



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
3851 ROGER BROOKE DRIVE
FORT SAM HOUSTON, TEXAS 78234-6200

January 19, 2010

Health Physics Service

U.S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section
Attention: Mr. Larry Donovan
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

RECEIVED

JAN 27 2010

DNMS

Reference: Nuclear Regulatory Commission Materials License No. 42-01368-01, Brooke Army Medical Center, Fort Sam Houston, Texas 78234-6200 – Fetal Dose Assessment

Dear Mr. Donovan:

As we have previously reported by telephone and email, we determined that a patient treated for metastatic thyroid cancer at Brooke Army Medical Center became pregnant near the time of her thyroid ablation treatment on November 4, 2009.

The majority of the medical findings indicate that the patient was likely not pregnant at the time of the procedure. These include:

- a. The patient signed a letter of consent indicating she had abstained from sexual intercourse for 14 days prior to treatment. The requirement for this statement is local and beyond the normal standard of care. The patient was previously scheduled for treatment two weeks prior but could not sign the statement verifying abstinence from sexual activity and, therefore, the treatment was delayed.
- b. The patient had a negative pregnancy test conducted the morning of the treatment and had three previous negative pregnancy tests in the three weeks prior to treatment.
- c. The patient was experiencing her menstrual cycle during her ablation treatment.
- d. The patient was on oral contraceptives at the time of treatment.
- e. The results of an ultrasound conducted on December 14, 2009 by her obstetrician state “based on US results today, this treatment was prior to expected ovulation and conception.”

A follow-up ultrasound was conducted on January 6, 2010 and interpreted by the maternal fetal medicine obstetricians at Wilford Hall Medical Center (an Air Force Hospital that is merging with Brooke Army Medical Center) indicating the patient was 11 weeks and zero days pregnant, thus placing the date of conception “around 3 Nov 2009.” Although this interpretation is contrary to the information presented above, it would place the date of conception on the day prior to treatment. Our authorized user indicates there is a degree of error associated with

ultrasound and the error increases as the fetus grows; however, if the new date of conception is accepted by the patient's obstetrician, it presents a reportable event.

Two case scenarios are presented below, the first is what we believe to be the most likely based on the factors listed above and the second is the worst case scenario based on a date of conception the day prior to treatment.

- a. I-131 ablation treatment date: November 4, 2009
- b. Treatment dose: 144.5 mCi
- c. Initial exposure rate measurement at 1 meter: 25 mR/hr
- d. Exposure rate measurement at 1 meter at 6:00 p.m. on November 5, 2009 prior to her release: 0.91 mR/hr (this was her second treatment; therefore, the effective half life of the I-131 was shorter than normal).
- e. Estimated remaining activity base on a ratio of exposure rate measurements: 5.26 mCi.
- f. Dose conversion factor for an Athyroid patient: 0.21 rad/mCi (from Oakridge Institute report Radiation Dose Estimates for Radiopharmaceuticals, table "Radiation Dose Estimates for I-131 Sodium Iodide in the Reference Adult – Athyroid Patient").

Case 1 dose estimate based on conception date on November 5, 2009 at 6:00 p.m. – 1.1 rad (5.26 mCi * 0.21 rad/mCi)

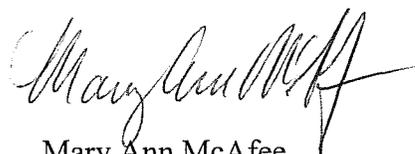
Case 2 dose estimate based on conception date of November 3, 2009 – 30.3 rad (144.5 mCi * 0.21 rad/mCi)

In each of these cases, we assumed the dose to the uterus was equivalent to the dose to the fetus.

As we have in the past, we plan to continue being ultra diligent evaluating and preventing the potential for pregnancy in our therapy patients, and we plan to maintain our multi-layered approach for assurance of such. While it is likely that the pregnancy occurred after the treatment, we are concerned about the possibility that it may have occurred prior. We provide written and verbal counseling to all our patients prior to the treatment, as well as after, regarding pregnancy and our desire that they refrain from becoming pregnant for one year after treatment to allow for possible retreatment options.

Please contact Colonel Mark Bower, Radiation Safety Officer, at (210) 295-2411 or mark.bower@us.army.mil, if you have any questions.

Sincerely,



Mary Ann McAfee
Colonel, Medical Corps
Radiation Safety Chairman



DEPARTMENT OF THE AIR FORCE
WILFORD HALL MEDICAL CENTER
LACKLAND AFB, TX 78236

14 January 2010

MEMORANDUM TO BROOKE ARMY MEDICAL CENTER
ATTN: RADIOLOGY/RADIATION ONCOLOGY

FROM: 59 MCCS/SGOBG

SUBJECT: Memorandum for Record Regarding Estimated Date of Confinement for
SSgt [REDACTED] SSN: [REDACTED]

1. After review of SSgt [REDACTED]'s obstetrical record and radiology images, we concur that her estimated date of confinement, or EDC, is 29 July 2010 based on an 11+0 week ultrasound. This would make her date of conception around 4 November 2009.
2. Any questions regarding this matter can be addressed with Lt Col (Dr.) Fausett or Maj (Dr.) Shields at (210) 292-6100.

ANDREA D. SHIELDS, Maj, USAF
SAMMC North
Director, Antenatal Counseling & Diagnostic Center

MERI J. B. FAUSETT, Lt Col, USAF, MC
SAMMC South
Chief, Obstetrics