

St. Joseph Regional Medical Center
415 6th Street
Lewiston, Idaho 83501

March 7, 2013

A NOTIFICATION to the Nuclear Regulatory Commission of a dose to an embryo/fetus greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of I-131 for thyroid ablation.

Notification Requirements:

Licensee Name: St. Joseph Regional Medical Center, 415 6th Street, Lewiston, Idaho 83501. NRC License 11-27371-01

Prescribing Physician: Dr. Kent Anderson, Radiation Oncologist

Referring Physician: Dr. David Martin

Physicists: Doug Heidorn, RSO and Dave Salmon, Consulting Health Physicist

Event Summary: On January 18, 2013 a 20 year old female patient of Dr. Kent Anderson received a 58 mCi dose of I-131 for ablation of a previously resected thyroid. At that time, the patient states that she was on birth control, but she was not given a pregnancy test. On February 21, 2013, the patient's primary care physician, Dr. Martin, calls Dr. Anderson to tell him that the patient has had a positive pregnancy test. At this time, the term of the pregnancy is unknown. Dr. Anderson informs Doug Heidorn, the RSO, and Dave Salmon, a consulting Health Physicist of the event. Assuming the patient was pregnant at the time of administration, Heidorn and Salmon independently calculate that the fetus (0-2 months) would have received a dose of 14.6 rem from a 58 mCi administration of I-131. (ANSI/HPS N13.54-2008, p.22)

February 22, 2013: Dr. Anderson orders a trans-vaginal ultrasound to confirm pregnancy status and determine the age of the fetus.

February 25, 2013: The ultrasound determines that the gestation age to be 6 weeks and 1 day which dates back to January 13, 2013.

February 26, 2013: Doug Heidorn calls the NRC to report an unintended dose to a fetus. The call was made at 9:23 PST and Mr. Heidorn spoke with Vince and gave him a timeline of events as well as the estimated fetal dose.

February 27, 2013: Doug Heidorn speaks with Jason Razo at the NRC to discuss the event. At that time, Mr. Heidorn informs Mr. Razo that no pregnancy test was performed prior to the I-131 administration. Mr. Razo will be the future point of contact for this case.

Follow Up: Dr. Anderson has been corresponding with an MD, Ph.D. Professor of Pediatrics and Radiology regarding this issue and has given him all the facts regarding the case: Date of I-131 administration 1/18/13, light menstrual cycle (spotting) on 1/14/13, gestation age on 2/25/13 is 6 weeks and 1 day, date of conception unclear. The expert physician responded in writing: “It appears, based on the sonogram determined gestation age, Jan. 14 was the first day of (the patient’s) last menstrual period. Conception took place on January 27 to 29, approximately... With regard to radiation exposure to the embryo, you did not have an embryo until 10 days after the dose of I-131 was administered. Secondly, from Jan 27 to Feb 25th is the ‘all or none period’ when the embryo is less likely to be born with an increased risk of birth defects.”

Based on the gestation age determined by the Feb. 25 ultrasound, an obstetrician at SJRMC and Dr. Martin concurred with the expert physician that the likely conception date was Jan. 27-29. If that is the case, then the dose to the fetus from any residual I-131 10 days post injection is estimated to be less than 20 mrem.

We, Dr. Anderson and Dr. Heidorn, are not experts in the field of obstetrics so we were not certain of the estimated conception date. Therefore, to be on the safe side, we reported the event to the NRC as a possible misadministration.

During this time period, Feb 21 to present, Dr. Anderson has had multiple conversations with Dr. Martin and consultations with the patient and her parents. He has kept them apprised of all the information he has received (see attached documents) as soon as he became aware of the facts as he knew them. By the way, the ultrasound showed a normal fetus (as best can be determined) with a heart rate of 120 BPM.

Actions: Obviously, this event revealed a large flaw in our I-131 policies and procedures. In short, the Radiation Department will immediately adopt a policy similar to the new policy drafted by the Radiology Department regarding I-131 administrations (see attached sheet). Specifically, any female aged 12-60 shall receive a pregnancy test 48 hrs. prior to an I-131 administration. We are currently in the midst of re-writing this policy for Radiation Oncology and the new policy will be sent to the NRC as soon as it has been drafted.

Conclusion: Based on the facts as we now know them, we do not think this incident resulted in a fetal dose greater than 5 rem and therefore is not a reportable event. The patient is scheduled for another ultrasound in a few weeks and Dr. Anderson will continue to follow her pregnancy.

Questions regarding this notification may be addressed to:

Douglas Heidorn, Medical Physicist

Email: dbheidorn@hotmail.com

Phone: (208) 799-5600

Attachment
Physician's notes

[redacted due to personally identifiable information]

ST. JOSEPH REGIONAL MEDICAL CENTER <small>Lewiston, Idaho</small>	DIVISION RADIOLOGY SERVICES
SUBJECT NUCLEAR MEDICINE THYROID TREATMENT/ABLATION	APPROVED:
ISSUED 5/90 REVIEWED 7/93, 3/99 REVISED 7/98, 3/99 2/13	

PROCEDURE DESCRIPTION

The thyroid is partially or completely destroyed using radioactive iodine. The iodine used is **100 times than** that used for a thyroid uptake.

PROCEDURE PREP

The patient must be off thyroid suppressive medication for 10 days. NPO one hour prior to treatment and one hour after treatment.

PREGNACY TESTING

All female ages 12-60 will be required to have a hCG lab test within the last 48 hours to determine pregnancy. Patients who have had a hysterectomy or other sterilization procedure will not be required to take a pregnancy test. Nuclear Medicine techs will check with the lab/physician before administering the I131.

LENGTH OF PROCEDURE

30 minutes

PROCEDURE

The patient is counseled by the radiologist prior to the treatment. The radiologist will write a prescription for the amount of Na I131 Rx to be administered. The patient will be given an I131 capsule to swallow. Generally the patient will be placed on Inderal for 2-3 weeks following the treatment.

SPECIFIC INSTRUCTIONS PER RADIOLOGIST

A recent thyroid blood panel including a TSH, history and physical must be obtained for the radiologist before the NaI131 Rx can be ordered for the patient. A recent thyroid uptake and scan is obtained.

FILMING FORMAT

None

SPECIAL EQUIPMENT REQUIRED

NaI131 dose will be ordered per radiologist for the patient and a prescription must be written prior to administering the dose.

EXAM/CHARGE CODES

Mnemonic	Description	Billing Code
TH HYPER*	NUCLEAR THERAPY HYPERTHYROID	9179000
TH ABL*	NUCLEAR THYROID ABLATION	9179030
NMTHY I131	NA I131	9190270

*ONE OR THE OTHER OF THESE EXAMS IS ORDERED