HENRY FORD MACOMB HOSPITALS

15855 Nineteen Mile Road
Clinton Township, Michigan 48038
(586) 263-2300

December 23, 2010

Ms. Tamara Bloomer
Chief, Materials Inspection Branch
Mr. Kenneth Lambert
Health Physicist
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Ms. Bloomer and Mr. Lambert:

As required under 10 CFR 35.30345, this correspondence is provided as written notification within 15 days after discovery of a medical event as defined in 10 CFR 35.3045 (a)(1)(i). This medical event was discovered and reported on December 10, 2010. The event number assigned by the NRC is 46472.

(i) Licensee Name
Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038
License No. – 21-11850-01
Docket No. – 030-02106

(ii) Prescribing Physician's
Dr. Jandranka Dragovic (2 patients)
Dr. Ibrahim Aref (2 patients)

(iii) Description of the event
Thursday, December 9th at approximately 4 pm, one of our attending radiation oncology physicians approached and notified me (Brett Miller, M.S., radiation physicist) that she had just recognized that there were two patients with skin reddening on their inner thighs. Both patients were treated with a vaginal cylinder. After arriving at work on Friday, December 10, I went to the therapist who treated the patients and asked for the transfer guide tube used to treat the patients. I took the guide tube, connected it to the flexible probe used to treat the patient and measured the length of that system. I recorded a measurement of 133.4 cm which would

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correspond to a treatment length of 132 cm. I then went to the first patient's medical record and noted the treatment length, which was 120 cm. At this point a 12 cm length difference was noted between the treatment length and treatment planning length. I then looked at the medical records of the second patient who had developed a skin reaction and noted the patient had the same length difference. This activity was completed by the morning of Friday, December 10. I immediately contacted both attending physicians (Drs. Aref and Dragovic), the radiation safety officer (RSO) and the Radiation Oncology and Radiology management team at HFHS main campus. After reviewing the medical records of his cylinder patients, Dr. Aref found a third patient who had some skin reddening on her inner thighs. After reviewing that patient's chart, I saw the same 12 cm length difference as was found with the first two patients. I then placed a phone call to the NRC at 2:57 pm on December 10, 2010 to report this medical event.

Following the phone call, I immediately began a thorough review of all vaginal cylinder patients treated since the inception of the HDR program at the HF-Macomb department of radiation oncology, which began on February 5, 2007. This activity was completed on Tuesday, December 14, 2010. I noted there was one additional patient treated in June 2010, who was also found to have a 12 cm length discrepancy. [Note that at this time (December 14, 2010), the NRC inspectors (Ms. Bloom and Mr. Lambert) were at our site reviewing the event reported on December 10. We informed them that there was a possible fourth patient, which was confirmed on Wednesday, December 14, 2010 at 3:30 pm.] Per the suggestion of the NRC inspectors, I then made a second call to the NRC to report the medical event regarding the fourth patient at 4:10 pm on December 15, 2010.

(iv) Information on patient and referring physician communication

Dr. Jadranka Dragovic, M.D., one of the attending radiation oncology physicians, has provided written attestation that she notified patient 1 within 24 hours of reporting the event to the NRC. Of note, patient 1 was self-referred to Dr. Dragovic and did not have a referring physician of record. She attempted to notify patient 2 within 24 hours of these events being reported to the NRC but was not able to reach the patient and left messages asking her to call back as soon as possible. A certified letter was sent to patient 2 on December, 22, 2010 informing her of the medical event. Dr. Dragovic has provided written attestation that she contacted the referring physician for patient 2 within 24 hours of reporting the event to the NRC.

Dr. Ibrahim Aref, M.D., one of the attending radiation oncology physicians, has provided written attestation that he contacted the two referring physicians for patients 3 and 4 within 24 hours of these events being reported to the NRC. He attempted to notify patient 3 within 24 hours but was not able to reach the patient and asked her to call back as soon as possible.

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Patient 3 called the department on Monday, December 20, 2010 and scheduled an appointment to be seen on Thursday, December 23, 2010. She was seen by the physician on Thursday, December 23, 2010. Patient 4 was notified within 24 hours of reporting of the event to the NRC.

(v) Retrospective review of all patients treated in the HDR program

A detailed retrospective review of all patients treated with HDR brachytherapy since the inception of the program was completed on the evening of Friday, December 17, 2010. The table below includes details of the different patient applications:

Applicator	*Total no. of Patients Treated*
Bronchial	9
Contura	20
Mammosite	10
Cylinder	19
Miami	3
Prostate	33
Ring and Tandem	6
Cylinder and Tandem	2

Other than the 4 patients reported, since the inception of the HDR program, no other patient treatment was found to have a discrepancy between the measured length and the treatment length.

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(vi) Treatment timelines and dose information related to the medical events

Patient Number	Fraction No.	Date Treated	*Prescription Dose (Gy)*
1	1	10/25/10	7
	2	10/27/10	7
	3	10/29/10	7
2	1	8/25/10	7
	2	8/27/10	7
	3	8/30/10	7
3	1	7/28/10	6
	2	7/30/10	6
	3	8/2/10	6
4	1	7/7/10	6
	2	7/9/10	6
	3	7/12/10	6
	4	7/14/10	6
	5	7/16/10	6

(vii) **The effect, if any, on the individuals who received the administration**

We have calculated or estimated the superficial dose and deep dose equivalent to each of the four patients. The superficial doses ranged from 270 – 450 rad and the deep dose ranged from 180 – 250 rad. No permanent biological or physical adverse effects are expected as a result of this administration. These doses were estimated from the treatment planning system using anatomical information available on the 3-D CT simulation scan.

Patient Number	Superficial Dose (rad or cGy)	Deep dose (rad or cGy)	*Physical effect observed*
*1	300	240	skin erythema
2	270	210	skin erythema
3	330	180	no effect observed
4	450	250	skin erythema

* For patient 1 not all the CT slices were available, however, the inferior treatment plan cuts were estimated based on the geometry of a similar patient.

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(viii) Clinical patient information and management plan regarding patient care

Patient #1
85 y/o Caucasian woman with T3NxMx endometrial carcinoma s/p inadequate surgical staging with laparoscopically assisted vaginal hysterectomy and BSO. Of note, surgical lymph node sampling/dissection was not done due to the patient's age and underlying condition. The patient then received adjuvant radiation therapy with external beam RT (EBRT) to the pelvis (which included the vaginal apex), 45 Gy in 25 fractions, followed by HDR brachytherapy (21 Gy in 3 fractions from 9/13/2010 through 10/29/2010). When the patient was seen for follow-up on 12/9/2010, it was noted on the pelvic exam that she had two strips of skin erythema with patchy moist desquamation on her upper inner thighs. This led the radiation oncologist to recognize that this might be a radiation effect, at which time this was immediately communicated with the radiation physicist for further evaluation, as above.

Within 6 weeks of completion of treatment, there was evidence of progression of disease with new pulmonary nodules and enlarged para-aortic lymph nodes, but no vaginal vault recurrence. As noted, the patient did not have full surgical staging (due to her co-morbidities and age) and may have had more advanced disease at presentation. The plan, as discussed by at team of radiation oncologists, is not to treat with vaginal brachytherapy at this time, as the patient is progressing systemically and thus local therapy would not be beneficial. The patient has been referred to medical oncology regarding systemic therapy options.

Patient #2
66 y/o Caucasian woman with FIGO stage IIIA clear cell adenocarcinoma of the endometrium (positive pelvic cytology), s/p TAHBSO/pelvic lymph node sampling. Based on the patient's histology and stage, the greatest risk for recurrence is abdominal (peritoneal) and/or systemic relapse. The patient received 3 cycles of platinum-based adjuvant chemotherapy, followed by adjuvant radiation therapy in July and August of 2010. This involved external beam RT (EBRT) to the pelvis, 45 Gy in 25 fractions (7/19/2010 through 8/20/2010), followed by HDR brachytherapy, 21 Gy in 3 fractions (on 8/25, 8/27 and 8/31/2010). Of note, the EBRT included the vaginal apex. Three additional chemotherapy cycles were given thereafter. The plan at this time, as discussed by at team of radiation oncologists, is to offer patient the intended HDR vaginal brachytherapy.

This patient had been seen by the medical oncologist (Dr. Henderson) in mid-September who noted that patient had "contact dermatitis (erythema with some central discoloration) in

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inner upper thighs". When the patient was seen for radiation oncology follow up visit in early November, no skin abnormality was noted. Based on seeing the skin reaction in patient #1 (above), the radiation oncologist recognized at that time that patient #2 had a similar history, and notified the physicist for further evaluation. The identification of patients #3 and #4 is described above.

Patient #3
56 y/o Caucasian woman with T1cN0M0 adenocarcinoma of the endometrium, grade 3, s/p TAH/BSO on 05/13/2010. She then received EBRT to the pelvis (45 Gy in 25 fractions), including the vaginal apex, from 06/16/2010 to 07/21/2010. This was followed by HDR brachytherapy (18 Gy in 3 fractions) between 07/28/2010 and 08/10/2010. The patient was seen in the clinic on 09/29/2010 and had no evidence of recurrent disease. The plan at this time, as discussed by a team of radiation oncologists, is not to offer her further treatment. The patient was seen in the radiation oncology clinic on 12/23/10. She indicated that, about 2 weeks after the brachytherapy, she had transient mild skin irritation of the inner thighs, which resolved. She was seen by her gynecologist on 12/22/10 and there was no evidence of recurrent disease. The patient will be seen for followup in 3 months, or sooner as needed.

Patient #4
87 y/o Caucasian woman with T1bN0M0 endometrial adenocarcinoma, grade 2, treated with TAH/BSO on 04/27/2010. She then received HDR brachytherapy (30 Gy in 5 fractions) in the interval between 07/07/2010 and 07/16/2010. She noted a skin reaction in her inner thighs in mid August for which she used Neosporin cream. She was seen in the radiation oncology clinic on 09/16/2010, by which time her skin reaction had resolved. The plan at this time, as discussed by a team of radiation oncologist, is to offer the patient the intended HDR vaginal brachytherapy. The patient indicated she was feeling well but opted not to come back to the clinic at this time (based on her schedule); she agreed to come back for a follow visit on Jan. 11, 2011. Dr. Aref further reviewed the information with her regarding this incident and discussed the above recommendation, but the patient declined further treatment at this time.

(ix) Why the event occurred

A detailed root cause analysis of the event was performed and the following factors were determined to be related to the cause.

1. The standard measured length for vaginal cylinder treatments is 121.4. cm which would correspond to a treatment length of 120.0 cm. During the time of simulation, the

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therapist selected a transfer tube that resulted in a measured length of 133.4 cm from a container which was ambiguously labeled. The container was labeled "Miami Applicator/Cylinder" and the therapist selected this container based on the name "cylinder" on the label. The therapist correctly recorded a measured treatment length of 133.4 cm on the CT simulation setup sheet based on the Miami applicator transfer tube they selected.

2. The dosimetrist, knowing this was a vaginal cylinder, which typically uses a treatment planning length of 120.0 cm, planned the treatment for a catheter length of 120.0 cm.
3. The physicist, in performing a second check of the treatment plan (standard procedure check), assumed the standard treatment planning length of 120.0 cm should be used in the plan and did not verify the length on the CT simulation setup sheet against the treatment plan length.
4. Immediately prior to treatment, during the "Time Out" procedure, there was no independent verification of the measured catheter length against the treatment length.

Because there are two transfer guide tubes of differing lengths which can be used with the vaginal cylinder, it is imperative to verify the treatment length at multiple points during CT simulation, treatment planning and treatment delivery process. During the record review, it was noted that prior to the June 2010 treatment, in which the Miami applicator transfer tube was selected by the therapist at the time of CT simulation, a vaginal cylinder treatment had not been performed since February, 2010. The relatively long lag between treatments indicates the need for "just in time" training so that the entire team is constantly reminded of the standard procedure.

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(x) Actions that have been taken or are planned to prevent recurrence:

ACTION	*DATE*
An item was added in the treatment Time-Out check list to have the physicist measure the catheter length and the physician verify it against the treatment length in the treatment room.	12/10/10
An item was added in the CT\SIM setup sheet to verify the measured catheter length by the therapist against the standard procedure length at the time of CT simulation.	12/13/10
An item in the check was added to ensure the dosimetrist and physicist verify catheter lengths against CT/SIM setup sheet at the time of treatment planning.	12/10/10
An item was added in the electronic record for the medical physicist to approve the CT/SIM setup sheet as part of the physics check.	12/13/10
Cases storing the transfer guide tubes have been clearly labeled and separated by length.	12/13/10
An item will be added to the "Time Out" policy stating that the treatment delivery will be halted immediately if *any member* of the HDR treatment expresses concerns regarding the treatment delivery or the safety of the patient.	12/13/10
Weekly chart checks will be performed by a physicist for all HDR patient treatments.	In progress
Monthly physics QA will perform a review of the lengths of all catheters in the container.	12/10/10
Peer review of HDR patient treatments will be performed by the radiation oncology physician team at weekly chart rounds.	12/22/10
The radiation oncology staff at Henry Ford Macomb Hospital has been educated on all of the changes made to the HDR program thus far.	12/22/10
A meeting was held with the HF-Macomb team including the director, physics staff, lead therapist, dosimetrist and therapist to review the HDR treatment process and steps for immediate correction.	12/20/10
A meeting was held including the radiation oncologist from HF-Macomb, the radiation oncology department chairman, the director of the radiation physics division, the director of clinical physics, the head of physics at HF-Macomb, the administrator at HF-Macomb, Risk Management and the radiation oncology department senior administrator to review the events in detail and to discuss the corrective action improvement process.	12/13/10
Just in time education and training will be performed quarterly effective immediately.	12/19/10

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Auditing of charts will be performed monthly and will be presented at the quarterly RSO meetings at HF-Macomb and the RSO meetings at the HFHS main campus.	In progress
Audit reviews will be presented at the monthly Department of Radiation Oncology QA committee meeting.	In progress
A quarterly review of the QA policies and procedures associated with the HDR program will be performed by the radiation oncology team.	In progress
Any changes in policies and procedures (planned changes) will be reviewed and approved by the Radiation Safety Committee and the Radiation Oncology QA committee.	Effective immediately
The Radiation Oncology QA committee will perform a detailed review of all current HDR procedures to ensure they are consistent across the HF Health System.	In progress
An independent, authorized medical physicist (AMP), will be consulted to perform an external review of all HDR procedures.	Feb, 2011

Sincerely,

Khurram Rashid, M.D.
Radiation Safety Officer
Henry Ford Macomb Hospital

Michael M. Cervenak
Vice President
Henry Ford Macomb Hospital

cc: Barbara Rossmann, President and CEO, Henry Ford Macomb Hospital
Gary Beaulac, Executive Vice President and COO, Henry Ford Macomb Hospital
Ibrahim Aref, M.D., Medical Director, Cancer Care Center, Henry Ford Macomb Hospital
Benjamin Movsas, M.D., Chairman, HFHS Department of Radiation Oncology
Indrin J. Chetty, Ph.D., Director, Physics Division, HFHS Department of Radiation Oncology
Deanne Miller, Director, Cancer Care Center, Henry Ford Macomb Hospital
Denise Winiarski, J.D., Risk Management, Henry Ford Macomb Hospital

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