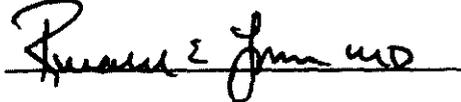


**Medical Consultant Report**  
(To be completed by medical consultant)

**Medical Consultant Name:** Ronald E. Goans, PhD, MD, MPH  
**Report Date:** 5/02/2005

**Signature** 

**Licensee Name** St. Joseph Regional Medical Center-South Bend (SJRMC-SB)  
801 East LaSalle Avenue.  
South Bend, IN 46617

**License No.** 13-02650-02  
**Event No.** 41532  
**PNO-III-05-006**

**Facility Name:** Radiation Oncology Department  
St. Joseph Regional Medical Center-South Bend  
801 East LaSalle Avenue.  
South Bend, IN 46617

**Patient ID Number:** Patient 1 ; patient 2 ; patient 3 , patient 4   
patient 5 

**Incident Date:** Patient 1 (1-26-04); patient 2 (2-18-04); patient 3 (2-23-04); patient 4 (3-1-04); patient 5 (3-19-04).

**Date of Notification** For patients 1-5; NRC notification of events to the Nuclear Regulatory Commission on 4-06-2005.

**Individuals' / Patient Physician Name and Address:**

Jon Frazier, MD, Radiology Oncology  
  
(574) 237-8000

John D. Sheu, PhD, RSO  
(574) 287-4146  
(574) 237-7287

Nate Davis, MS, Medical Physicist  
(574) 237-5711

**Individuals Contacted During Investigation:**

Gary Pereko, President, SJRMC-South Bend  
[REDACTED]

Jon Frazier, MD, Radiology Oncology  
(574) 237-8000

John D. Scheu, PhD, RSO  
(574) 287-4146  
(574) 237-7287

Nate Davis, MS, Medical Physicist  
(574) 237-8000

**Records Reviewed: (General Description)**

1. Personal visit to SJRMC-SB and medical records review (5 patients)
2. NRC Enclosure - Description of the Medical Event
3. NRC Preliminary Notification of Event (Event # 41532)
4. NRC Medical Event Reporting and supporting literature
5. NRC Conversation Record
6. Detailed review of patient records
7. SJRMC-SM memo (Nate Davis, Medical Physicist) on methodology for dose estimation to skin.
8. SJRMC-SB QMP Annual Training Outline
9. Minutes, Radiation Safety Committee of May 19, 2004

**Estimated Dose to Unattended Anatomic Region:**

Patient 1 – Dose to thigh < 300 cGy

Patient 2 – Dose to thigh < 300 cGy

Patient 3 – Dose to thigh 1800 cGy < D < 2200 cGy ( $\pm 25\%$ , clinical determination)

Patient 4 – Dose to thigh 1500 cGy < D < 2000 cGy ( $\pm 25\%$ , clinical determination; decreased dose estimate due to Cisplatinum simultaneously administered.)

Patient 5 – Dose to thigh 1800 cGy < D < 2200 cGy ( $\pm 25\%$ , clinical determination)

**Probable Error Associated with Estimation: ~25 %.**

**Prescribed Dose (Medical Misadministration Only):**

Patient 1 – Prescribed Dose: vagina 7000 cGy (4500 cGy external and 2500 cGy brachytherapy boost). In spite of the source slippage during the brachytherapy treatment, the dose to the vaginal cuff is thought to be within 20% of the intended dose. Since there are no physical signs and symptoms from unintentional irradiation to the patient thigh, the time the source was out of position was likely minimal.

**Patient 2 - Prescribed Dose: 65 Gy intracavitary vaginal brachytherapy (64 x 100 cGy/h). The medical chart was reviewed and the patient experienced no signs and symptoms of radiation injury to the thigh or perineum. I feel the actual dose to the vaginal mucosa is likely within 20% of the prescribed dose.**

**Patient 3 – 5040 cGy (4500 cGy whole pelvis 18 MeV photon; 540 cGy pelvic boost) + 2850 cGy vaginal boost (total 7350 cGy). Patient 3 did experience unintended local radiation injury to the thigh due to source slippage, but I believe the actual dose to the vaginal mucosa was within 20% of the prescribed dose.**

**Patient 4– Whole pelvis 45 Gy with 18 MeV photons, cone down to limited pelvic field 540 cGy = 5040 cGy; vagina 4500 cGy external beam = 2850 cGy to vaginal surface – 7350 cGy to vaginal mucosa. Patient 4 experienced local radiation injury to the thigh due to source slippage during brachytherapy, but I believe the actual dose to the vaginal mucosa is within 20% of the prescribed dose.**

**Patient 5– 6500 cGy Cs-137 at 100 cGy/h. Patient 5 experienced local radiation injury (moist desquamation) to the thigh due to source slippage during brachytherapy, but I believe the actual dose to the vaginal mucosa is within 20% of the prescribed dose.**

**Method Used to Calculate Dose: Time course of clinical symptoms, radiation medicine clinical dose profile and physical dosimetry.**

#### **Description of Incident:**

**The St. Joseph Regional Medical Center – South Bend (SJRMC-SB) reported to the NRC in March 2005 that several patients had received unintended radiation exposure to the upper thigh and perineum during treatment for endometrial and cervical cancer. The unintended exposures occurred when the sealed brachytherapy capsule shifted during treatment, resulting in a radiation dose to the skin of the patient's thigh in excess of that expected for the prescribed brachytherapy regimen. The medical center has notified the patients and their physicians of the treatment problems. An NRC physician consultant visit to SJRMC-SB was made April 4-5 to examine patient charts and to interview staff of the Radiation Oncology Center.**

**The unintended radiation event is thought to have occurred because the Wang applicator was loaded with Cs-137 brachytherapy sources manufactured by Amersham Corporation, having a smaller diameter (2.6 mm vs. 3.1 mm) than sources manufactured by 3M and recommended for use with the Wang applicator. The smaller diameter sources have the ability to slide out of the intended treatment position through the placement spring of the tandem assembly, particularly when the patient is in an upright position. Therefore it is possible to have unintentional irradiation of the patient thigh.**

**This issue was addressed and corrective action recommended in the minutes of the Radiation Safety Committee meeting dated May 19, 2004. This same report of May 19,**

2004 also erroneously notes that these adverse events do not rise to reporting thresholds for the NRC. Appendix 1 illustrates representative skin lesions on the thigh for patients 3, 4 and 5 in 2004 and in 2005. Patients 1 and 2 had no observable lesions.

### **Clinical Details (See Appendix 1 for clinical pictures)**

#### **Patient 1**

Patient 1 [REDACTED] has a diagnosis of grade II infiltrating adenocarcinoma of the uterus (T1C N0 M0; s/p TAH/BSO) with invasion to 78.6% of the myometrial thickness. She received 4500 cGy external beam therapy at 180 cGy/fraction and intracavity boost with Cs-137 (49.09 radium equivalent; 1301 mg-h). Total vaginal dose is approximately 7000 cGy (4500 cGy external, 2500 cGy brachytherapy boost).

There appears to be no significant signs of radiation damage to the thigh and perineum due to the source slippage.

#### **Patient 2**

Patient 2 [REDACTED] has a diagnosis of endometrial cancer, stage IC (T1C, N0, M0, G1), s/p modified radical TAH. Uterine pathology showed cancer invasion to 70% of the myometrium. The patient received intracavitary vaginal brachytherapy with Cs-137 to 65 Gy at 100 cGy/h. This is equivalent to 3562 mg-h radium equivalent.

There appears to be no significant signs of radiation damage to the thigh and perineum due to the source slippage.

#### **Patient 3**

Patient 3 [REDACTED] has a diagnosis of moderately differentiated adenocarcinoma of the endometrium and s/p modified radical TAH/BSO with involvement at pathological examination of the endocervical stroma (T2b, N0, M0, G2). In particular, at pathology examination, the posterior lower uterine segment and upper endocervical canal were noted to be involved. By staining techniques, the cancer was noted to be of uterine (endometrial) origin. The patient received whole pelvic irradiation with 18 MeV photons to 4500 cGy with a limited pelvic boost of 540 cGy for a limited pelvic field of 5040 cGy. In addition, a vaginal boost of 2850 cGy at 100 cGy/h was given. The total vaginal dose is therefore 4500 cGy + 2850 cGy = 7350 cGy to the vaginal mucosa. During therapy, she was also treated for radiation proctitis.

Patient 3 did show delayed effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1800 and 2200 cGy with at least an uncertainty of  $\pm 25\%$ . Patient [REDACTED] has been referred to a plastic and reconstructive surgeon [REDACTED] at Memorial Hospital in South Bend for wound care and debridement of necrotic tissue. The wound is healing well with the formation of granulation tissue.

#### **Patient 4**

Patient 4 [REDACTED] has the clinical diagnosis of Stage IB2 endocervical adenocarcinoma, but pathological state III. She had a large exophytic mass arising from the uterus with extensive disease also to the parametrium. There is also metastatic disease to the external iliac and pelvic nodes. The patient received whole pelvic irradiation concurrent with Cisplatin chemotherapy. External beam radiotherapy to 45 Gy whole pelvis with 18 MeV photons was carried out along with 2850 cGy to the vaginal mucosa.

Patient 4 showed delayed moist desquamation effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1500 and 2000 cGy with at least an uncertainty of  $\pm 25\%$ . The wound is healing well with the formation of granulation tissue.

#### **Patient 5**

Patient 5 [REDACTED] has a diagnosis of poorly differentiated adenocarcinoma of the endometrium with superficial invasion (T1b, N0, M0, G3) of the myometrium. She is s/p extrafascial TAH/BSO and bilateral lymphadenectomy and s/p bilateral periaortic lymph node sampling. Pathology of the uterus indicates 0.2 cm invasion of the myometrial wall. The patient also received intracavity brachytherapy with Cs-137 to 6500 cGy at 100 cGy/h.

Patient 5 showed delayed moist desquamation effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1800 and 2200 cGy with at least an uncertainty of  $\pm 25\%$ . She has been referred to the Wound Center at St. Joseph Regional Medical Center-Michiwaka [REDACTED]

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

Patients 1 and 2 as described above showed no deterministic skin effects. Patients 3, 4 and 5 showed moist desquamation of the skin and late effects due to skin breakdown.

Acute local irradiation events to the skin occur with deterministic thresholds as follows for certain clinical signs:

- (1) 300 cGy threshold for epilation, beginning 14-21 days post-accident.
- (2) 600 cGy for erythema, soon post-accident, and possibly again 14-21 days thereafter. The pathophysiology for erythema includes arteriolar constriction with capillary dilation and local edema. Erythema may occur in a few hours post-accident (primary erythema) or come and go in waves. Secondary erythema occurs 14-21 days post-accident.
- (3) 1000-1500 cGy for dry desquamation of the skin secondary to radiation to the germinal layer. Dry desquamation results from response of the germinal epidermal layer to

radiation. There is diminished mitotic activity in cells of the basal and parabasal layers with thinning of the epidermis and desquamation of large macroscopic flakes of skin.

- (4) 2000-5000 cGy for wet desquamation (partial thickness injury) at least 2-3 weeks post-exposure, depending upon dose. In moist desquamation, microscopically, one finds intracellular edema, coalescence of vesicles to form macroscopic bullae, and a wet dermal surface, coated by fibrin.
- (5) For dose  $\gg$  5000 cGy, overt radionecrosis and ulceration secondary to endothelial cell damage and fibronoid necrosis of the arterioles and venules in the affected area.

It is likely that patients 3, 4 and 5 received unintended dose to the thigh of between 1500-2200 cGy, with at least an uncertainty of  $\pm$  25%.

**Briefly describe the current medical condition of the exposed individual:**

Patient 3 did show delayed effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1800 and 2200 cGy. Patient [REDACTED] has been referred to a plastic and reconstructive surgeon [REDACTED] at Memorial Hospital for wound care and debridement. The wound is healing well with the formation of granulation tissue.

Patient 4 showed delayed moist desquamation effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1500 and 2000 cGy, a somewhat decreased dose due to simultaneous administration of Cisplatin. The wound is healing well with the formation of granulation tissue.

Patient 5 showed delayed moist desquamation effects to the thigh, due to Cs-137 source slippage. The estimated dose from physical signs and symptoms is estimated to be between 1800 and 2200 cGy. She has been referred to the Wound Center at St. Joseph Regional medical Center-Michiwaka [REDACTED]

**References**

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

GH Fletcher. *Textbook of Radiotherapy*. 3<sup>rd</sup> 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.

**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.

Staff at SJRMC-SB indicated to me that they misinterpreted the reporting requirements as noted in 10 CFR 35.3045. Details of these adverse events were known by oncology staff by the Radiation Safety Committee meeting of May 19, 2004. It would have been highly desirable to have reported to the NRC prior to this date.

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 delayed reporting of the event to the NRC.

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.

**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.

**Appendix 1 (Clinical Pictures)**

**Patient 3**  
**April 15<sup>th</sup>, 2004**

Photograph deleted  
to protect patient's  
personal privacy

**April 15, 2005**

Photograph deleted  
to protect patient's  
personal privacy

**Patient 4**  
**April 15<sup>th</sup>, 2004**

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Photograph deleted  
to protect patient's  
personal privacy

**March 21, 2005**

Photograph deleted  
to protect patient's  
personal privacy

**Patient 5**  
**April 26, 2004**

Photograph deleted  
to protect patient's  
personal privacy

**April 5, 2005**

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Photograph deleted  
to protect patient's  
personal privacy