deliver an exposure of 5 rem to an embryo/fetus during a pregnancy of less than 3 months. There were a total of 85 treatments performed by the four permittees during the selected timeframe. WHMC performed 38 of the 85 treatments identified. In addition, WHMC was the only permit holder that performed in-patient therapeutic treatments with dosages greater than 33 mCi of I-131. Of the total 38 treatments performed at WHMC, 23 of those treatments were in-patient treatments performed during the selected timeframe.

The licensee's special inspection report documented a qualitative risk assessment that was performed across eight different medical permittees authorized to use I-131 for medical purposes. The risk assessment reviewed the standard operating procedures, questionnaires, pregnancy test requirements and tracking between clinics of the identified permits. The licensee determined that all permittees who used I-131 for medical purposes had processes in place to prevent dosages being administered to pregnant or nursing females. The licensee concluded that the risk assessment results obtained, based on probability and consequence analysis, suggested that the potential for an occurrence of an event of this type in the future would be extremely low based on a review of the previous 2 years operational experience, review of current standard operating procedures, pregnancy test requirements, post-procedure pregnancy instructions and other factors.

The licensee's special inspection report evaluated the different phases of the event which included: (1) patient's pregnancy test to RSO notification, (2) RSO's preliminary investigation to licensee's notification to the NRC, and (3) post notification to the NRC. As part of the evaluation, the licensee identified the root causes and evaluated the extent of conditions for each phase of the event.

As part of the licensee's special inspection, the USAF RIC contacted the Radiation Dose Assessment Resource (RADAR) to assist with the re-evaluation of the dose estimate to the embryo/fetus. Based on the re-evaluation by RADAR, the licensee determined that the dose estimate was 35 rem to the embryo/fetus. The licensee stated in part, that this value accounts for all biological removal and physical decay of the sodium iodide I-131 in

the body organs, and in particular with the radioactivity passing through the urinary bladder, which is the most important contributor to fetal dose. However, the dose estimate should be viewed as an estimate since all biokinetics of individuals may vary from the median model.

The licensee's investigation into the inadvertent exposure to an embryo/fetus determined this was an isolated event and that there was not any deviation from policy or standard of care exhibited by the permittee. The USAF RIC identified the lack of communication between clinics as contributing to the delay in notifying the WHMC RSO and nuclear medicine of the post-therapy pregnancy test results. The licensee documented that there had been changes to procedures to enhance the process and to close potential communication gaps between clinics. The licensee stated in part, that all measures taken to prevent radiation exposure to an embryo/fetus were contingent upon the participation of the patient to the fullest extent; and therefore, education of the patient had been incorporated in the clinical process.

The licensee's investigation assessed the USAF RIC's delay in reporting the inadvertent exposure of the embryo/fetus to the NRC. The reporting delay was prompted by the licensee's misinterpretation of the definition of embryo/fetus when trying to determine if the incident was reportable to the NRC under 10 CFR 35.3047. The licensee identified their corrective actions to ensure the delay in reporting does not happen in the future. Section 5 of this report provides a detailed description of these corrective actions. The licensee also acknowledged that the delay in reporting the event to the NRC did not affect or alter medical care to the fetus or patient.

3.2 Conclusions

The NRC's inspection team determined that the licensee had conducted a thorough inspection of the event. The licensee reviewed the specific factors associated with the event and determined the extent of circumstances by evaluating all medical permits that were authorized I-131. The licensee had adequately evaluated the breadth and depth of the program regarding any risk for a potential recurrence of the event.

The NRC's inspection team also determined that the licensee had evaluated the circumstances and reasoning for not reporting the unintended exposure of an embryo/fetus to greater than 5 rem total effective dose equivalent. However, the inspection team did not agree with the licensee's root cause for not reporting the unintended exposure, as described below.

4. NRC Assessment of Contributing and Root Causes

4.1 Inspection Scope

The inspectors reviewed the licensee's 15-day written report as required by 10 CFR 35.3047 and the licensee's special inspection report submitted on January 14, 2009.

4.2 Observations and Findings

The licensee's special inspection report evaluated root causes for two different phases of the event which included: (1) the patient's positive pregnancy test result up to the time the RSO was notified of the positive pregnancy test result, and (2) the licensee's notification of the event to the NRC. In addition, the licensee evaluated the extent of conditions as part of their root cause analysis.

The permittee and licensee identified that the pregnancy test was appropriate and was delivered consistent with the standard of care applied throughout the United States. The patient was provided sufficient instructions prior to the therapy and the patient signed consent forms and a statement of understanding of the instructions that warned about pregnancy and the potential consequences to the health of the fetus associated with the therapy.

The licensee evaluated the delay in notification to the WHMC RSO regarding the patient's positive pregnancy test that was taken by the endocrinology clinic after the therapeutic procedure. The licensee identified the root cause as a lack of communication between the referring physician from endocrinology and the RSO. The licensee determined that the lack of notification between the respective parties was due to insufficient training of the hospital's staff regarding communications of any post-therapy pregnancy. The licensee evaluated the extent of conditions and determined that this was an isolated event. Based on the licensee's assessment of eight permits that authorized I-131 procedures, seven out of eight permittees had specific instructions that were provided to the patient regarding post-therapy pregnancy. The licensee stated that the one permittee who did not have specific instructions had not used radioiodine during the past 2 years and had requested, as a result of the incident, removal of the radioiodine authorization from this permit. Based on the licensee's assessment, all permittees with radioiodine authorization have a process for tracking patients between clinics. In addition, Notice to Airman was developed that contains policy for the physician to immediately contact nuclear medicine and/or radiation safety should one of their patient's have a positive pregnancy test within 3 months post-therapy.

The licensee identified the root cause for the delay in notifying the NRC of the inadvertent exposure to the embryo/fetus as required by 10 CFR 35.3047 was due to the lack of a definition for *embryo/fetus* in 10 CFR Part 35. This lack of a definition in 10 CFR Part 35 caused the licensee to rely upon widely held scientific definitions of an embryo/fetus and a zygote. Based on the permittee's and consultant's evaluation of the dose, the licensee understood that the product of conceptus was classified as a 7-day old zygote but failed to recognize that embryo/fetus is defined in 10 CFR 20.1003 as the developing human organism from conception until the time of birth. The licensee evaluated the extent of conditions and determined that this was an isolated event. The licensee evaluated historical reportable events and determined that the USAF RIC had not previously failed to notify the NRC of a reportable event in accordance with the regulations. The licensee evaluated internal and permittee procedure requirements for reportable events and determined that seven of the eight permittee programs (WHMC included) had written instructions on the subject reporting criteria and that AFI 40-201, *Managing Radioactive*

Materials in the US Air Force, is being currently revised to address the NRC reporting requirements described in 10 CFR 35.3047.

4.3 Conclusions

The NRC inspectors determined that the licensee had conducted a thorough investigation of the event, including determination of the root cause for the exposure and root cause for the WHMC internal notification delay. The root cause of the inadvertent exposure of the embryo/fetus was attributed to human error by the patient, in that the patient believed and affirmed in writing that she was not pregnant. In addition, the negative yielding pregnancy test result administered during the early state of pregnancy served as a contributing cause. The inspectors agreed with the licensee's determination of the root cause and the conclusion that the appropriate standard of care was applied during this procedure.

The root cause identified by the licensee for the delay in communicating the positive pregnancy test result between the referring physician and the RSO was attributable to lack of communications training by the staff at WHMC. The RSO had been informed by the patient at 71 days post therapy of the positive pregnancy test results. The referring physician was aware of the positive pregnancy test at 21 days post therapy, but did not communicate the results to the RSO. The inspectors agreed with the licensee's identification of the root cause.

The licensee stated that the root cause for the delay in notifying the NRC of the embryo/fetus exposure event as required by 10 CFR 35.3047 was attributable to a lack of a definition for embryo/fetus in 10 CFR Part 35. The NRC's assessment determined that the direct cause for the delay in notifying the NRC of the event in accordance with 10 CFR 35.3047 was a failure to research, investigate, and evaluate all pertinent regulations associated with the event, and in particular to evaluate 10 CFR Parts 20 and 35. The failure to properly review and evaluate the regulations resulted in a misinterpretation of the definition for embryo/fetus which then resulted in the failure of the USAF RIC to make a 24 hour report as required by 10 CFR 35.3047. It is incumbent upon the NRC's licensees to recognize and be familiar with all pertinent regulations affecting their radiation safety programs.

5. Licensee Corrective Actions

5.1 Inspection Scope

The inspectors discussed the proposed corrective actions with the permittee's staff on September 5, 2008, and with the licensee on September 5 and 19, 2008, and February 26, 2009. The inspectors reviewed the licensee's 15-day written report, submitted to NRC in accordance with 10 CFR 35.3047, and the licensee's special inspection report dated January 14, 2009. These written reports collectively document the corrective actions that have been implemented and that are planned to be implemented by the USAF RIC.

5.2 Observations and Findings

The licensee's special inspection report stated, in part, that WHMC endocrinology and radiation safety staff had revised the patient consent form to provide specific instructions regarding administration of the pregnancy test, pre- and post-therapy abstinence instructions, and post-therapy precautions against pregnancy. The consent form process also advised the patient to inform the physician and the nuclear medicine clinic immediately if the patient believed she may be pregnant before or following the therapeutic procedure. The permit staff implemented the policy changes in an attempt to reduce the risk of repeat occurrences for any procedure utilizing unsealed radioactive material in quantities requiring a written directive.

The licensee issued a Surgeon General Notice to Airmen (NOTAM) in September 2008 that required physicians to contact nuclear medicine and/or radiation safety should one of their patients have a positive pregnancy test within 3 months after a therapeutic radionuclide administration. The NOTAM also prescribed what type of quantitative pregnancy test should be administered prior to any therapeutic radionuclide administration.

The licensee implemented a revised standard operating procedure (SOP) which clearly reflected the 10 CFR Part 20 definition for an embryo/fetus. The SOP established the criteria for initiating an event review team and required the immediate notification to the USAF RIC Chair for all potential medical events.

The Surgeon General NOTAM also delineated that the USAF RIC would immediately discuss with the NRC any potential reportability requirements.

5.3 Conclusions

The inspectors determined that the licensee's corrective actions were reasonable to ensure that communications between clinics at the permit facilities were sufficient for all responsible clinics to be aware of any potential pregnancy of a patient involved with a therapeutic radionuclide administration. In addition, the inspectors determined that the corrective actions taken by the permittees and licensee should be adequate to ensure notifications are made to the NRC as required. The licensee also plans to contact the NRC MML Project Manager to discuss potential reportability requirements.

6 Notification and Reports

6.1 Inspection Scope

The inspectors interviewed the permittee staff, selected members of the radiation safety staff, and the USAF RIC to determine what event notifications and reports had been provided by the permittee to the USAF RIC. The inspectors also reviewed the licensee's event notification and its 15-day written report dated September 22, 2008.

6.2 Observations and Findings

The USAF RIC received a telephonic notification on August 13, 2008, by the permittee that WHMC had experienced an unplanned exposure to an embryo/fetus. In this notification to the USAF RIC, the permittee RSO was able to provide detailed information regarding the event, estimated dose, and approximate age of the conceptus. This prompt notification to the USAF RIC was due, in part, to the expeditious involvement of both the permittee staff and the third-party medical consultants who were contacted regarding the event. Upon receipt of the telephonic report from the permittee, the USAF RIC requested a 2-week written report from the permit RSO. After receiving the notification from the permittee, the USAF RIC had given deliberate consideration to the reporting requirement required by 10 CFR 35.3047(a). However, in its deliberations, the USAF RIC had focused on the scientific fact that a zygote, not an embryo/fetus, was present during administration of the sodium iodide I-131 therapeutic dose. The USAF RIC had based their assessment on the information that the cells were in the zygote phase of development and were approximately 7 days post-conception. The USAF RIC, in its assessment of the event, did not recognize that 10 CFR 20.1003 defines an embryo/fetus as the developing human organism from conception until the time of birth.

6.3 Conclusion

One violation was identified during the inspection. The violation involved the failure of the USAF RIC to make a 24-hour report pursuant to 10 CFR 35.3047, for the unplanned exposure of an embryo/fetus that is greater than 5 rem dose equivalent as a result of the therapeutic administration of I-131 to a pregnant individual (VIO 030-28641/08-003).

7. NRC Medical Consultant's Review

As part of the special inspection charter, the NRC staff contracted with a medical consultant to review the possible health effects associated with the unplanned dose to the embryo/fetus. The NRC medical consultant's report indicated that the estimated dose to the embryo/fetus was approximately 30.4 rem based on a prudent assumption of 5 percent thyroid uptake, since the patient had some residual functioning thyroid tissue as demonstrated by her post-therapy I-131 scan. The dose conversion factor used by the NRC medical consultant was based on ICRP Publication 53, "Radiation Dose to Patients with Radiopharmaceuticals." Both the NRC medical consultant's report and the licensee's report assumed that the embryo/fetus exposure was based on the estimated radiation dose to the uterus from I-131. The NRC medical consultant's report concurred with the licensee's assessment that radiation exposure of this magnitude to an embryo/fetus of this age would be expected to result either in spontaneous abortion or survival with no deterministic effects.

The NRC medical consultant's report indicated agreement with a large majority of the licensee's corrective actions with the exception of the adopted policy of performing quantitative serum beta-hCG testing rather than qualitative testing for females undergoing therapy using I-131. The NRC medical consultant stated, in part, that qualitative testing was the accepted standard of care and that the slightly greater sensitivity of the quantitative test did not justify the expense and the longer analysis time.

The NRC medical consultant report indicated that the justification for not intensifying the surveillance for childhood cancer in this situation is based on the probability that the child will not develop cancer is approximately 99.5 percent versus 99.7 percent in the absence of radiation (ICRP Publication 84: Pregnancy and Medical Radiation).

8. Exit Meeting Summary

The inspectors discussed the scope, findings and conclusions described in this report with the licensee during a final exit meeting on April 3, 2009. The licensee did not identify as proprietary any information provided to, or reviewed by the inspectors.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Major General Thomas Travis, Commander, 59th Medical Wing
Colonel Iddins, Executive Officer, 59th Medical Wing
Colonel Sven Berg, Chief Medical staff, 59th Medical Wing
Colonel Martin, Deputy Chief, Medical Staff, 59th Medical Wing
Colonel Thomas Seay, Chief, Department of Radiology, 59th Medical Wing
Dr. Cindy Elmore, Senior Medical Physicist, 59th Medical Wing
Captain David Winter, Permit Radiation Safety Officer, 59th Medical Wing
* Lt. Col. Craig Adams, Secretariat, USAF Radioisotope Committee
* Colonel Robert Todaro, Chair, USAF Radioisotope Committee
* Barry A. Siegel, M.D. NRC Medial Consultant

in person
* by telephone

INSPECTION PROCEDURES USED

87103 Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing

ITEMS OPENED, CLOSED AND DISCUSSED

Opened

030-28641/08-003 SL III Failure to report an event pursuant to 10 CFR 35.3047

Discussed
None

LIST OF ACRONYMS USED

CFR	*Code of Federal Regulations*
MML	Master Materials License
NRC	Nuclear Regulatory Commission
NOTAM	Notice to Airman
RIC	Radioisotope Committee
RSO	Radiation Safety Officer
USAF	U. S. Air Force
WHMC	Wilford Hall Medical Center