March 31, 2011

EA-11-037
NMED No. 100448 (Closed)

Dr. Michael Wiemann, Ph.D.
Chief Executive Officer
Providence Hospital
16001 West Nine Mile Road
Southfield, Michigan 48037

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03002022/2010-001(DNMS) – PROVIDENCE HOSPITAL

Dear Dr. Wiemann:

On September 16, 2010, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through March 17, 2011, NRC inspectors conducted a reactive inspection at Providence Hospital facilities in Novi, Michigan, and Southfield, Michigan. The in-office review included, in part, 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 to a reported medical event that occurred on August 30, 2010. Michael LaFranzo of my staff discussed with selected members of your staff the findings of the inspection at a preliminary exit meeting on September 16, 2010, and at a final telephonic exit meeting on March 18, 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 involves the licensee's failure to develop adequate procedures to provide high confidence that a manual brachytherapy iodine-125 seed implant therapy was performed in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR) Section 35.41(a).

The circumstances surrounding this 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 March 18, 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 (PEC) in order to enable the NRC to make an enforcement decision.

In addition, because you identified the violation, 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 NRC Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the inspectors 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 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 PEC.

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. 03002022/2010-001(DNMS); EA-11-037" 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. 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. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website at http://www.nrc.gov/ reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. 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 the NRC has not granted an extension of time, the NRC will proceed with its enforcement decision or schedule a PEC. Please notify Tamara E. Bloomer at 630-829-9627 of your intentions within seven days of the date of this letter.

In addition, please be advised that the characterization of apparent violation described in the enclosed inspection report may change as a result of the further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR Section 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's Public Document Room or from the NRC's

Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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 publicly available without redaction.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02022
License No. 21-02802-03

Enclosure:
Inspection Report No. 03002022/2010-001(DNMS)

cc w/encl.: Allan Fraiberg, M.D., Radiation Safety Officer
Karen North, Director, Providence Cancer Center
Vrinda Narayana, Ph.D., Medical Physicist
Al McKendrick, M.D., Referring Physician
Louis Potters, M.D., NRC Medical Consultant
State of Michigan

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Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02022
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Enclosure: Inspection Report No. 03002022/2010-001(DNMS)

cc w/encl.: Allan Fraiberg, M.D., Radiation Safety Officer
Karen North, Director, Providence Cancer Center
Vrinda Narayana, Ph.D., Medical Physicist
Al McKendrick, M.D., Referring Physician
Louis Potters, M.D., NRC Medical Consultant
State of Michigan

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REGION III

Docket No.:	030-02022
License No.:	21-02802-03
EA No.:	EA-11-037
Report No.:	03002022/2010-001(DNMS)
Licensee:	Providence Hospital
Location:	47601 Grand River Avenue Novi, Michigan
Dates of Inspection:	September 16, 2010, with continuing NRC in-office review through March 17, 2011
Exit Meeting:	March 18, 2011
Inspectors:	Aaron T. McCraw, Senior Health Physicist Michael M. LaFranzo, Senior Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Providence Hospital
Novi, Michigan
NRC Inspection Report No. 03002022/2010-001(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on September 16, 2010, to review the events and circumstances associated with a medical event that Providence Hospital (the licensee) reported to the NRC on September 2, 2010. During a palliative treatment of a rectal tumor with an anal extension on August 30, 2010, the licensee mistakenly implanted the iodine-125 (I-125) seeds superior to the intended site. The licensee discovered the mistake during a post-operative computerized tomography (CT) scan on September 1, 2010. The mispositioning of the sources resulted in an underdose to the treatment site that differed from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differed from the prescribed dose by 20 percent. The mispositioning of the sources also resulted in doses to tissues other than the treatment site (bladder and seminal vesicles) that exceeded 50 rem and 50 percent of the doses expected from the administration defined in the written directive. The licensee did not anticipate any long-term medical effects on the patient as a result of the medical event. The NRC's medical expert consultant determined that the radiation from the sources within the pelvis was not likely to manifest any clinical sequelae, either acute or chronic.

The root cause of the medical event was human error in that the authorized user did not accurately place the sources in the patient, as intended. A contributing factor that increased the risk of human error was that the authorized user divided his attention in at least three ways during the procedure. First, the authorized user focused his sight primarily on the fluoroscope, which he used to sight the placement of the needles. Second, the authorized user used a fast and forceful manual movement with his left hand to penetrate the hard tumor to insert the needle. Third, the authorized user had to ensure, with his right hand, that the plunger used to push the seeds out of the needle was not inadvertently pressed during the placement of the needle, which would have prematurely released the seeds. The authorized user did not notice that he placed the first needle too deep and propagated the error by using the first seed strand as a reference on the fluoroscope for the placement of nine subsequent needles.

The inspectors identified an apparent violation involving the licensee's failure to develop written procedures to provide high confidence that each administration was in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR) Section 35.41(a).

The inspectors determined that the licensee initiated corrective actions to prevent recurrence of a similar event. As corrective action, the licensee revised its written procedure for interstitial brachytherapy treatments to require: (1) the use of tissue markers during treatments that require the use of fluoroscopy alone to confirm source placement, and (2) a needle depth check using two different measurements for verification during treatments that require the use of fluoroscopy alone. To ensure the written directive will be administered with high confidence in the future, the licensee provided training for the above to all appropriate authorized users by October 1, 2010.

REPORT DETAILS

1 Program Scope and Inspection History

The NRC License Number, 21-02802-03, authorizes the licensee to use, in part, byproduct material for diagnostic and therapeutic administrations, which includes the permanent implantation of I-125 seeds, at its facilities in Novi, Michigan, and Southfield, Michigan. The licensee performs, on average, 60 interstitial brachytherapy implants annually. The licensee performs palliative brachytherapy treatments once every couple of years.

No violations of NRC regulatory requirements were cited during two prior routine inspections conducted on October 19, 2006, and August 19, 2008.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors interviewed the authorized user, the medical physicist, the radiation safety officer and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspectors reviewed selected licensee records and procedures, and reviewed compliance with regulatory requirements relative to the implant procedure.

2.2 Observations and Findings

The licensee planned to insert six strands of four I-125 sources each into and around an anal/rectum tumor (treatment site) on August 30, 2010. The licensee developed a written directive for the treatment on August 30, 2010. The written directive had indicated that the treatment site was to receive 90 Gray (Gy) (1 Gy = 100 rads).

On August 30, 2010, and prior to the administration of radioactive material, the authorized user determined that the size and dimensions of the tumor had changed sufficiently that a change in the written directive was necessary to treat the tumor and added four strands of two I-125 seeds each to the treatment and expanded the distance between the seeds but not the depth. The revised written directive called for 32 I-125 seeds with a total source strength of 10.03 millicuries. The licensee had planned to start inserting the seeds approximately 5 centimeters (cm) into the patient. The licensee was using a combination of palpation and fluoroscopy to ensure the I-125 seeds were implanted as intended. The licensee had two additional methods, which had been used in past similar administrations of I-125 seeds, to ensure the proper placement of the seeds. These were: (1) to place several tissue markers around the tumor to more accurately determine the location of the tumor via fluoroscopy, and (2) to place a visible mark on the needle to more accurately determine the depth of the source insertion needle in the patient. Neither of these additional methods was used in this administration. The inspectors reviewed the licensee's interstitial brachytherapy procedure and discovered that neither of these methods is required to implement the written directive per the procedure, but voluntary.

During the administration, the authorized user inadvertently inserted the seeds approximately 4 cm superior to the intended site. The licensee did not discover the error until two days later, on August 31, 2010, when a CT scan was performed and identified the misplaced sources. Based on source placement, the licensee calculated that the treatment site only received approximately 2.9 percent of the prescribed dose. The licensee recognized the treatment met the criteria for a medical event under 10 CFR Section 35.3045(a) and notified the NRC of the medical event on September 2, 2010. From the CT images, the licensee noted either three strands of four seeds each were protruding into or were in the bladder. The licensee removed these strands from the patient via cystoscopy on September 3, 2010.

Title 10 CFR Section 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. The written procedures must meet the requirements described in 10 CFR Section 35.41(b). At the time of this administration, the licensee's interstitial brachytherapy procedure did not require the use of available means to ensure that brachytherapy sources are accurately placed in accordance with the written directive; therefore, the licensee's procedure did not provide high confidence that manual brachytherapy administrations were in accordance with the written directives. The licensee's failure to develop an adequate procedure to provide high confidence that the I-125 seeds were implanted in accordance with the written directive is an apparent violation of 10 CFR Section 35.41(a).

Follow-up positron emission tomography (PET) and CT studies to determine specific dosimetric calculations were performed on September 10, 2010, and September 13, 2010, respectively. The licensee provided the NRC with the following table that contains the licensee's calculations for the tumor and four nearby target organs or tissues:

Organ or Tissue	Preplan with PET Avg. Dose in Gy (Rad)	Final with PET and CT Avg. Dose in Gy (Rad)	Dose Difference in Gy (Rad)	Percent Difference
Target Anus (Tumor)	90 (9,000)	2 (200) avg. 8 (800) max.	-88 (-8,800) avg. -82 (-8,200) max.	-98% avg. -91% max.
Bladder	0.07 (7)	3.75 (375)	+3.68 (+368)	+5,257%
Prostate	6.24 (624)	4.2	-2.04 (-204)	-33%
Seminal Vesicle	5.38 (538)	25.17 (2,517)	+19.79 (+1,979)	+368%
Rectum	45.18 (4,518)	3.16 (316)	-42.02 (-4,202)	-93%

Based on the information in the above table, the administration of the I-125 seeds resulted in a medical event as defined in 10 CFR 35.2. The administration resulted in doses that differed from the prescribed 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. As indicated in the table, the treatment site received between an average of 2 Gy and a maximum of 8 Gy, an

underdose to the treatment site in the range of 82 to 88 Gy, or 91 to 98 percent of the intended dose. In addition, the administration resulted in doses to tissues other than the treatment site (bladder and seminal vesicles) that exceeded 50 rem and 50 percent of the dose expected from the administration defined in the written directive. The bladder received an overdose of 3.68 Gy, or 5,257 percent of the expected dose. The seminal vesicles received an overdose of 19.79 Gy, or 368 percent of the expected dose.

The licensee did not anticipate any long-term radiological consequences as the result of the additional unanticipated dose to the bladder or seminal vesicles. The licensee acknowledged that the dose delivered to the tumor was "medically insufficient." The licensee subsequently provided dose to the target area via external beam therapy to make up for the underdose from the brachytherapy procedure.

The licensee determined that the root cause of the medical event was the authorized user mistakenly believed the 10 cm mark on the insertion needle was the 5 cm mark. The inspectors concurred with the licensee's assessment that the root cause was human error. The licensee also determined that a contributing factor to the event was the failure to use tissue markers to more accurately determine the location of the tumor in relation to the needle under fluoroscopy. The inspectors identified an additional contributing factor to the event in that the authorized user divided his attention in at least three ways during the procedure. First, the authorized user focused his sight primarily on the fluoroscope, which he used to sight the placement of the needles. Second, the authorized user used a "swift stroke" technique with his left hand to place the needle. This technique requires a fast and forceful manual movement to penetrate a hard tumor that was surrounded by soft tissue. Third, the authorized user had to ensure, with his right hand, that the plunger used to push the seeds out of the needle was not inadvertently pressed during the "swift stroke" placement of the needle, which could have prematurely released the seeds. The authorized user did not notice that he placed the first needle too deep and propagated the error by using the first seed strand as a reference on the fluoroscope for the placement of nine subsequent needles.

2.3 Conclusions

The inspectors identified an apparent violation of 10 CFR 35.41(a), concerning the licensee's failure to develop adequate procedures to provide high confidence that a manual brachytherapy I-125 seed implant therapy was performed in accordance with the written directive.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors interviewed the radiation safety officer, the medical physicist, and the authorized user to determine what event notifications had been made. The inspectors also reviewed the licensee's telephonic event notification to the NRC Headquarters Operations Center on September 2, 2010, and the licensee's written report dated September 16, 2010.

3.2 Observations and Findings

The medical event occurred on August 30, 2010; however, the licensee did not discover that the medical event occurred until a followup CT scan performed on September 1, 2010, showed that the seeds had been inserted approximately 4 cm superior to the intended location. The licensee notified the referring physician and the patient on September 2, 2010.

The medical physicist reported the medical event to the NRC Headquarters Operations Center on September 2, 2010, the next calendar day after discovery of the medical event. The NRC received the written report, dated September 16, 2010, on September 17, 2010, within 15 days after discovery of the medical event. The written report contained all required information.

3.3 Conclusions

The inspectors did not identify any violations of NRC requirements concerning the reporting of the medical event to the NRC Headquarters Operations Center or providing notifications to the patient and the referring physician.

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspectors interviewed selected licensee personnel concerning the licensee's proposed corrective actions and reviewed the corrective actions described in the licensee's written report.

4.2 Observations and Findings

The inspectors determined that the licensee initiated corrective actions to prevent recurrence of a similar event. The corrective actions included revising procedures to specify:

(1) Any interstitial procedure that requires the use of fluoroscopy alone will be done with the use of tissue markers to confirm source placement.
(2) Interstitial procedures that use fluoroscopy alone will check needle depth in two ways:
    a. The depth of insertion of the needle will be marked on the needle; and
    b. The depth of the needle that is not introduced into the patient will be checked.

To ensure the written directive will be administered with high confidence in the future, the licensee provided training for the above to all appropriate authorized users by October 1, 2010.

4.3 Conclusions

The inspectors determined that the licensee planned and implemented corrective actions to prevent similar violations and medical events.

5 Independent Patient Dose Assessment

5.1 Inspection Scope

NRC contracted a medical expert consultant to assess probable deterministic effects of the radiation exposure to the patient as a result of the medical event. The inspectors reviewed the medical expert consultant's report.

5.2 Observations and Findings

The medical expert consultant determined that the patient had no clinical adversity from the implant and that the radiation from the sources in the pelvis was not likely to manifest any clinical sequelae, either acute or chronic. However, the consultant noted that had the patient lived, he might have experienced potency issues. The medical expert consultant confirmed that the underdosing would not have offered local control of the tumor, and therefore, additional treatment would have been necessary. The patient passed away on December 18, 2010, from conditions unrelated to the anal/rectal tumor and I-125 therapy. The medical expert consultant confirmed that the patient's death was caused by other conditions and not the persistence of his anal/rectal tumor. The medical expert consultant stated that the I-125 treatment would not have added to the patient's life expectancy had it been performed in accordance with the written directive.

5.3 Conclusions

The medical expert consultant determined the patient had no clinical adversity from the implant and that the radiation from the sources in the pelvis was not likely to manifest any clinical sequelae, either acute or chronic.

6 Exit Meeting Summary

The inspectors discussed the conclusions described in this report with the licensee during a preliminary exit meeting conducted at the licensee's Southfield, Michigan facility on September 16, 2010. The licensee did not identify any information provided to the inspector during this inspection as proprietary in nature. A final telephonic exit meeting was conducted on March 18, 2011.

LIST OF PERSONS CONTACTED

+^ Laura Dailey-Pelle, Director of Radiation Oncology
+^ Allan Fraiberg, M.D., Radiation Safety Officer
+^ Patrick McLaughlin, M.D., Radiation Oncologist
+^ Vrinda Narayana, Ph.D., Medical Physicist
+^ Karen North, Corporate Director – Providence Cancer Center

+ Attended the on-site exit meeting on September 16, 2010
^ Participated in the telephone exit meeting on March 18, 2011