

Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: 7/13/2007

Signature Ronald E Goans MD

Licensee Name Washington University in St. Louis
St. Louis, MO 63110

License No. 24-00167-11

Event No. 43400

Docket No. 030-02271

Facility Name: Barnes-Jewish Hospital (BJH)
Department of Radiation Oncology
One Barnes-Jewish Hospital Plaza
St. Louis, MO 63110
(314)-747-3000

Incident Date: May 29, 2007. Discovered May 31, 2007.

Date of Notification June 1, 2007 telephone report to NRC Operations Center; Written report by Dr. Susan Langhorst submitted June 11, 2007.

Individuals' / Patient Physician Name and Address:

Susan M. Langhorst, PhD, CHP
Radiation Safety Officer
(314)-362-2988

Perry W. Grigsby, MD
Radiation Oncology Department
(314)-362-8502

Individuals Contacted During Investigation:

Susan M. Langhorst, PhD, CHP
Radiation Safety Officer
(314)-362-2988

Perry W. Grigsby, MD
Radiation Oncology
(314)-362-8502

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
3. NRC Preliminary Notification of Event (Event # 43400)
4. NRC Medical Event Reporting and supporting literature
5. June 11 letter from Dr. Langhorst (RSO) to the NRC.
6. Detailed corrective action recommendations by BJH.

Estimated Dose to Unintended Anatomic Region:

This case involves administration of 125.5 mCi I-131 NaCl for thyroid ablation in a 22 year old patient with papillary thyroid cancer. She is subsequently found to be 3-4 weeks pregnant. This presents an unintentional dose of approximately 34 rad to the embryo via MIRD calculations using the method of Russell and Stabin (0.27 rad/mCi). Using the methodology from ICRP Report 53, the dose conversion factor is 5.4 E-02 mGy/MBq. This results in an embryo dose of approximately 250 mGy. Therefore, the best estimate of embryo dose is 25-34 rad. These results are consistent with dose estimates supplied by the BJH health physics staff and by consultants retained by BJH.

Probable Error Associated with Estimation: <25 %. MIRD technique used for early pregnancy. ORNL phantom series.

Prescribed Dose (Medical Misadministration Only):

125 mCi I-131 NaCl.
Calibrated dose 125.5 mCi.

Method Used to Calculate Dose: MIRD technique and results of Russell and Stabin as well as dose coefficients from ICRP Report #53.

Description of Incident and Clinical Details:

The patient is a 22 year old female with a history of papillary thyroid cancer. She had a thyroidectomy on May 2, 2007 and was referred to BJH Radiation Oncology Clinic for I-131 ablation of residual thyroid tissue. The following chronology results:

1. Patient signed consent form May 22, 2007 for the I-131 administration. A quantitative serum β -HCG was negative at that time and the patient signed that she did not believe she was pregnant.
2. 125 mCi I-131 was prescribed for administration, but the patient elected to have the procedure May 29, 2007 in order to rearrange her work schedule.
3. The patient was administered 125.5 mCi I-131 at 10:45 am on May 29, 2007.
4. On May 30, 2007 the patient called the radiation oncology department and said that she had had a positive home pregnancy test. A quantitative serum β -HCG was repeated at BJH, and found to be positive with an estimated gestation age of 4-5 weeks. The patient was referred to the High Risk Obstetrics Clinic.
5. Current pregnancy tests using the beta subunit of human chorionic gonadotropin (HCG) are quite sensitive and have improved dramatically in sensitivity over the last ten years. Typical serum HCG tests are positive 6-18 days after fertilization, which is nominally around day 15 of the cycle. A urine pregnancy test is positive sometimes before a missed menstrual period, but generally positive within 4 days after a missed period.

Assessment of Probable Deterministic Effects of the Radiation Exposure on the Individual:

The traditional health physics literature regarding pre-implantation irradiation describe an all or none effect. However, generally the obstetric literature indicates a transit time of 5-8 days through the fallopian tubes and then implantation in the endometrium. In this case, the embryo was slightly older and likely either in the blastocyst phase and in the process of implantation in the endometrium or in the early post-implantation phase.

Wake and Little (2003) have reviewed the estimates of the risk of childhood cancer per unit dose of radiation received in utero. Data from the Oxford Survey of Childhood Cancers (OSCC) case-control study of fetal exposure to diagnostic X-rays and from the cohort studies of the Japanese survivors of the atomic bombings of Hiroshima and Nagasaki were used, together with associated dose estimates. Excess relative risk and excess absolute risk coefficients were compared, fully taking into consideration the various sources of uncertainty.

The excess relative risk coefficient for childhood (< 15 years of age) cancer obtained from the OSCC yielded an excess absolute risk coefficient for incident cases of about 8%

per Gy of exposure to the fetus. Using these conclusions and an assumed embryo dose of 0.3 Gy, we might expect a maximum risk of childhood cancer of approximately 2%. However, this is likely a very elevated estimate. In addition, these studies represent irradiation during fetal organogenesis, not in the early blastocyst phase that we have in this case.

This case was discussed with three leaders in the field of internal and fetal dosimetry (J. Bushberg; R. Toohey, F. Mettler; 2007; private communication). We all conclude that the most likely situation is delivery of a normal infant with regard to thyroid function because the I-131 was given in the stem cell blastocyst stage. In addition, the fetal thyroid does not take up iodine until 10-11 weeks gestation. However, in order to be medically complete, a complete thyroid evaluation of the infant would be appropriate after delivery.

Briefly describe the current medical condition of the exposed individual:

The patient is doing well and the pregnancy is currently intact. She will receive prenatal care in the BJH High Risk Obstetrics Clinic. A full thyroid work-up will be performed on the newborn.

References

LF Fajardo L-G, M Berthrong, and RE Anderson. *Radiation Pathology*. Oxford Press. 2001.

GH Fletcher. *Textbook of Radiotherapy*. 3rd edition. Lippincott, Williams & Wilkins. 1980.

RE Goans. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In *The Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims*. Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

JR Russell, MG Stabin, RB Sparks, and LF Miller. Radiation Absorbed Dose to the Embryo/Fetus From Nuclear Medicine Procedures. University of Tennessee, Knoxville, Tennessee, and the Oak Ridge Institute for Science and Education, Oak Ridge, TN (RIDIC), 1997.

JR Russell, MG, Stabin, RB Sparks, and E Watson. Radiation Absorbed Dose to the Embryo/Fetus from Radiopharmaceuticals. *Health Phys.* 73(5): 756-69, 1997.

R Wakeford, MP Little. Risk Coefficients for Childhood Cancer after Intrauterine Irradiation: A Review. *Int. J. Radiat. Biol.* 79(5): 293-309, 2003.

J Wallach. *Interpretation of Diagnostic Tests*. Eight Edition. Lippincott Williams & Wilkins. 2007.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

Yes

If yes, would the individual like to be included in the program?

No

COMPLETE FOR MEDICAL MISADMINISTRATION

(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes.

b. Effect on the patient – Yes.

My independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC, once the incident was noted.

d. Improvements needed to prevent recurrence - Yes. This is a human factors issue, correctable by education and improved procedures. The issue was also addressed through the hospital Radiation Safety Committee. Pregnancy tests will be ordered on all women who could potentially be pregnant based on a review of the medical history. In addition, all pertinent clinical issues, including medications, will be documented.

Every pregnancy test has a period in very early gestation where it will be negative until HCG levels reach a critical point. BJH was unlucky here in that the test turned positive over the week from order of the I-131 thyroid ablation until delivery of the treatment. It would have been reasonable to repeat the pregnancy test on May 29, 2007, but there are timing circumstances where that could also have been negative in the face of a very early gestation.

In summary, I believe that actions of BJH were quite reasonable.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patients will be followed clinically by private physicians as indicated. I believe that the hospital system and, specifically the radiation oncology department, will institute an effective program to prevent a recurrence of this event. An NRC Region III inspector has reviewed issues regarding this occurrence at the licensee's facility. The NRC Office of Nuclear Materials Safety and Safeguards has also been notified. The information in the preliminary notification has also been reviewed with licensee management.

VOUCHER FOR PROFESSIONAL SERVICES

INSTRUCTIONS

This form shall be completed by all NRC consultants for claiming compensation for official authorized personnel services. A signed original and two copies shall be submitted to the NRC office authorizing the service.

| | | | | | |
|--|-------------|-------------------|--|---------------------|------------------------|
| TO: U. S. Nuclear Regulatory Commission | | | FROM: NAME OF CLAIMANT Ronald E Goans, MD | | |
| ATTENTION: NRC OFFICE AUTHORIZING THIS SERVICE Geoffrey M. Warren US NRC Region III | | | STREET ADDRESS [REDACTED] | | |
| CITY Lisle | STATE IL | ZIP CODE 60532 | CITY [REDACTED] | STATE [REDACTED] | ZIP CODE [REDACTED] |

| | |
|-----------------------------|--|
| I-131 case Washington Univ. | DESCRIPTION OF CLAIM (All blocks must be completed) |
|-----------------------------|--|

| | | | | |
|---|----------------------|----------------------|----------------|-------|
| CONTRACT: # AT-(49-24) | NUMBER | DATE | AMOUNT CLAIMED | |
| PERIOD COVERED (Dates) | FROM | TO | DOLLARS | CENTS |
| SERVICES PERFORMED: (Itemize on reverse) | NUMBER OF DAYS | PER DAY \$ | 537 | 76 |
| | NUMBER OF HOURS 8 | PER HOUR \$ 67.22 | | |
| RETIRED ANNUITANT: <input type="checkbox"/> YES <input type="checkbox"/> NO | TOTAL AMOUNT CLAIMED | | 537 | 76 |

| | | | |
|---|---|-----------|------|
| CERTIFICATION I CERTIFY that the above account is accurate and true in all respects; that my statement of services correctly sets forth the services on official business; that the payment therefor has not been received; and that no compensation for any of the time shown above is payable from or will be claimed from any other source of the Federal Government or its cost-reimbursable contractors. | OFFICE OF THE CHIEF FINANCIAL OFFICER USE ONLY | | |
| | DIFFERENCE | | |
| | AMOUNT VERIFIED CORRECT | | |
| SIGNATURE - CLAIMANT [REDACTED] | DATE 2/18/2007 | SIGNATURE | DATE |

| | |
|---|--|
| APPROVAL I CERTIFY that the above claim is accurate; that the above services were officially requested and performed; and that the expenses claimed are authorized. | METHOD OF PAYMENT (Claimant - Check one block) The Government Management Reform Act of 1994 requires agencies to use Direct Deposit via Electronic Funds Transfer as the method for making recurring Federal wage and salary payments. <input type="checkbox"/> DIRECT DEPOSIT FORM SF 1198A ATTACHED <input checked="" type="checkbox"/> DIRECT DEPOSIT FORM PREVIOUSLY SUBMITTED <input type="checkbox"/> TREASURY CHECK (For one-time payments only) |
| | |

[illegible]

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1. **AUTHORITY:** Pub. L. 104-193, Personal Responsibility and Work Opportunity Reconciliation Act of 1996; 5 U.S.C. 8334; 31 U.S.C. 716, 1104, 1108, 1114, 3325, 3511, 3512, 3701, 3711, 3717, 3718; Executive Order 9397.
2. **PRINCIPAL PURPOSE(S):** To claim compensation for official authorized personnel services rendered by government consultants.
3. **ROUTINE USES:** Information on this form is used for transmittal to the U.S. Treasury for payment. It may also be disclosed to the IRS, State and local taxing authorities, Social Security Administration, labor unions, insurance carriers, OPM, charitable institutions concerning any authorized withholdings or deductions, Office of Child Support Enforcement, and NARA. Data may also be used in various management records and reports and for identifying reimbursable and fee billable work performed. Information may be disclosed to an appropriate Federal, State, local or Foreign agency in the event the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, local and Foreign agency to the extent relevant and necessary for an NRC decision about you or to the extent relevant and necessary for that agency's decision about you. Information from this form may also be disclosed, in the course of discovery under a protective order issued by a court of competent jurisdiction, and in presenting evidence, to a Congressional office to respond to their inquiry made at your request, or to NRC-paid experts, consultants, and others under contract with the NRC, on a need-to-know basis.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** It is voluntary that you furnish the requested information, however, failure to supply the information may result in the delay in the processing or denial of your claim for compensation.
5. **SYSTEM MANAGER AND ADDRESS:** Chief, Time, Labor and Payroll Services Team, Division of Financial Services, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

RONALD E. GOANS, M.D.



FIRST CLASS MAIL

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