May 13, 2011

EA-11-088
NMED NO. 100601(Closed)

Mr. Gary Beaulac, Executive Vice President
and Chief Operating Officer
Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-02106/2010-001(DNMS);-
HENRY FORD MACOMB HOSPITAL

Dear Mr. Beaulac:

This letter refers to the inspection conducted on December 14-15, 2010, at your Clinton Township, Michigan facility, with continued Nuclear Regulatory Commission (NRC) review through April 14, 2011. The in-office review included the receipt and review of the NRC Medical Consultant's report. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for the medical events reported to the NRC on December 10 and 15, 2010. The findings of the inspection were discussed with you and selected members of your staff during a preliminary exit meeting conducted on December 15, 2010, and at a final, telephonic exit meeting on April 21, 2011. The enclosed report presents the results of this inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation of Title 10 of the Code of Federal Regulations (CFR) Part 35.42(a), involves the failure to develop adequate procedures to provide high confidence that iridium-192 high dose-rate remote afterloader treatments were performed in accordance with the written directive.

The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff during the telephonic exit meeting on April 21, 2011, and are described in detail in the subject inspection report. As a result, it may not be necessary to conduct a pre-decisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter, or (2) request a Pre-decisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. A PEC should be held within 30 days of the date of this letter. Please contact Tamara Bloomer at 630-829-9627 within 10 days of the date of this letter to inform us of your choice.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 030-02106/2010-001(DNMS); EA-11-088" and should include for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Tamara Bloomer of my staff at 630-829-9627.

Sincerely,

/RA/ by Patrick L. Louden
For

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02106
License No. 21-11850-01

Enclosure:
Inspection Report No. 030-02106/2010-001(DNMS)

cc w/encl: Khurram Rashid, M.D., Radiation Safety Officer
Brett Miller, Chief Medical Physicist
Douglas Einstein, M.D., Ph.D, NRC Medical Consultant
State of Michigan

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State of Michigan

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REGION III

Docket No.	030-02106
License No.	21-11850-01
Report:	030-02106/2010-001(DNMS)
Licensee:	Henry Ford Macomb Hospital
Location Inspected:	15855 Nineteen Mile Road Clinton Township, Michigan
Inspection Date:	December 14 and 15, 2010, with continued in-office review through April 14, 2011
Exit Meeting:	April 21, 2011
Inspector:	Kenneth E. Lambert, Senior Health Physicist
Approved by:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Henry Ford Macomb Hospital
Clinton Township, Michigan
NRC Inspection Report No. 030-02106/2010-001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on December 14 and 15, 2010, to review the events and circumstances associated with four medical events that Henry Ford Macomb Hospital (licensee) reported to the NRC on December 10, 2010. The licensee treated four patients with an iridium-192 sealed source in a high dose-rate remote (HDR) afterloader using a vaginal cylinder between July and October 2010. During the treatments the licensee used a transfer tube assembly that was 12 cm longer than the transfer tube assembly length entered into the treatment planning software. This resulted in the HDR source traveling 12 cm shorter than planned. The mispositioning of the iridium-192 source during the treatments resulted in a dose to the treatment site that differed from the prescribe dose by more than 50 rem; and the total dose delivered to the treatment site differed from the prescribed dose by 20 percent or more. In addition, the treatments resulted in a dose to the skin of the patients' inner thighs that exceeded 50 rem and was greater than 50 percent more than the dose expected from the administration defined in the written directive. The licensee did not anticipate any long term radiological consequences as a result of the unintended dose to the patients' thighs. The licensee indicated in its December 23, 2010 letter, that it would be following up with the patients to determine what additional treatments and in what form may be necessary. The NRC's medical expert consultant determined that the overall impact on each patient from the unintended dosing of the skin and muscle was minimal.

The license determined that the root cause of the medical events was the failure to verify the transfer tube assembly length during the CT simulation, treatment planning, and treatment delivery process. The inspector determined that a contributing cause of the medical event was the failure of the licensee's Vaginal Cylinder HDR procedure to provide sufficient steps to verify that the transfer tube assembly length, measured during the simulation, was entered into the treatment planning program or to verify the transfer tube assembly length used during the actual treatment matched that in the treatment planning program.

The inspector identified an apparent violation of Title 10 of the Code of Federal Regulations (CFR) 35.41(a) regarding the licensee's failure to develop adequate procedures to provide high confidence that iridium-192 HDR afterloader treatments were performed in accordance with the written directives.

The inspector determined that the licensee initiated corrective actions to prevent recurrence of a similar event. The licensee took prompt corrective actions to prevent recurrence that included: (1) reviewing all vaginal treatments since inception of program;(2) revising its procedure to include steps to document the transfer tube assembly length on the setup sheet, to input transfer tube assembly length from the setup sheet into the treatment planning program, to have the physicist checking the treatment plan against the setup sheet, and for the physicist and physician to check the transfer tube assembly length being used just prior to the treatment; (3) instituting a time out prior to beginning treatment to check/hear any concerns from participants; and (4) training its staff on the revised procedure. The licensee completed its review of the vaginal treatments by December 15, 2010, and a review of all HDR afterloader treatments performed since the inception of the program in 2007. The licensee revised its procedure and provided training to its staff on December 28 and 29, 2010.

Report Details

1 Program Scope and Inspection History

The NRC License Number 21-11850-01 authorizes Henry Ford Macomb Hospital to use, in part, byproduct materials for in-vitro clinical testing, diagnostic and therapeutic nuclear medicine, prostate seed implants, and HDR afterloader treatments. The HDR afterloader contained a nominal 11 curie iridium-192 sealed source. The licensee has performed 19 vaginal cylinder treatments since the inception of the program in 2007.

No violations of NRC requirements were identified during the NRC's last two radiation safety inspections conducted in March 2010, and January 2008.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector interviewed the authorized user, medical physicist, radiation safety officer, and selected other staff, to determine the sequence of events that resulted in the medical events. In addition, the inspector reviewed selected licensee records and procedures, and the licensee's compliance with regulatory requirements involving HDR afterloader treatments.

2.2 Observations and Findings

A reactive inspection was conducted on December 14 and 15, 2011, to review the circumstances surrounding the medical events that occurred between July and October 2010, involving four patients treated with an iridium-192 sealed source in a HDR afterloader using a vaginal cylinder. Late in the day on December 9, 2010, one of the licensee's authorized users notified the Chief Physicist that she recognized that two of her patients had erythema on their inner thighs. On December 10, 2010, the chief physicist indicated that he asked the therapist who treated the patients for the transfer tube assembly that was used to treat the patients. The chief physicist measured the transfer tube assembly and noted the length was 133.4 centimeters (cm), which corresponded to a treatment length of 132 cm. The chief physicist reviewed the two patient's medical records and noted that the treatment length entered into the treatment planning software was 120 cm, resulting in a 12 cm difference between the actual treatment length and the treatment planning length. This resulted in the HDR source traveling 12 cm shorter than planned.

The chief physicist notified the authorized users of the incident. After a second authorized user reviewed medical records of his patients that had been treated with the HDR afterloader, he identified a third patient who had erythema on her inner thighs. The chief physicist reviewed the patient's medical records and identified the same error as the previous two patients. The chief physicist notified the NRC of the medical events on December 10, 2010, and began a review of all 19 HDR afterloader patients treated since the inception of the program in February 2007. This review was completed on December 14, 2010, and identified one additional patient who had the same 12 cm error regarding the treatment length and the treatment planning length. No skin erythema was identified for this patient. The licensee updated its medical event notification to the NRC on December 15, 2010, to include four patients.

During the inspection, the inspector identified that the licensee did not verify the length of the transfer tube assembly used during the initial planning simulation with the length entered into the treatment planning program and the HDR afterloader. The inspector determined that the transfer tube assembly consisted of two parts, a vaginal cylinder and a transfer tube. The licensee's practice was to combine a long vaginal cylinder with a short transfer tube or a Miami (short) cylinder with a long transfer tube resulting in a 120 cm transfer tube assembly. However, because either cylinder could be used with either tube, and the labeling on the transfer tube containers was ambiguous, the therapist paired the long cylinder with the long transfer tube, resulting in a 132 cm transfer tube assembly. This longer than normal transfer tube assembly length was not entered into the treatment planning computer by the dosimetrist; instead the "standard" 120 cm assembly length was entered. Since the same therapist was involved with the simulation as the treatment, the 132 cm transfer tube assembly was used during the patient treatments.

The written directives called for a total dose of 21 gray (2,100 rads) delivered in three fractions for patients 1 and 2. The written directive called for a total dose of 18 gray (1,800 rads) delivered in three fractions for patient 3. The written directive called for a total dose of 30 gray (3,000 rads) delivered in five fractions for patient 4. The HDR afterloader treatments involved the source traveling through the guide tube and into the proximal end of the vaginal cylinder and then retracting through eight dwell positions at 0.5 cm per dwell position or 4 cm total. The 12 cm difference between the measured transfer tube assembly length and the length entered into the treatment planning program and HDR afterloader resulted in the source only traveling to the distal portion of the vaginal cylinder with the last several dwell positions being outside the vaginal cavity, but inside or just out of the vaginal cylinder. The dwell positions outside of the vaginal cavity irradiated the inner thighs of the patients and resulted in erythema of the skin on three of the four patients.

The licensee determined the dose to the patients' intended treatment sites was minimal due to the source not starting at the proximal end of the cylinder. Based on the treatment plan, the patients' skin of the inner thighs was expected to receive a negligible dose. The licensee calculated the superficial dose and deep dose equivalent to each of the four patients' inner thighs. The superficial doses ranged from 270 – 450 rad and the deep dose ranged from 180 – 250 rad. These doses were estimated from the treatment planning system using anatomical information available on the three dimensional computerized tomography (CT) simulation scans. The following table presents the doses received to the inner thighs of the patients:

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

Based on the information above, the administration of iridium-192 in a HDR afterloader resulted in a medical event as defined in 10 CFR 35.2. The administrations resulted in doses that differed from the prescribe doses by more than 50 rem (1 rad = 1 rem for this type of radiation) to an organ or tissue; and the total dose delivered to the treatment site

differed from the prescribed dose by 20 percent or more. In addition, the administrations resulted in a dose to the skin other than the treatment site that exceeded 50 rem and was greater than 50 percent more than the dose expected from the administration defined in the written directive.

As indicated in the licensee's December 23, 2010 letter, the licensee did not anticipate any long term radiological consequences as a result of the unintended dose to the patients' thighs. The licensee was following up with the patients to determine what additional treatments and in what form may be necessary.

Title 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. At the time of the administrations, the licensee's Vaginal Cylinder HDR procedure did not include steps to verify the transfer tube assembly length used at the time of the treatment was in accordance with the transfer tube assembly length identified in the treatment plan and entered into the HDR afterloader. The licensee's failure to develop an adequate procedure to provide high confidence that the iridium-192 HDR afterloader treatment was performed in accordance with the written directive is an apparent violation of 10 CFR 35.41(a).

The licensee determined that the root cause of the medical events was the failure to verify the transfer tube assembly length during the CT simulation, treatment planning, and treatment delivery process. The licensee identified four factors related to the root cause: (1) the therapist selected a transfer tube that resulted in transfer tube assembly length of 132 cm due to an ambiguously labeled container; (2) the dosimetrist, knowing that the standard treatment used the vaginal cylinder with the 120 cm transfer tube assembly, planned the treatment using 120 cm; (3) the physicist, in performing a second check of the treatment plan, assumed the standard transfer tube assembly was used and did not verify the length; and (4) immediately prior to the treatment, there was no independent verification of the transfer tube assembly length against the treatment plan length. The licensee also identified that four months had elapsed since the last treatment and the long time between treatments indicated the need for "just in time" refresher training to remind involved individuals of the standard procedures, which they did not conduct. The inspector agreed with the licensee's assessment.

The inspector also determined that a contributing cause of the medical event was the failure of the Vaginal Cylinder HDR procedure to provide sufficient steps to verify that the transfer tube assembly length, measured during the simulation, was entered into the treatment planning program or to verify the transfer tube assembly length used during the actual treatment matched that in the treatment planning program.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.41(a) regarding the licensee's failure to develop adequate procedures to provide high confidence that Vaginal Cylinder iridium-192 HDR afterloader treatments were performed in accordance with the written directives.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to prevent similar events and violations by interviewing selected staff, and by reviewing the licensee's revised Vaginal Cylinder HDR procedure and corrective actions described in the licensee's written report.

3.2 Observations and Findings

The licensee initiated corrective actions to prevent recurrence of a similar event that included: (1) reviewing all HDR afterloader vaginal treatments since inception of the program; (2) revising its procedure to include steps to document the transfer tube assembly length on the setup sheet, to input transfer tube assembly length from the setup sheet into the treatment planning program, to have the physicist check the treatment plan against the setup sheet, and for the physicist and physician to check the transfer tube assembly length being used just prior to the treatment; (3) instituting a time out prior to beginning treatment to check/hear any concerns from participants; (4) training its staff on the revised procedure; and (5) performing quarterly "just in time" training.

As stated in the December 23, 2010 letter from the licensee, the licensee completed its review of the HDR afterloader vaginal treatments by December 14, 2010, and a review of all HDR afterloader treatments performed since the inception of the program on December 17, 2010. The licensee revised its procedure and provided training to its staff on December 28 and 29, 2010. In addition, the licensee indicated in its written response that it planned to have an audit conducted by an independent authorized chief physicist.

3.3 Conclusion

The licensee initiated corrective actions to prevent similar violations and medical events.

4 Notifications and Reports

4.1 Inspection Scope

The inspector interviewed the radiation safety officer, the chief physicist, and the authorized users to determine what event notifications had been made. The inspector also reviewed the licensee's notification of the medical event to the NRC Operations Center, dated December 10, 2010, and the updated notification made to the Operations Center on December 15, 2010. In addition, the inspector reviewed the licensee's written report of the medical event, dated December 23, 2010.

4.2 Observations and Findings

On December 9, 2010, one of the licensee's authorized users notified the chief physicist that two patients had been identified with erythema on their inner thighs. The

following day, the chief physicist investigated the issue and identified a discrepancy in the transfer guide tube used and the length in the patient's medical records. The chief physicist then notified the authorized users, the radiation safety officer and licensee management. A second authorized user reviewed medical records for several of his patients and found that a third patient with indications of erythema on the inner thighs and the same transfer guide tube length discrepancy. The chief physicist contacted the NRC operations center and reported the three medical events on December 10, 2010.

After notifying the NRC, the chief physicist began a review of all vaginal cylinder patients treated since the inception of the program. On December 14, 2010, the chief physicist identified a fourth patient with the same transfer guide tube discrepancy and notified the NRC Operations Center of the fourth medical event on December 15, 2010. The licensee provided its written report of the medical events to the NRC on December 23, 2010, within 15 days of the medical events being reported to the NRC.

The inspector interviewed the authorized users who indicated that the patients referring physicians were notified within 24 hours of the medical events being discovered. The licensee's written report indicates that the licensee also attempted to contact each of the patients within 24 hours of notifying the NRC. Patients 1 and 4 were notified within 24 hours. The licensee was unable to reach patient 3 and 4, and left voice messages for the patients to call back as soon as possible. Patient 3 called the hospital on December 20, 2010, and was notified of the medical event. Patient 2 did not return the phone call and was sent a registered letter on December 22, 2010.

4.3 Conclusions

The inspector did not identify any violations of NRC reporting requirements regarding the reporting of the medical events to the NRC Headquarters Operation Center or providing notification to the patients and referring physicians.

5 Independent Patient Dose Assessment

5.1 Inspection Scope

NRC contracted a medical expert consultant to assess potential deterministic effects of the radiation exposure to the patients as a result of the medical events. The inspector reviewed the medical expert consultant's report.

5.2 Observations and Findings

The medical expert consultant stated that the medical impact of the treatment was two-fold. First was the unintended dosing of the skin and muscle of the inner thighs, and second was the under dosing of the intended target tissue. The medical expert consultant indicated that erythema and temporary or permanent hair loss could occur in all patients due to the unintended dosing to the skin and muscle of the inner thighs. Patients 3 and 4 may have long term fibrotic changes from the administration that will likely not interfere with function, but may produce long-term cosmetic effects. The medical expert consultant also indicated that there is not a significant risk of skin

necrosis for patients 1 or 2. Patients 3 and 4 have a small risk to a very small volume of skin necrosis. The medical expert consultant concluded that the impact on each patient from the unintended dose to the skin and muscle of the inner thighs was minimal. Regarding the under dosing of the intended target tissue, the medical expert consultant indicated the target tissue would have received minimal dose and therefore control of the cancer would be compromised. The medical consultant indicated that the licensee was following up with each patient to determine what additional treatment may have been necessary.

5.3 Conclusions

The medical expert consultant determined that the overall impact on each patient from the unintended dosing of the skin and muscle was minimal.

6 Exit Meeting Summary

The inspector discussed the preliminary conclusions described in this report with licensee management during a preliminary exit meeting conducted at the licensee=s facility on December 15, 2010. The inspector discussed the activities reviewed, the inspection findings, and the apparent violation. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature. A final telephonic exit meeting was conducted on April 21, 2011.

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

*^ Gary Beaulac, Executive Vice President and Chief Operating Officer, Henry Ford Macomb Hospital
*^ Deanne Miller, Director, Cancer Care Center, Henry Ford Macomb Hospital
^ Denise Winiarski, J.D., Risk Management, Henry Ford Macomb Hospital
* Ibrahim Aref, M.D., Radiation Oncologist/Medical Director, Cancer Care Center
*^ Brett Miller, Chief Physicist, Henry Ford Macomb Hospital
*^ Khurram Rashid, M.D., Radiation Safety Officer, Henry Ford Macomb Hospital
*^ Donald Peck, Radiation Safety Officer, Henry Ford Hospital
* Indrin Chetty, Division Head, Radiation Oncology Physics HFHS/HN
*^ Teamour Narushev, Director, Clinical Physics, Henry Ford Hospital
*^ Alan Jackson, Radiation Safety Officer, Henry Ford Hospital and Medical Centers

* attended preliminary exit meeting on December 15, 2010
^participated in the telephone exit meeting on April 21, 2011