



SAINT JOSEPH  
Regional Medical Center  
South Bend

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South Bend, Indiana 46617  
574.237.7111  
[www.sjmed.com](http://www.sjmed.com)

4-6-05

Department of Inspections  
United States Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, STE 210  
Lisle, IL 60532-4352

RE: Medical Event Report. Saint Joseph Regional Medical Center South Bend, South Bend, Indiana, NRC license number: 13-02650-02.

Dear Sir/Madam:

The following report of a medical event is provided in accordance with 10 CFR 35.3045 (d) and following telephone notification to the NRC Operations Center on 3-28-05. The patient identification used was A.M. and the dates of the medical event occurrence were 2-23-04 to 2-24-04. The prescribing physician was Jon Frazier, M.D., Radiation Oncologist.

During treatment for adenocarcinoma of the endometrium using a Wang front loading vaginal applicator loaded with Cs-137 sources the patient received an unintended radiation exposure dose to the skin of the inner thighs. The medical event resulted when the patient received a dose to the skin other than the treatment site that exceeds 0.5 Sv (50 Rem) and is 50 per cent or more of the dose expected from the administration defined in the written directive (35.3045 (a) (3)).

This medical event occurred because the Wang applicator tandem was loaded with Cs-137 sources manufactured by the Amersham Corporation which have a smaller diameter than the sources manufactured by 3M which are recommended for use by the Wang applicator manufacturer. Also, the physicist loading the sources did not know that the storage safe for radioactive sources contained both Amersham and 3M sources. The smaller diameter sources had the ability to slide out of the intended treatment position through the placement spring of the flexible tandem source assembly provided with the Wang applicator. When the patient would sit in a more upright position the sources would slide out of position irradiating the skin of the patient's inner thighs.

APR 12 2005

The patient received external beam radiation treatments to the pelvis to a total dose of 5,040 cGy and finished on 3-1-04. Over two weeks she developed moist desquamation over the perineum and buttocks which was felt to be from external beam radiation treatments and/or the wearing of radiation implant briefs. The patient had moist desquamation of the skin of the inner thighs when seen on 4-6-04 by her referring physician. Follow-up on 4-15-04 showed an area of moist desquamation which was felt to be from unintended radiation exposure from the sources in the tandem of the Wang applicator. The skin healed over the next few months. On follow-up on 2-15-05 the patient had developed a 1.5 cm by 1.0 cm ulcer of the left inner thigh in the area of the scarring from the previous radiation exposure.

In April 2004, immediately following the discovery that skin reactions to the inner thighs of patients were the result of improper use of the Wang applicator, corrective action was taken. The action taken was to discontinue the use of the flexible tandem source carrier assembly provided by the Wang applicator manufacturer and replace it with a clear plastic tandem carrier with pushers. This then would accommodate sources of both sizes and prevent them from moving during the treatment period. The long term corrective action is to educate physicians, medical physicists, and dosimetrists in the use of the Wang front loader applicator. The radiation oncology staff will, also, be made aware that both Amersham and 3M sources are in the storage safe.

The patient's physician was informed 4-14-04 of the unintended exposure. The situation was discussed with the patient on follow-up. The patient and her physician have been notified on 4-6-05 that the unintended radiation exposure is now considered a medical event and has been reported to the NRC.

Yours truly,

A handwritten signature in black ink that reads "John D. Scheu". The signature is written in a cursive style with a large initial "J".

John D. Scheu, Ph.D.  
Radiation Safety Officer



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RE: Medical Event Report. Saint Joseph Regional Medical Center South Bend, South Bend, Indiana, NRC license number: 13-02650-02.

Dear Sir/Madam:

The following report of a medical event is provided in accordance with 10 CFR 35.3045 (d) and following telephone notification to the NRC Operations Center on 3-28-05. The patient identification used was R.M. and the dates of the medical event occurrence were 3-1-04 to 3-2-04. The prescribing physician was Jon Frazier, M.D., Radiation Oncologist.

During treatment for adenocarcinoma of the Cervix using a Wang front loading vaginal applicator loaded with Cs-137 sources the patient received an unintended radiation exposure dose to the skin of the inner thigh. The medical event resulted when the patient received a dose to the skin other than the treatment site that exceeds 0.5 Sv (50 Rem) and is 50 per cent or more of the dose expected from the administration defined in the written directive (35.3045 (a) (3)).

This medical event occurred because the Wang applicator tandem was loaded with Cs-137 sources manufactured by the Amersham Corporation which have a smaller diameter than the sources manufactured by 3M which are recommended for use by the Wang applicator manufacturer. Also, the physicist loading the sources did not know that the storage safe for radioactive sources contained both Amersham and 3M sources. The smaller diameter sources had the ability to slide out of the intended treatment position through the placement spring of the flexible tandem source assembly provided with the Wang applicator. When the patient would sit in a more upright position the sources would slide out of position irradiating the skin of the patient's inner thigh.

The patient finished external beam radiation treatments to the pelvis with cisplatin chemotherapy on 3-8-04 to a total dose of 5,040 cGy. In mid March the patient developed a sore on the left inner thigh felt to be from the radiation implant briefs. On follow-up exam on April 15, 2004 the sore was felt to be an area of moist desquamation from unintended radiation from sources in the tandem of the Wang applicator.

In April 2004, immediately following the discovery that skin reactions to the inner thighs of patients were the result of improper use of the Wang applicator, corrective action was taken. The action taken was to discontinue the use of the flexible tandem source carrier assembly provided by the Wang applicator manufacturer and replace it with a clear plastic tandem carrier with pushers. This then would accommodate sources of both sizes and prevent them from moving during the treatment period. The long term corrective action is to educate physicians, medical physicists, and dosimetrists in the use of the Wang front loader applicator. The radiation oncology staff will, also, be made aware that both Amersham and 3M sources are in the storage safe.

The patient's physician was informed on 4-14-04 of the unintended exposure. The situation was discussed with the patient at the time of follow-up. The patient and her physician have been notified on 4-6-05 that the unintended exposure is now considered a medical event and has been reported to the NRC.

Yours truly,

A handwritten signature in black ink that reads "John D. Scheu". The signature is written in a cursive style with a large initial "J".

John D. Scheu, Ph.D.  
Radiation Safety Officer

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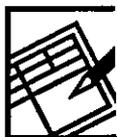


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