March 15, 2012

NMED No. 110567 (CLOSED)

Ms. Alice Gerard, Chief Executive Officer
Bay Regional Medical Center
1900 Columbus Avenue
Bay City, Michigan 48708

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03013900/11-001(DNMS) ─ BAY REGIONAL MEDICAL CENTER

Dear Ms. Gerard:

On October 27 through 28, 2011, and January 11 through 12, 2012, with continued in-office review through February 21, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of your facility located in Bay City, Michigan. The NRC in-office review included receipt and review of information that was unavailable during the onsite inspection, including information about reported medical events. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. On February 29, 2012, an inspector conducted a final exit meeting by telephone with members of your staff to discuss the inspection findings. The enclosed report presents the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety, compliance with the Commission's rules and regulations, and compliance 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, a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation involved the failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the NRC inspectors.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03013900/11-001(DNMS). Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective

actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

As discussed in Section 2.2.b of the subject report, the potential medical events that were identified by the inspectors during the onsite inspection in October 2011 were based on information that the inspectors obtained during interviews with members of your staff. The inspectors communicated their understanding of the facts to provide the bases for those potential medical events to your staff members prior to leaving your facility in October. It was not until late November that the inspectors were notified by your staff that the bases for the potential medical events were incorrect. It is imperative that the information providing the bases for inspection findings is accurate. As such, it is incumbent on a licensee's staff to take prompt action as necessary to ensure that they provide accurate information to the inspector, upon which inspection findings are based. For example, if an inspector states their understanding of a demonstrated or discussed issue and your staff member identifies an inaccuracy, it is important for your staff member to discuss the inaccuracy with the inspector as soon as possible.

In accordance with Title 10 of the Code of Federal Regulations 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-13900
License No. 21-18585-01

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03013900/11-001(DNMS)

cc w/encl: Tyre Jones, M.D., Radiation Safety Officer
State of Michigan

actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

As discussed in Section 2.2.b of the subject report, the potential medical events that were identified by the inspectors during the onsite inspection in October 2011 were based on information that the inspectors obtained during interviews with members of your staff. The inspectors communicated their understanding of the facts to provide the bases for those potential medical events to your staff members prior to leaving your facility in October. It was not until late November that the inspectors were notified by your staff that the bases for the potential medical events were incorrect. It is imperative that the information providing the bases for inspection findings is accurate. As such, it is incumbent on a licensee's staff to take prompt action as necessary to ensure that they provide accurate information to the inspector, upon which inspection findings are based. For example, if an inspector states their understanding of a demonstrated or discussed issue and your staff member identifies an inaccuracy, it is important for your staff member to discuss the inaccuracy with the inspector as soon as possible.

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We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

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Enclosures:
1. Notice of Violation
2. Inspection Report No. 03013900/11-001(DNMS)

cc w/encl: Tyre Jones, M.D., Radiation Safety Officer
State of Michigan

DISTRIBUTION:
Jennifer Uhle
Anne Boland
Patrick Louden
Steven Orth
Carole Ariano
Paul Pelke
Patricia Buckley
Tammy Tomczak
MIB Inspectors

*See previous concurrence
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NOTICE OF VIOLATION

Bay Regional Medical Center
Bay City, Michigan

Docket No. 030-13900
License No. 21-18585-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 27 through 28, 2011, and January 11 through 12, 2012, with continued NRC in-office review through February 21, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the Code of Federal Regulations (CFR) Part 35.41(a) requires, in part, that for any administration requiring a written directive, the licensee shall maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Contrary to the above, at the time of the inspection on October 27, 2011, the licensee had not revised its written procedures to provide high confidence that each manual brachytherapy administration is in accordance with the written directive since August 1998. Specifically, the procedure was not based on the current version of 10 CFR Part 35, and it did not include "medical event" per 10 CFR 35.2 and it did not require the "treatment site" as part of the written directive prior to implantation per 10 CFR 35.40(b)(6)(i).

This is a Severity Level IV Violation (Section 6.3.d.1).

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-13900
License No.	21-18585-01
Report No.	03013900/11-001(DNMS)
NMED No.	110567
Licensee:	Bay Regional Medical Center
Facility:	1900 Columbus Avenue Bay City, Michigan 48708
Exit Date:	February 29, 2012
Inspectors:	Robert G. Gattone, Jr., Senior Health Physicist Claire E. Wellinghoff, Health Physicist
OI Assist:	Scott Kryk, Special Agent
Approved By:	Tamara E. Bloomer, Chief Nuclear Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Bay Regional Medical Center
NRC Inspection Report 03013900/11-001(DNMS)

During a routine inspection, the inspectors identified two potential medical events involving iodine-125 prostate implants. During interviews with licensee staff members, the inspectors learned that the staff had the patients return about 2 to 3 weeks after the implant was done to have a Post-Op treatment plan based on a computerized axial tomography (CAT scan) of the prostate gland and adjacent organs and tissues. At that time the licensee used its treatment planning system to assess the quality of the prostate implants, including the administered doses versus the prescribed doses to, in part, determine if a medical event occurred. Based on a review of recent implant records, the inspectors identified two potential medical events involving Post-Op administered doses that differed from the prescribed doses by 20 percent or more. Based on these findings, the licensee conducted an extent of condition review per the inspectors' request and it identified and reported to the NRC 14 additional medical events that involved Post-Op administered doses that differed from the prescribed doses by 20 percent or more.

In late November, the licensee notified the inspectors that, as of the inspection, they did not use the Post-Op treatment plan to assess the administered doses versus the prescribed doses to determine if a medical event occurred. The licensee stated that it used the Pre-Op treatment plan that was conducted on the day of implant to determine if a medical event occurred. The Pre-Op treatment plan was actually conducted after all of the sources were implanted and it involved ultrasound imaging and the treatment planning system to, in part; determine the administered dose on the day of implant. In addition, the licensee stated that they rescinded all of the medical event reports because, for each case, the administered doses did not differ from the prescribed doses by 20 percent or more based on the Pre-Op treatment plan data. The inspectors confirmed the information provided in the letter dated November 29, 2011, by interviewing the selected licensee staff members on January 11 and 12, 2012. Based on this new information, the inspectors determined that the 15 reported medical events involving authorized user 2 (AU2) were not medical events.

The inspectors identified a violation regarding licensee failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee implemented corrective actions. On December 27, 2012, the licensee revised its procedure to: (1) reflect the prostate implant procedure they currently perform; (2) include the means of assessment for prescribed versus administered dose to determine if a medical event occurs; (3) and include relevant Title 10 of the Code of Federal Regulations Part 35 information.

Report Details

1 Program Scope and Inspection History

The NRC License Number 21-18585-01 authorizes Bay Regional Medical Center (licensee) to use byproduct material for manual brachytherapy, radiopharmaceutical therapy, diagnostic imaging, and uptake and dilution studies. Manual brachytherapy and radiopharmaceutical therapy were not conducted during the onsite inspection. The licensee's manual brachytherapy activities were limited to about one prostate implant per month using iodine-125 seeds. The licensee's radiopharmaceutical therapy activities were limited to approximately 24 iodine-131 thyroid treatments per year. The licensee conducted the full spectrum of diagnostic nuclear medicine studies.

No violations of NRC requirements were identified as a result of the last two routine safety inspections conducted on April 29, 2008, and July 27, 2006.

2 Manual Brachytherapy

2.1 Inspection Scope

The inspectors reviewed the licensee's manual brachytherapy activities by interviewing selected staff, including two authorized users, a medical physicist, and a dosimetrist. In addition, the inspectors reviewed selected records including the licensee's written procedures to provide high confidence that prostate gland treatments were in accordance with the written directives and treatment plans and records of the nine most recently performed prostate implants. The inspectors reviewed actions taken to ensure that the treatments were in accordance with the written directives and treatment plans.

2.2 Observations and Findings

a. Prostate Brachytherapy Methodology

As of October 27, 2011, the authorized users used "total dose" as the prescribed dose for prostate gland treatments. The licensee imaged the patients' prostate glands using ultrasound to determine the prostate volume. Afterward, the licensee used a nomogram to determine the total radioactivity of iodine-125 seeds needed to achieve the prescribed dose based on the measured prostate volume.

On the day of treatment, the authorized users signed and dated written directives for the treatments. The licensee conducted several checks to ensure that the prescribed dose was administered to the correct patient in accordance with the written directives and the treatment plans. For example, members of the licensee's staff verified that the dose calibrator was set to measure iodine-125 before they measured a sample of the seeds to verify that they contained the correct radioactivity per seed based on a comparison with the vendor's records of radioactivity per seed. In addition, a medical physicist verified treatment planning parameters prior to implantation, such as verification of the patient's identity by two methods, the prostate volume, the number of iodine-125 seeds, the radioactivity per seed, the seed positions, and agreement with the written directive. The licensee conducted intraoperative planning using ultrasound imaging and the treatment planning system to visualize isodose lines in three dimensions. As the seeds

were put into the patient real time, the authorized users watched the dose cloud to verify correct seed placement.

After the last seed was implanted, the treatment planning system and ultrasound images were used to generate a Pre-Op treatment plan that indicated dose information on the day of the implant, including, but not limited to, V100 and D100. V100 is defined as the percentage of the prostate volume that received greater than or equal to 100 percent of the prescribed dose. D100 is defined as the minimum dose that covers 100 percent of the prostate volume.

Authorized User 1 (AU1) stated that he used D100 as the criterion for assessing the administered versus prescribed dose to determine if a medical event occurred. AU1's goal was to get a D100 of 100 percent. In addition, AU1 used the Pre-Op treatment plan to determine if the implant resulted in a medical event (e.g., if the D100 is 80 percent or less, a medical event may have occurred if not addressed while the patient was being treated). The authorized user and a medical physicist evaluated the Pre-Op treatment plans to assess the quality of the implants. For example, the doses to critical tissues, V100, and D100 were evaluated.

The patients returned about 2 to 3 weeks after the implant; the licensee brought the patients back to perform a "Post-Op" treatment plan based on a computerized axial tomography (CAT scan) of the prostate gland and adjacent organs and tissues and the licensee's use of its treatment planning system to assess the quality of the prostate implants.

On October 27, 2011, authorized user 2 (AU2) stated that V100 was used as the criterion for assessing the administered versus prescribed dose to determine if a medical event occurred. AU2's goal was to get a V100 of 100 percent (i.e., 100 percent of the prescribed dose is delivered to 100 percent of the prostate volume). In addition, AU2 and a medical physicist indicated that the Post-Op treatment plan was used to determine if the implant resulted in a medical event. AU2 and a medical physicist evaluated the Post-Op treatment plans to assess the quality of the implants. For example, the doses to critical tissues, V100, and D100 were evaluated.

b. Identification of Medical Events

1. Identification Based on Initial Information

On January 11, 2011, the licensee implanted 31 iodine-125 seeds containing a total of 14.4 millicuries into a patient's prostate gland based on a written directive that was signed and dated by AU2; however, four seeds were recovered from the patient's urine by the licensee after implantation prior to release of the patient from the recovery suite. The prescribed dose was 90 Gray to be delivered to the prostate gland, which was the treatment site. As previously discussed, AU2 stated that V100 was used to determine if prostate implants resulted in a medical event as of the October 27, 2011 inspection, with the goal of achieving a V100 of 100 percent. In addition, AU2 and a medical physicist indicated that the Post-Op treatment plan was used to determine if implants resulted in a medical event.

On January 26, 2011, the licensee conducted a CAT scan and, on February 3, 2011,

the licensee conducted a Post-Op treatment plan based on the CAT scan to evaluate the treatment. The Post-Op treatment plan printout stated, in part, that the V100 was 80 percent. In addition, based on the inspectors' observation of the medical physicist's use of the treatment planning system, portions of the prostate gland received more than 50 rem less than what was prescribed based on analysis of the Post-Op treatment plan.

On August 23, 2011, the licensee implanted 27 iodine-125 seeds containing a total of 12.4 millicuries into a patient's prostate gland based on a written directive that was signed and dated by AU2. The prescribed dose was 90 Gray to be delivered to the prostate gland, which was the treatment site.

On September 14, 2011, the licensee conducted a CAT scan and, on September 15, 2011, the licensee conducted a Post-Op treatment plan based on the CAT scan to evaluate the treatment. The Post-Op treatment plan printout stated, in part, that the V100 was 68 percent. In addition, based on the inspectors' observation of the medical physicist's use of the treatment planning system, portions of the prostate gland received more than 50 rem less than what was prescribed based on analysis of the Post-Op treatment plan.

Title 10 CFR 35.2 defines "medical event" as administration of radiation from byproduct material that results in a dose that differs from the prescribed dose by more than 50 rem to an organ or tissue and the total dose delivered differs from the prescribed dose by 20 percent or more. The inspectors initially identified that the prostate implants that were conducted on January 11 and August 23, 2011, were medical events because they were administrations of radiation from byproduct material that resulted in a dose 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 or more.

The inspectors requested the licensee to review all of the other prostate implant cases that were conducted since the last NRC inspection that was done in April 2008 to determine if additional medical events had occurred. As a result of its review, the licensee identified 14 additional medical events out of about 44 cases that were conducted since April 2008 using the assessment parameters discussed in the October 27, 2011 inspection (i.e., using the Post-Op treatment plan and V-100). AU1 was involved with 1 of the 14 licensee identified medical events, and AU2 was involved with the remaining 13 licensee-identified medical events. Each of the 14 licensee identified medical events involved administrations of radiation from byproduct material that resulted in a dose 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 or more based on AU2's criteria to assess administered versus prescribed dose to determine if a medical event occurred. That is, if the Post-Op treatment plan V100 is 80 percent or less, then a medical event occurred.

The inspectors determined that the licensee-identified medical event involving AU1 was not a medical event because it did not meet AU1's criteria to assess administered versus prescribed dose to determine if a medical event occurred. As discussed in Section 2.2.a., AU1 used D100 as the criterion for assessing the administered versus prescribed dose to determine if a medical event occurred.

AU1's goal was to get a D100 of 100 percent (i.e., a minimum dose covering 100 percent of the prostate). In addition, AU1 used the Pre-Op treatment plan to determine if the implant resulted in a medical event (e.g., if the D100 is 80 percent or less, a medical event occurred). The licensee-identified medical event involving AU1 had a Pre-Op treatment plan D100 of greater than 80 percent; therefore, the licensee-identified medical event involving AU1 was not a medical event.

The inspectors determined that the causes of the medical event that occurred on January 11, 2011, were that: (1) between the Pre-Op treatment plan and the Post-Op CAT scan, the patient's prostate gland swelled 10 percent larger, resulting in less dose being delivered to the treatment site; and (2) the licensee's recovery of four seeds in the patient's urine shortly after the implant, which represented about 13 percent of the total radioactivity that was to be administered to achieve the prescribed dose. In addition, the inspectors determined that the contributing factors for the medical event were that: (1) the licensee conducted the Post-Op CAT scan only 15 days after the implant, which reduced the potential for the prostate gland swelling to subside; and (2) the licensee did not conduct another CAT scan and Post-Op treatment plan to determine if the administered dose changed incident to a reduction of prostate gland swelling.

The licensee determined that the medical event occurred because: (1) the patient's prostate gland swelled 10 percent larger; and (2) of the expected variability in the drawing of prostate volume contours based on ultrasound and CT images.

The inspectors determined that the cause of the medical event that occurred on August 23, 2011, was that between the Pre-Op treatment plan and the Post-Op CAT scan, the patient's prostate gland swelled 28 percent larger, resulting in less dose delivered to the treatment site. In addition, the inspectors determined that the contributing factors for the medical event were that: (1) the licensee conducted the Post-Op CAT scan 22 days after the implant, which reduced the potential for the prostate gland swelling to subside; and (2) the licensee did not conduct another Post-Op CAT scan and treatment plan to determine if the administered dose changed incident to a reduction of prostate gland swelling.

The licensee determined that the medical event occurred because: (1) the patient's prostate gland swelled 28 percent larger; and (2) of the expected variability in the drawing of prostate volume contours based on ultrasound and CT images.

2. Final Determination

On November 30, 2011, AU2 submitted a facsimile letter to the inspectors dated November 29, 2011, stating that, as of the inspection, the Post-Op treatment plan was not used to assess the administered doses versus the prescribed doses to determine if a medical event occurred. Instead, the Pre-Op treatment plan that was conducted on the day of implant was used to determine if a medical event occurred. The Pre-Op treatment plan was actually conducted after all of the sources were implanted and it involved ultrasound imaging and the treatment planning system to, in part; determine the administered dose on the day of implant. In addition, the letter stated that the licensee is rescinding all of the medical event reports because, for each case, the administered doses did not differ from the prescribed doses by

20 percent or more based on the Pre-Op treatment plan data. The inspectors confirmed the information provided in the letter dated November 29, 2011, by interviewing selected licensee staff members on January 11 and 12, 2012. Based on this new information, the inspectors determined that the 15 reported medical events involving AU2 were not medical events.

c. Written Procedures for Prostate Brachytherapy

The licensee developed written procedures to provide high confidence that the patient's identity is verified before each administration and each administration is in accordance with the written directive. However, the procedures had not been maintained. Specifically, the procedures had not been revised since August 1998 and they were based on the version of 10 CFR Part 35 that existed prior to the last major revision that occurred approximately ten years ago. For example, the licensee's procedures referenced obsolete terms such as "misadministrations" and "recordable events," and did not include "medical event" per 10 CFR 35.2 and did not require the "treatment site" as part of the written directive prior to implantation per 10 CFR 35.40(b)(6)(i). In addition, the procedures did not fully reflect the licensee's current prostate brachytherapy methodology. For example, the procedures were silent regarding: (1) AU1's use of D100 as the criterion for assessing the administered versus prescribed dose to determine if a medical event occurred; (2) AU2's use of V100 as the criterion for assessing the administered versus prescribed dose to determine if a medical event occurred; (3) AU1's use of the Pre-Op treatment plan to determine if the implant resulted in a medical event; and (4) AU2's use of the Pre-Op treatment plan to determine if the implant resulted in a medical event (as stated in the aforementioned letter dated November 29, 2011, and during interviews on January 11 and 12, 2012).

Title 10 CFR 35.41(a) requires that, for any administration requiring a written directive, the licensee shall 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 licensee's failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive is a violation of 10 CFR 35.41(a). The violation occurred because the staff involved with prostate implants had not referenced the procedures since about five years before the onsite inspection. In fact, the staff did not know where the procedures were kept when the inspectors requested to review them, and had to search for them until they were found in a hot lab.

Although the licensee's procedures had not been reviewed by applicable staff for about five years, several applicable portions of the outdated procedures were implemented. For example, the licensee verified the patients' identities by at least two methods, recorded the methods used to verify the patients' identities, used the initial prostate volume and a nomogram to estimate the number of seeds and total activity for the implants, verified the radioactivity of the seeds by measuring a sample of the seeds prior to implantation, and imaged the prostate glands with ultrasound.

2.3 Conclusions

The inspectors identified a violation involving licensee failure to maintain written

procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a). In addition, the inspectors identified two medical events, and the licensee identified 14 additional medical events based on its review of all other prostate implant cases that were conducted since the last NRC inspection. The two inspectors identified medical events and the 14 licensee identified medical events were subsequently rescinded following receipt of new information that was provided by the licensee.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors reviewed selected records and interviewed selected staff to assess the licensee's notification and reporting of medical events. The inspectors reviewed the licensee's notification of the inspector identified medical events to the NRC Operations Center dated October 28, 2011, and the licensee's update notification of the licensee-identified medical events to the NRC Operations Center dated November 1, 2011. The inspectors also reviewed the licensee's associated written reports of the medical events that were submitted via email on November 11, 2011, to assess compliance with reporting requirements. In addition, the licensee's notification to rescind all reported medical events dated November 29, 2011 was reviewed by the inspectors.

3.2 Observations and Findings

On October 28, 2011, the licensee notified the NRC Operations Center of the inspector identified medical events in a timely manner. On November 1, 2011, the licensee notified the NRC Operations Center about the licensee identified medical events in a timely manner. The licensee notified the referring physicians about the medical events. The licensee notified most of the patients about the medical events (one was deceased). The licensee attempted to notify the remaining patients about the medical events, but it was unable to do so. Nonetheless, the licensee continued to try and notify those patients.

The licensee provided its written reports of the medical events in an email to an inspector dated November 11, 2011. The inspectors identified errors with some of those written reports and they requested the licensee to submit corrected information. On November 15, and December 22, 2011, the licensee submitted the requested information. The inspectors determined that the written reports included the information required by 10 CFR 35.3045(d).

On November 29, 2011, the licensee submitted a notification to the inspectors retracting the 16 reported medical events. In addition, on December 1, 2011, the licensee notified the NRC Operations Center that it was retracting all 16 medical event notifications.

3.3 Conclusions

The inspectors determined that the licensee provided the notifications and written report as required by 10 CFR 35.3045.

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspectors interviewed selected staff and reviewed selected records to identify the corrective actions that the licensee implemented and planned to address the aforementioned violation.

4.2 Observations and Findings

The licensee's failure to maintain written procedures to provide high confidence that each administration is in accordance with the written directive is a violation of 10 CFR 35.41(a). The violation occurred because the procedure had not been revised since August 1998 and was not consistent with their current process.

On December 27, 2012, the licensee revised its procedure to: (1) reflect the prostate implant procedure they currently perform; (2) include the means of assessment for prescribed versus administered dose to determine if a medical event occurs; and (3) include relevant 10 CFR Part 35 information. The licensee revised the procedure prior doing the first prostate implant after October 28, 2011. In addition, the licensee committed to have its Radiation Safety Committee conduct annual reviews of its procedure to ensure that it is maintained.

4.3 Conclusions

The inspectors determined that the licensee developed corrective actions to address the violations.

5 Other Areas Inspected

5.1 Inspection Scope

The inspectors reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspectors, and reviewing selected records. Areas reviewed included radioactive spill response, implementation of procedures to provide high confidence that radiopharmaceuticals are administered in accordance with written directives, preparation and administration of diagnostic dosages, and program oversight.

5.2 Observations and Findings

The inspectors observed a nuclear medicine technologist (NMT) decontaminate a minor spill of a technetium-99m labeled diagnostic radiopharmaceutical on a floor. The inspectors noted that the NMT used proper decontamination technique. The NMT wore personal protection equipment (PPE) to prevent personal contamination (e.g., booties and gloves). Additionally, the NMT wore his whole body and extremity radiation dosimeters.

The inspectors noted that several selected iodine-131 labeled sodium iodide administrations were administered with actions taken to provide high confidence that the dosages were administered in accordance with the written directives. For example, properly prepared written directives were used and compared with the dosages prior to administration.

A nuclear medicine student prepared and administered a diagnostic technetium-99m labeled radiopharmaceutical while wearing PPE, including gloves and a lab coat. In addition, the student wore his whole body and extremity radiation dosimeters. The student also properly measured the dosage radioactivity prior to administration and used a syringe shield during the injection.

During review of the licensee's oversight of its radiation protection program, the inspectors noted that the licensee had a consultant conduct quarterly audits of its radiation protection program. The audit records indicated that applicable areas of the program were audited regularly. The consultant also conducted sealed source inventories and leak tests. In addition, the inspectors noted that the licensee's Radiation Safety Committee met regularly and the attendees included, in part, a medical physicist, the Radiation Safety Officer, a management representative, and an NMT.

5.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program.

6 Exit Meeting Summary

At the completion of the onsite inspection, the inspector discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on February 29, 2012.

Attachment: Partial List of Persons Contacted

PARTIAL LIST OF PERSONNEL CONTACTED

^Chris Cossins, Manager
Michele Davis, Dosimetrist
^*Steve Gerhardt, Lead Nuclear Medicine Technologist
^*Tyre Jones, M.D., Radiation Safety Officer
^*Dennis Kehoe, Medical Physicist
Paul Kocheril, M.D., Authorized User
^Tom Kumpuris, Consultant
*Julie Laskowski, Diagnostic Imaging Manager
^*Kim Ligney, Registered Nurse
James Littles, M.D., Authorized User
Fred Srankoski, Nuclear Medicine Technologist
Stephanie Schnell, Nuclear Medicine Technologist
Pete Schuller, Nuclear Medicine Student
Brad Strong, Nuclear Medicine Student
^Jay Summer, M.D., Vice President of Medical Affairs
^*Ellen Talbott, Vice President of Patient Care Services
Carrie Wetherell, Nuclear Medicine Technologist

* Attended preliminary exit meeting on October 28, 2011
^ Participated in final telephonic exit meeting on February 29, 2012

INSPECTION PROCEDURES USED

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87131