DEPARTMENT OF THE ARMY
HEADQUARTERS, TRIPLER ARMY MEDICAL CENTER
1 JARRETT WHITE ROAD
HONOLULU HI 96859-5000

REPLY TO
ATTENTION OF

MCHK-PVR

11 August 2010

MEMORANDUM TO U.S. Nuclear Regulatory Commission, Region IV, Material Radiation Protection Section, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011-4005

SUBJECT: Tripler Army Medical Center Report of a Dose to an Embryo/Fetus (Event Number 46157)

1. References.

a. ANSI/HPS N13.54-2008, American National Standard, Fetal Radiation Dose Calculations, Health Physics Society, 2008.

b. Exposure of the Pregnant Patient to Diagnostic Radiations, A guide to Medical Management, Second Edition, Louis K. Wagner, PhD., Richard G. Lester, M.D., Luis R. Saldana, M.D., Medical Physics Publishing, 1997.

c. ICRP Publication 84, Pregnancy and Medical Radiation, November 1999.

d. Medical Use of Byproduct Material, Report and notification of a dose to an embryo/fetus or a nursing child, 10 CFR 35.3047.

2. Notification Requirements.

a. Department of the Army; Commander, Tripler Army Medical Center, NRC License 53-00458-04.

b. Referring physician: Dr. Jonathan Parks

c. Prescribing physician: Dr. Jerry M. Brown and Dr. Bryan D. Berkey

d. Event Summary.

(1) On July 8, 2010 Dr. Jonathan Parks' patient, recently informed him that she is pregnant. The patient was administered 154.9 mCi of I-131 on June 7, 2010 at 1105 hrs.

(2) The beta HCG blood test (pregnancy test) done just prior to the I-131 ablation therapy administration (June 7, 2010) indicated she was not pregnant.

(3) Initial assumption by Dr. Parks was that the patient became pregnant after discharge from the ablation therapy room (June 9, 2010 at 0900). A fetal dose assessment dated 12 July

2010 was conduct under that assumption and was calculated to be 1.435 rad using the most conservative calculations.

(4) Dr. Park escorted the patient to the Health Physics Staff to visit Mr. Shimabuku to allow her to pose any questions she may have pertaining to effects of radiation exposure. She was informed that due to the timing of the exposure that there were no acute affects associated with the dose that her fetus has/will received due to the I-131 procedure she had recently undergone. The patient appeared comfortable with the assurances given by Mr. Shimabuku and had no further questions.

(5) In the email from Ms Jennifer Bojanowski, Genetic Counselor, dated 4 August 2010, Dr. Brian Pierce determined based on a crown-rump length from an ultrasound performed by ultrasonographer Terry Humphry on 3 August 2010 that the actual date of the conception was 1 June 2010.

(6) The following assessment was conduct on 4 August 2010 to account for this new information.

3. Fetal Dose Assessment.

a. TAMC HPS Ablation Monitoring Records; the patient had been administered 154.9 mCi of I-131 on 7 June 2010.

b. Assessment conduct by Mr. Lou Shimabuku, TAMC Radiation Safety Officer.

(1) Per Reference 1a: for an activity administered to the mother with a fetal age of "less than 3 months", the dose is 41.27 rad.

(2) Per Reference 1b: for an activity administered to the mother with a fetal age between 1.5 – 6 weeks, the dose is 23.23 rad.

(3) Due to the age of the fetus, there was no thyroid present to conduct a dose assessment.

c. The patient's laboratory HCG results indicated she was still pregnant during her visit to the TAMC Health Physics Office on July 9, 2010.

4. Actions planned to prevent recurrence

a. Review and update the patient consent to reflect that the beta serum HCG pregnancy test may not show a positive result until the embryo has implanted which may not occur until 7 to 10 days after conception.

b. Consulted with CAPT Judith Dickert; Chief, Endocrinology Clinic. Per consultation, CAPT Dickert will reinforce the need for the clinic to inform the patients of the potential false negative results of the beta Serum HCG pregnancy test and for the patient to refrain from action that may lead to pregnancy.

5. Conclusion. Using the more conservative of our two results the dose to the fetus will be taken to be 41.27 rad. At this stage of the pregnancy, there should not be any acute effects to the fetus.

a. The fetal thyroid will not develop until around the 8th week of gestation, so irradiation prior to this is not expected to damage the fetal thyroid.

b. Per paragraph 3.1 (24) of Reference 1.c. "The effects of exposure to radiation on the conceptus depend on the time of exposure relative to conception and the amount of absorbed dose. When the number of cells in the conceptus is small and their nature is not yet specialized, the effect of damage to these cells is most likely to take the form of failure to implant or of an undetectable death of the conceptus; malformations are unlikely or very rare. Exposure of the embryo in the first two weeks following conception is not likely to result in malformation or fetal death, despite the fact that the central nervous system and the heart are beginning to develop in the third week."

c. The patient was counseled by Dr. Tamara Biega (Staff Physician, Nuclear Medicine Service, TAMC) about the facts and effects of the exposure to the embryo discussed in this report on 11 August 2010 at 1100 hrs. The following were also present during the counseling: Lou Shimabuku, CHP (RSO, TAMC) and Ms Jennifer Bojanowski (Genetic Counselor, TAMC).

d. A fetal dose greater than 5 rad is reportable to the NRC (Reference 1.d).

(1) Mr. Roberto J. Torres (NRC Region IV) was notified by phone at 0730 local time on 5 August 2010. He was not available so a message was left on his phone.

(2) Ms. Lizette Roldan (NRC Region IV) was contacted on 6 August 2010 via telephone, the NRC Emergency Operations Center was notified immediately after this phone conversation. Call-in Time: 1614 hrs Eastern Daylight Time Event Number: 46157

(3) This memorandum will be submitted not more the 15 days after the event.

6. This memorandum will be presented at the next TAMC Radiation Safety Committee meeting.

7. Questions pertaining to this memorandum may be addressed to MAJ Joseph Beckman, Chief, Health Physics Section, TAMC (Joseph.Beckman@US.Army.Mil or (808) 433-2334) or Mr. Lou Shimabuku, RSO, TAMC ( Lou.Shimabuku@US.Army.Mil or (808) 433-2335).

JOSE A. ACOSTA
CAPT, MC, USN
Deputy Commander for Clinical Services

**Single Event Report**

## NMED Item Number: 100400

**Narrative:** **Last Updated:** 08/11/2010

The Army (dba Tripler Army Medical Center) reported that a pregnant patient was administered 5.73 GBq (154.9 mCi) of I-131 for thyroid ablation on 6/7/2010. Prior to the administration of the I-131 capsules, the patient received a blood serum test to check for pregnancy and the results were negative. On 7/8/2010, the patient returned for a follow-up visit and informed the doctor that she was pregnant. An ultrasound estimated that the date of conception was 6/1/2010. The patient was notified on 8/11/2010.

| Event Date: | Discovery Date: | Report Date: |
|---|---|---|
| 06/07/2010 | 07/08/2010 | 08/06/2010 |

**Licensee/Reporting Party Information:**

| | | | |
|---|---|---|---|
| Regulated By: | NRC | Reciprocity: | NONE |
| License Number: | 53-00458-04 | Name: | DEPARTMENT OF THE ARMY |
| Docket Number: | 03003537 | City: | HONOLULU |
| Program Code: | 02120 | State: | HI |

Responsible NRC Region: 4

**Site of Event:**

Site Name: HONOLULU State: HI

**Additional Involved Party:**

License Number: NA City: NA
Name: NA State: NA

**Other Information:**

| | | | |
|---|---|---|---|
| NRC Reportable Event: | Y | Abnormal Occurrence: | P |
| Agreement State Reportable Event: | N | Investigation: | N |
| Atomic Energy Act Material: | Y | Record Complete: | N |
| Consultant Hired: | N | Event Closed by Region/State: | N |

**Event Cause:**

| Event Type: | Cause: |
|---|---|
| OTH - OTHER PATIENT OTHER | |

**Corrective Actions Information:**

| Event Type: | Number: | Action: |
|---|---|---|
| OTH | 1 | NOT REPORTED |

**Source/Radioactive Material Information:**

OTH

| | | | |
|---|---|---|---|
| Source Number: | 1 | | |
| Source/Material: | UNSEALED SOURCE RADIOPHARM | Radionuclide: | I-131 |
| Manufacturer: | NR | Activity (Ci): | 0.1549 |
| Model Number: | NA | Leak Test Results (uCi): | |
| Serial Number: | NA | | |

**Reporting Requirement Information:**

| Event Type: | Requirement: |
|---|---|

| | |
|---|---|
| OTH | 35.3047(a) - Dose to an embryo/fetus greater than 50 mSv (5 rem) DE from administration of byproduct material or radiation from byproduct material to a pregnant individual unless specifically approved, in advance, by the authorized user. |

**Keywords:**

| Event Type: | Keyword: |
|---|---|
| OTH | EMBRYO/FETUS OR NURSING CHILD DOSE |

**Reference Documents:**

| Reference Document Number: | Entry Date: | Retraction Date: | Type of Report: |
|---|---|---|---|
| EN46157 | 08/11/2010 | | EVENT NOTIFICATION |