SAINT JOSEPH
Regional Medical Center
South Bend

801 East LaSalle Avenue
South Bend, Indiana 46617
574.237.7111
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 possible medical event is provided in accordance with 10 CFR 35.3045 (d) and following telephone notification to the NRC Operations Center on 4-5-05. The patient identification used was D.T. and the dates of the possible medical event occurrence were 1-26-04 to 1-27-04. 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 may have received an unintended radiation exposure dose to the skin of the inner thighs. The potential of a medical event resulted when the patient may have received a dose to the skin other than the treatment site that exceeds 0.5 Sv (50 Rem) as described in 35.3045 (a) (3).

This potential medical event may have 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 may have slid out of position irradiating the skin of the patient's inner thighs.

On subsequent examinations of this patient, no skin desquamation, breakdown or even erythema was noted. The patient denied seeing any skin redness in the upper inner thigh area, nor was she ever aware of itching, burning or other signs of irritation in this area.

In April 2004, immediately following the discovery that the skin reactions to the inner thighs of other patients were the result of improper use of the Wang applicator, correction 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 has been notified on 4-6-05 that a possible unintended radiation exposure had taken place and that it has been reported to the NRC as a potential medial event. The patient was not available by telephone, so a letter has been sent to notify her of the possible unintended radiation exposure to her inner thighs, and that it has been reported to the NRC as a potential medical event.

Yours truly,

John D. Scheu

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

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Dear Sir/Madam:

The following report of a possible medical event is provided in accordance with 10 CFR 35.3045 (d) and following telephone notification to the NRC Operations Center on 4-5-05. The patient identification used was M.S. and the dates of the possible medical event occurrence were 2-18-04 to 2-21-04. The prescribing physician was Steven Gregoritch , 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 may have received an unintended radiation exposure dose to the skin of the inner thighs. The potential of a medical event resulted when the patient may have received a dose to the skin other than the treatment site that exceeds 0.5 Sv (50 Rem) as described in 35.3045 (a) (3).

This potential medical event may have 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 may have slid out of position irradiating the skin of the patient's inner thighs.

On subsequent examinations of this patient, no skin desquamation, breakdown or even erythema was noted. The patient denied ever seeing any skin redness in the upper inner thigh area, nor was she ever aware of itching, burning, or other signs of irritation in this area.

In April 2004, immediately following the discovery that skin reactions to the inner thighs of other 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 and her physician have been notified on 4-6-05 that a possible unintended radiation exposure had taken place to her inner thighs and that it has been reported to the NRC as a potential medial event.

Yours truly,

John D. Scheu

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

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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 4-1-05. The patient identification used was K.B. and the dates of the medical event occurrence were 3-19-04 to 3-22-04. 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.

In the first two week of April 2004 the patient developed areas of moist desquamation of skin of the inner thighs. Initially this was felt to be from radiation implant briefs. On follow-up on 4-26-04 the areas of moist desquamation had increased in size over both inner thighs. Over the next few months the skin healed. On 4-15-05 follow-up she has a 1 cm superficial ulcer of the left inner thigh over the area of prior scar from prior radiation exposure.

In April 2004, immediately following the discovery that the 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 and her physician have been notified on 4-6-05 that unintended radiation exposure had taken place to her inner thighs and that it has been reported to the NRC as a medical event.

Yours truly,

John D. Scheu

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

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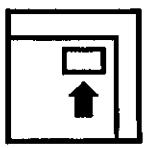

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