

June 20, 2008

EA-08-180
NMED No. 080273

Bruce Backus
Assistant Vice Chancellor
Environmental Health & Safety
Washington University in St. Louis
Campus Box 1010
350 North Skinker Boulevard
St. Louis, MO 63130

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-02271/2008-001(DNMS) –
WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Backus:

This refers to the inspection conducted on May 22, 2008, at the Washington University in St. Louis. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a loss of two prostate implant seeds, each containing a nominal 0.518 millicuries of iodine-125 that occurred following a prostate implant patient procedure. The enclosed report presents the results of this inspection.

This inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, two apparent violations were identified and are 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>. On May 8, 2008 your Radiation Safety Officer notified the NRC regarding the loss of two iodine-125 prostate implant seeds that occurred on May 7, 2008. The first apparent violation involves the failure to control and maintain constant surveillance of licensed materials that were in a controlled area and were not in storage. Specifically, upon the completion of a prostate implant, your staff lost control of two iodine-125 seeds and subsequently lost the seeds into the sanitary sewer. The second apparent violation involves the failure to perform a survey to ensure the location and accountability of these two iodine-125 seeds which were subsequently lost.

The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with your staff during the exit meeting on May 22, 2008. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

You should be aware that Section VII.A.1.g of the NRC Enforcement Policy states that for violations involving the loss of a sealed source or device, the NRC should normally exercise discretion when proposing the imposition of a civil penalty of at least the base amount. Since the apparent violation involves the loss of two sealed sources containing 0.518 millicuries of iodine-125, the NRC is considering proposing imposition of a civil monetary penalty. The base civil penalty amount is based on approximately three times the expected average cost of authorized disposal; however, the NRC may consider adjusting the civil penalty amount to a more appropriate base amount if you can demonstrate that three times the actual cost of disposal would be significantly less than the base amount. However, NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases, i.e., \$3,250.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in the inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. Please contact Patrick Loudon at (630) 829-9627 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 030-02271/2008-001; EA-08-180" and should include for each 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. 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 the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. 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 predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report 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.

B. Backus

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This letter and Inspection Report No. 030-02271/2008-001 will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), and will be made publicly available for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adamas.html>.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-02271
License No. 24-00167-11

Enclosures:

- 1. Inspection Report No. 030-02271/2008-001(DNMS)
- 2. Excerpt from NRC Information Notice 96-28

cc w/encls: Susan Langhorst, Ph.D., CHP, Radiation Safety Officer
State of Missouri

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Letter to Bruce Backus from Steven A. Reynolds dated June 20, 2008

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WASHINGTON UNIVERSITY IN ST. LOUIS

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REGION III

Docket No. 030-02271

License No. 24-00167-11

Report: 030-02271/2008-001(DNMS)

Licensee: Washington University in St. Louis

Locations Inspected: Barnes-Jewish Hospital
Departments of Surgery and Radiation Oncology
St. Louis, Missouri

Date: May 22, 2008

Exit Meeting: May 22, 2008

Inspector: Deborah A. Piskura, Health Physicist

Approved by: Patrick L. Loudon, Chief
Materials Inspection Branch

NMED No. 080273

Enclosure 1

EXECUTIVE SUMMARY

Washington University in St. Louis St. Louis, Missouri NRC Inspection Report 030-02271/2008-001 (DNMS)

This was a reactive inspection conducted on May 22, 2008, to review the circumstances, root cause, and proposed corrective actions associated with the licensee's report of two lost prostate implant seeds, each containing a nominal 0.518 millicuries of iodine-125 that occurred during a cleaning process following the patient implant procedure. Two iodine-125 seeds remained in a cartridge in a Mick applicator, a brachytherapy device used for implanting the seeds in the patient. At the conclusion of the implant a technologist improperly removed the magazine from the applicator, causing the two seeds to slip out into the applicator. The technologist also failed to survey the applicator and the source magazine to verify the location of the two iodine-125 seeds. The technologist took the applicator to a sink for cleaning and presumably washed the two seeds into the sewer system.

The inspector identified an apparent violation of Title 10 Code of Federal Regulations (CFR) Part 20.1802 associated with failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Specifically, upon the completion of a prostate implant, licensee staff lost control of two iodine-125 seeds and subsequently lost the seeds into the sanitary sewer. In addition, the inspector identified an apparent violation associated with the licensee's failure to survey and account for these two iodine-125 seeds which were not implanted, as required by 10 CFR 35.404(a).

The inspector determined that the root cause of the event was licensee's failure to perform adequate surveys to verify the location of the iodine-125 seeds. While a technologist surveyed the operating room and the patient, no survey was performed of the Mick applicator and the source cartridge in order to account for two iodine-125 seeds which were not implanted. Contributing causes for the loss of the seeds included: (1) the technologist's limited experience in handling the Mick brachytherapy applicator and sources; and (2) the authorized user's and medical physicist's failure to communicate with the technologist to ensure that the seeds were properly accounted for prior to releasing the equipment from the surgical suite for cleaning. The licensee's proposed corrective actions included: (1) conducting in-service training to the hospital staff directly involved with the event of May 7, 2008; (2) developing a competency training program for brachytherapy technologists; (3) conducting a training session for the entire radiation oncology staff; and (4) requiring visual and survey verification of any extra seeds within the cartridge (at the conclusion of an implant) while in the operating room prior the releasing the equipment for cleaning.

Report Details

1 Program Scope and Inspection History

Washington University in St. Louis (licensee) operates a large Type A broad scope medical program. The licensee is authorized by NRC License No. 24-00167-11 to possess and use a variety of isotopes for teaching, research and medical uses including permanent iodine-125 prostate seed implants. All authorized users, uses, and locations of use are approved by the licensee's radiation safety committee. Prostate implants are performed at the surgery center at Barnes-Jewish Hospital. The licensee administers approximately 50 to 60 iodine-125 prostate implants annually.

A reactive inspection on June 5, 2007, was conducted to review a medical event involving an unintended dose to an embryo/fetus. No violations were identified during the reactive inspection on June 5, 2007, or the previous routine inspection conducted October 30 to November 3, 2006.

2 Event Chronology and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the circumstances surrounding the loss of two iodine-125 seeds containing a total nominal activity of 1.036 millicuries. The inspector interviewed selected licensee personnel, reviewed selected records, and observed related equipment and activities.

2.2 Observations and Findings

On May 8, 2008, the licensee's RSO reported to the NRC Operations Center, the loss of two iodine-125 seeds, each having a nominal activity of 0.518 millicuries, for a total loss of 1.036 millicuries of iodine-125, which occurred on May 7, 2008. The licensee administered a permanent iodine-125 prostate implant, using a Mick Radio-Nuclear Applicator®, with a source magazine (also referred to as a "cartridge") containing 15 seeds, as an additional dosage for a previous implant on April 16, 2008. The licensee receives the seeds from its vendor in sterile cartridges. The "cartridge" or magazine as referenced by the vendor is comprised of a head and a threaded "cartridge" which contains the seeds. Each magazine contains 15 seeds, and each seed has a specific isotopic radioactivity (activity). The source magazine is placed in the magazine receptor of the applicator for the implant and is removed and placed in a Loading V-Block (shield) at the completion of the implant.

The prescribed dose to the prostate was 145 Gray to 90 percent of the tumor volume, using 13 seeds. At the conclusion of the implant, the authorized user placed the applicator with the magazine containing two iodine-125 seeds, on a surgical tray and attended to the patient's additional medical needs. Typically, at the completion of an implant, the authorized user removes the magazine from the magazine receptor of the applicator and secures the magazine in a Loading V-Block. However, in this case, the authorized user left the magazine in the applicator and attended to the patient's additional medical needs. A brachytherapy technologist, assisting in the procedure, noted that the magazine was still in the applicator. The technologist improperly removed

the cartridge from the applicator by unscrewing the cartridge from the head, believing the head still contained the two seeds, and placed the head in a Loading V-Block. The technologist was unaware that by unscrewing the head from the cartridge, the seeds would not remain secured within the magazine head and; therefore, the seeds could slip out. It is believed that when the technologist removed the cartridge, the iodine-125 seeds slipped out of the magazine, into the magazine receptor of the applicator.

At the completion of the implant procedure, the technologist surveyed the surgical suite and the patient; however, the technologist failed to survey the Mick applicator or the magazine head in order to properly account for the two iodine-125 seeds. Title 10 Code of Federal Regulations Part 35.404(a) requires immediately after implanting sources in a patient, the licensee shall make a survey to locate and account for all sources that have not been implanted. The licensee's failure to survey the Mick applicator or the magazine in order to properly account for the two iodine-125 seeds is an apparent violation of 10 CFR 35.404(a).

The technologist transported the applicator (presumably with the seeds in the shield) and the magazine to the decontamination suite and placed the applicator in a wash basin. The technologist soaked the applicator in a wash solution and manually scrubbed, rinsed and drained the applicator. The seeds were presumably washed down a drain when the apparatus was cleaned and were not recoverable. The technologist did not visually check the magazine or survey the cartridge to verify the location of the seeds. However, the technologist had never previously handled the applicator or the cartridge, and she was unaware that the part she unscrewed secured the seeds within the cartridge. The technologist cleaned the applicator (which presumably contained the seeds) and unknowingly washed the seeds down the sink drain and into the sanitary sewer system. Believing the iodine-125 seeds were in the magazine, the technologist hand-wiped the magazine and placed it in the Loading V-Block. The technologist transported the devices to the radiation oncology hot lab for storage. Another brachytherapy technologist removed the magazine from the Loading V-Block and placed the cartridge in the manufacturer's shipping vial for storage. This brachytherapy technologist also failed to recognize that the magazine had been improperly disassembled and was empty.

The licensee discovered the iodine-125 seeds were missing at approximately 4:30 p.m. when a medical physicist attempted to assay the seeds as confirmation of the source activity for the implant procedure. As the medical physicist examined the magazine, he noted that the two iodine-125 seeds were missing. He informed other staff medical physicists of the apparent missing seeds and the staff surveyed the operating room in an attempt to locate the seeds. The medical physics staff contacted the technologist at home who informed him that she had cleaned the applicator and the magazine and placed the magazine, which she believed still contained the two iodine-125 seeds, in the hot lab. The medical physics staff contacted the Radiation Safety Office for assistance in search and survey efforts. Additional search and survey efforts included the trash from the surgical suite as well as the decontamination suite.

Search and survey efforts on May 7 and 8, 2008, to locate the missing sources were unsuccessful. The licensee concluded that the seeds were probably lost during the cleaning and decontamination of the applicator. The licensee did not believe that the technologist came in direct contact with the seeds during the washing process and

estimated that the technologist would have received only a very minor dose if contact did occur.

Title 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee. The licensee's loss of the iodine-125 seeds was an apparent violation of 10 CFR 20.1802 for failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

The licensee determined that the root cause of the event was attributed to inadequate training provided to the technologist. The technologist involved in the incident was in training as a brachytherapy technologist. The technologist received refresher radiation safety training through the radiation safety office and passed a written exam on February 5, 2008. This individual worked in this position since November 2007 and observed three to four prostate implant procedures. Training provided to this technologist consisted of on-the-job training and observations of various implant procedures within the radiation oncology department. Prior to the May 7, 2008, event, the technologist had not personally handled a Mick applicator or the cartridge and; therefore, was not knowledgeable in how the iodine-125 seeds were secured within the cartridge. The inspector attributed the technologist's limited experience in handling a Mick applicator and the source cartridge as a contributing cause to the lost seeds. The inspector also identified that a lack of verbal communication between the authorized user, the physicist, and the technologist contributed to the event.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 20.1802 involving the licensee's failure to maintain control of two iodine-125 sources which were inadvertently lost in the sanitary sewer system. In addition, the inspector identified an apparent violation of 10 CFR 35.404(a). The licensee conducted an appropriate review into the loss of the iodine-125 seeds, including determining the root cause. The inspector concurred with the licensee's root cause determination. In addition, the inspector identified that the staff failed to survey the Mick applicator or the magazine in order to properly account for the two iodine-125 seeds. The inspector also identified contributing factors to the medical event that included: (1) the limited experience of the individual in handling the applicator and sources; and (2) the authorized user's and medical physicist's failure to communicate with the technologist to ensure that the seeds were properly accounted for prior to releasing the equipment from the surgical suite for decontamination/cleaning. The licensee implemented corrective actions in response to the apparent violations.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude a similar event. The inspector also interviewed selected licensee personnel and observed demonstrations of surveys and the technique to remove the magazine from the Mick applicator.

3.2 Observations and Findings

The licensee's proposed corrective actions to preclude the likelihood of a similar event included: (1) conducting in-service training to the hospital staff directly involved with the event of May 7, 2008; (2) developing a competency training program for brachytherapy technologists; (3) conducting a training session for the entire radiation oncology staff; and (4) requiring visual and survey verification of any extra seeds within the magazine and the applicator (at the conclusion of an implant), while in the operating room, prior the releasing the equipment for decontamination.

3.3 Conclusions

The inspector concluded that the licensee developed and implemented corrective actions to address the root causes of the loss of the iodine-125 seeds.

4 Notifications and Reports

4.1 Inspection Scope

The inspector interviewed the Radiation Safety Officer and reviewed the licensee's event report to determine what notifications and reports had been made to the NRC concerning the event. The inspector also reviewed the licensee's telephonic event notification to the NRC Operations Center on May 8, 2008, and the licensee's written report dated June 5, 2008

4.2 Observations and Findings

The licensee notified the NRC regarding the lost sources on May 8, 2008, as required by 10 CFR 20.2201(a)(i). The licensee provided its 30-day report in accordance with 10 CFR 20.2201(b).

4.3 Conclusions

The licensee made all of the notifications and submitted the 30-day report required by 10 CFR 20.2201 within the specified time period. The inspector determined that the licensee included all of the required information in the report. No violations of NRC reporting requirements were identified.

5 Exit Meeting Summary

The inspector discussed the preliminary conclusions, as described in this report, with licensee management during the exit meeting conducted at the licensee's facility on May 22, 2008. The inspector discussed the activities reviewed, the inspection findings, and the apparent violations. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

List of Personnel Contacted

- *Bruce Backus, Assistant Vice Chancellor, Environmental Health & Safety
 - Jackie Esthappan, Ph.D., Authorized Medical Physicist
 - *Jose Garcia-Ramirez, M.S., Medical Physicist
 - *Jerry Glotzer, M.S., Director, Environmental Health and Safety
 - *Susan Langhorst, Ph.D., CHP, Radiation Safety Officer
 - *David Luechtefeld, Health Physicist
 - Wei Lu, Ph.D., Medical Physicist
 - Janet Lynch, R.N., Brachytherapy Technologist
 - *Jeff Michalski, M.D., Radiation Oncologist, Authorized User
 - Arvis Moore, RT(T), Brachytherapy Technologist
 - *Sasa Mutic, M.S., Authorized Medical Physicist
 - W. John Smith II, Ph.D., Associate Radiation Safety Officer
 - Daniel J. Szatkowski, CHP, Health Physicist
- +Charles Smith, Quality Manager, Mick Radio-Nuclear Instruments, Inc.
- *Individuals present during exit meeting
+Individual contacted by telephone