Memorial Healthcare

April 27, 2011

U.S. Nuclear Regulatory Commission
Region III
Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

RE: Written Report of Medical Event

Dear Sir or Madam:

This letter is a report and notification of a Medical Event pursuant to 10 CFR § 35.3045. The Medical Event occurred on February 23, 2010 at McLaren – Owosso Cancer Center ("Medical Event"). McLaren – Owosso Cancer Center is a joint venture between McLaren Region Medical Center ("McLaren") and Memorial Healthcare ("Memorial"). The Medical Event occurred on the premises of Memorial Healthcare in Owosso, Michigan under the supervision of a physicist assigned and provided by McLaren. The Medical Event was identified during a routine NRC inspection at Memorial on April 13, 2011, and the NRC Operation Center was notified of the Medical Event on April 14, 2011 at 12:02 p.m.

1) **The Licensee's Name** Memorial Healthcare Center
License Number: 21-11475-01

2) **Prescribing Physician** Jack L. Nettleton, M. D.

3) **Description of the Event**

On February 23, 2010, a 59-year-old patient with prostate cancer received permanent prostate Brachytherapy via Pd-103 seed implant. The implant was performed after months of neo-adjuvant hormone treatments to reduce his large prostate size. Seventy five Pd-103 seeds (127.78 mCi total) (stranded and loose seeds) were implanted into the patient's prostate gland, using 29 needles. The last four seeds were placed as single seeds to cover any perceived cold spots. The patient underwent fluoroscopy at the termination of the procedure and the seeds appeared to adequately cover the prostate gland. On March 23, 2010, the patient underwent a post-seed CT simulation, and a post-plan calculation was performed on April 1, 2010. Dr. Jack Nettleton, Radiation Oncologist, reviewed the post-plan.

When the patient returned on April 12, 2010 to discuss his prostate seed implant, the dosimetry plan showed significant swelling of the prostate and areas of low radiation dose within the prostate, due to the swelling. Dr. Jack Nettleton, Radiation Oncologist, discussed the situation with the patient, including the option of implanting additional seeds to improve the dosimetry. The patient agreed to proceed with additional implants. The referring physician, Dr. Mandell Bookman, was notified and arrangements were made for a second implant.

A telephone call was placed to the NRC Region III Office during the week of April 12-16, 2010. Memorial's Medical Physicist, Arthur Ewald, spoke directly to an NRC Inspector, about performing a second seed implant to improve the radiation dose within the prostate gland. The NRC Inspector advised that in order to prevent the case from becoming a NRC Medical Event, (1) the Authorized User must fill out a second Written Directive for the prostate implant; (2) the Authorized User must write down the same dose (matched peripheral dose) as was written on the original Written Directive; and (3) the number of new seeds and their activity must be included on the second Written Directive. The NRC Inspector explained that by using this method the original implant was still open to receive a second implant as a boost, because the matched peripheral dose remained the same and the seeds from the initial implant were still radioactive. The second Written Directive was filled out according to the NRC Inspector's advice. Eight loose Pd-103 seeds were ordered and the OR procedure was scheduled.

On May 5, 2010, eight loose Pd-103 seeds (14.40 mCi total) were implanted into the patient's prostate gland using eight needles. The patient underwent fluoroscopy at the termination of the procedure and the seeds appeared to adequately cover the prostate gland. On May 11, 2010, the patient underwent a second post-seed CT simulation, and a second post-plan calculation was performed on May 13, 2010. Once again, Dr. Jack Nettleton, Radiation Oncologist, reviewed the plan, and according to the second post-seed dosimetry calculation plan, the total radiation dose delivered to the prostate volume was within ±20% of the prescribed dosage. On October 21, 2010, the patient was seen for a follow-up visit. The patient reported doing well at that time. Subsequently, the patient moved out of state and will not be scheduled for further post-radiation follow-up at Memorial.

On April 13, 2011, NRC conducted a routine, on-site inspection at Memorial. While evaluating the Brachytherapy cases from 2009-2011, The NRC Inspector's, Deborah Piskura, attention was drawn to this case. After examining the paperwork from the two implant procedures, interviewing Dr. Jack Nettleton, Radiation Oncologist, Arthur Ewald, Medical Physicist, and reviewing NRC Inspector's advice from April 2010, the on-site NRC Inspector, Deborah Piskura, disagreed with the advice the NRC Inspector gave Memorial in April 2010. Moreover, at the NRC inspection exit interview, the on-site NRC Inspector, Deborah Piskura, advised Memorial to report this incident to the NRC Operation Center as a Medical Event, and Memorial did so on April 14, 2011 at 12:02 p.m.

4) Why the Event Occurred

The dosimetry plan showed significant swelling of the prostate gland after the initial prostate seed implant. For this reason, low radiation dose areas were present within the prostate. Twenty four of the twenty nine needles used during this implant contained stranded seeds. Thus, the swelling could have pushed or pulled the stranded seeds to locations different from their initial

placement within the prostate gland. Additionally, the patient was on neo-adjuvant hormone therapy, and this treatment could affect the size of the prostate gland. Lastly, based on the April 2010 advice of an NRC Inspector, Memorial did not believe this incident was a reportable Medical Event.

5) The Effect on the Individual that Received the Administration

The calculated minimum dose received by 90% of the CT defined prostate volume (D90) was 81.05 Gy. The 20% prescribed dose range of the D90 for 125 Gy is between 100 Gy and 150 Gy. This dose was below, at 35.14%, and out of range. After the second implant, the D90 was re-calculated to a dose of 138.33 Gy. This dose is within the 20% prescribed dose range for treating the patient's prostate cancer. The patient came to Memorial for an eight month post-seed follow-up visit and reported doing well at that time.

6) Actions Taken to Prevent Recurrence

This incident will be fully discussed at the next meeting of the Radiation Safety Committee. The following policies will be implemented to avoid a similar occurrence in the future:

a) Anytime the NRC is called with a question or for advice, the caller will document the name of the Inspector with whom the caller spoke, the date and time of the conversation, and ask the Inspector to confirm the advice in writing.

b) The Brachytherapy Authorized Users and the Brachytherapy Medical Physicists will receive annual training on the reporting and notification requirements of a Medical Event.

c) The use of stranded seeds will be reviewed on a case-by-case basis with the Authorized Users.

d) When a patient leaves the OR department, the Written Directive for that case will be closed.

7) Certification that the Licensee Notified the Individual

The patient was notified before the incident was identified as a Medical Event. On April 12, 2010, Dr. Jack Nettleton, Radiation Oncologist, saw the patient for a follow-up visit concerning his prostate seed implant. Dr. Jack Nettleton, Radiation Oncologist, discussed the situation with the patient and offered the option of implanting additional seeds for improved dosimetry. Dr. Jack Nettleton, Radiation Oncologist, explained to the patient the rationale for the additional seeds, possible side effects, and the nature of the procedure. The patient agreed to proceed with the additional implants.

8) Notifying the Referring Physician

On April 12, 2010, Dr. Jack Nettleton, Radiation Oncologist, notified the patient's referring physician, Dr. Mandell Bookman, of the event, and the urologist's office helped make arrangements for the second implantation.

Memorial's Radiation Safety Officer, Dr. Apparao Mukkamala, has been notified of this event and is currently out of the country. He has been furnished a copy of this letter.

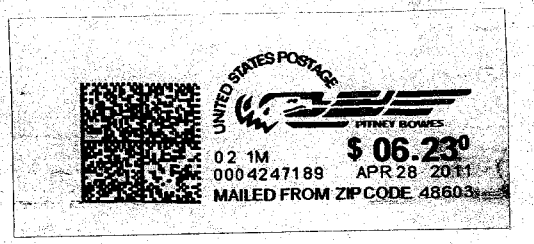
Please contact Senior Medical Physicist, Arthur Ewald, M.S. at (810) 342-3805 if you are in need of additional information.

Sincerely,

James M. Full, FACHE
President/CEO

cc: Dr. Apparao Mukkamala

Memorial Healthcare
826 W. King Street
Owosso, MI 48867



RETURN RECEIPT REQUESTED

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