February 7, 2011

EA-11-010
NMED No. 100597 (CLOSED)

Mr. Eric Widner, MBA
President and Chief Executive Officer
Oakwood Hospital – Annapolis Center
33155 Annapolis Avenue
Wayne, MI 48184

SUBJECT: NRC INSPECTION REPORT NO. 03002099/2010-001(DNMS)
OAKWOOD HOSPITAL – ANNAPOLIS CENTER

Dear Mr. Widner:

On December 14, 2010, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection at the Oakwood Hospital – Annapolis Center with continued NRC in-office review through January 11, 2011. The in-office review included a review of your staff's written report dated December 20, 2010. The enclosed report presents the results of this inspection.

The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on December 4, 2010. During this inspection, the NRC staff also examined activities conducted under your license related to public health and safety, and security. Additionally, the staff examined your compliance with the Commission's rules and regulations, orders, 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). The apparent violations involve the administration of a diagnostic dosage that differed from the prescribed dosage by more than 20 percent and the failure to verify the quantity of byproduct material and the physical/chemical form of the dosage prior to the administration. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the preliminary exit meeting on December 14, 2010, and during the final telephone exit meeting with Ms. Dawn Baker of your staff on January 11, 2011. 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.

Further, the inspector identified prostate brachytherapy post-treatment plans where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. Due to questions regarding the methodology for assigning the dose to the treatment site, this issue has been identified as an open item. You will be notified in separate correspondence of the results of our review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). If a PEC is held, it will be opened to the public. Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time.

In your case, the NRC has concluded that information regarding the reason for the violation and the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in the enclosed report. 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 action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. Therefore, you are not required to either respond in writing or to attend a PEC unless the description herein does not accurately reflect your corrective actions or your position. Please contact Tamara E. Bloomer at 630-829-9627 within seven days of the date of this letter of your intentions.

If you choose to provide a written response, it should be clearly marked as a Response to the Apparent Violation in Inspection Report No. 03002099/2010-001(DNMS); EA-11-010 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 violations. 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 an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

Please be advised that the number and characterization of any 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.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, 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.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02099
License No. 21-11457-02

Enclosure:
Inspection Report 030-02099/2010-001(DNMS)

should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02099
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Enclosure:
Inspection Report 030-02099/2010-001(DNMS)

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U.S. NUCLEAR REGULATORY COMMISSION
REGION III

Docket No.:	030-02099
License No.:	21-11457-02
Report No.:	030-02099/2010-001(DNMS)
Licensee:	Oakwood Hospital – Annapolis Center
Location:	33155 Annapolis Avenue Wayne, Michigan
Dates:	December 14, 2010, with continued in-office review through January 11, 2011
Final Exit Meeting:	January 11, 2011 (Telephone)
Inspector:	Deborah A. Piskura, Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials

Enclosure

EXECUTIVE SUMMARY

Oakwood Hospital – Annapolis Center
Wayne, Michigan
Inspection Report No. 03002099/2010-001(DNMS)

The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a medical event that occurred on December 4, 2010, involving an inadvertent administration of 124.5 millicuries of sodium pertechnetate technetium-99m (Tc-99m) to a patient rather than the prescribed dosage of 10 millicuries Tc-99m tetrofosmin (Myoview™) for a resting cardiac imaging study as part of a cardiac exam. The error was initially discovered while imaging the patient and subsequently determined to be a medical event by the licensee's consultant when he calculated the whole body dose. The licensee's consultant estimated that the whole body dose to the patient was approximately 6 rem rather than the expected dose of 0.481 rem. The licensee concluded that the medical event would not result in adverse health consequences for the patient.

To reduce the likelihood of a similar event, the licensee's proposed corrective actions included: (1) increased supervision of the technologist directly involved with the medical event; (2) requesting that bulk Tc-99m be only dispensed from the radiopharmacy in vials; (3) re-instruction of nuclear medicine staff on the hospital's policies and procedures for handling doses prior to administration which included documentation of competency training; and (4) random audits of staff to evaluate performance including assays of doses prior of administration.

The inspector identified an apparent violation of Title 10 of the Code of Federal Regulations (CFR) 35.63(d) involving the administration of a bulk quantity of Tc-99m that differed from the prescribed dosage by more than 20 percent. The inspector also identified an apparent violation of License Condition 15.A, referencing the licensee's policies and procedures for safe handling of radiopharmaceuticals, which requires the licensee to verify that the assayed dosage was within ±10 percent of the prescribed activity, and to check the prescribed radiopharmaceutical and dosage prior to administering the dosage to a patient.

Report Details

1 Program Scope and Inspection History

License Number 21-11457-02 authorizes Oakwood Hospital – Annapolis Center (licensee) to use a variety of byproduct materials for medical purposes, including diagnostic nuclear medicine, and sealed sources for permanent prostate brachytherapy implants. The nuclear medicine department operated seven days per week and typically administered 200-250 diagnostic studies monthly. The licensee obtained its radiopharmaceuticals from a licensed commercial nuclear pharmacy in unit doses (cardiac procedures) and bulk quantities of thallium-201 and Tc-99m for kit preparation of all other diagnostic studies. Prior to December 8, 2010, the licensee received its bulk Tc-99m in a three cubic centimeter syringe, the same volume as a unit dose. The licensee retained the services of a consulting physicist to audit the radiation safety program on a quarterly basis.

The U.S. Nuclear Regulatory Commission (NRC) previously inspected the licensee's activities on September 12, 2002, and February 15, 2008, with no violations noted.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the licensee's investigation of the medical event. The inspector also interviewed selected licensee personnel, and observed related equipment and facilities.

2.2 Observations and Findings

On the morning of Saturday, December 4, 2010, a 77 year-old female was scheduled for a cardiac study. The licensee's procedures specified a dosage of 10 millicuries of Tc-99m Myoview™ to be administered for a resting cardiac imaging study. The hospital received its Myoview™ in unit doses. The majority of other diagnostic studies were prepared in the nuclear medicine hot lab from bulk Tc-99m. Earlier that morning, the technologist on duty prepared a kit from the syringe containing 150 millicuries bulk Tc-99m (calibrated at 12:00 p.m.) for a lung perfusion study on the first scheduled patient. The technologist withdrew approximately 64 millicuries of technetium-99m from the syringe containing the bulk quantity. The technologist administered the material for the lung study; however, the imaging took longer than expected and resulted in delays for the remaining scheduled patient studies.

Approximately mid-morning, prior to the administration of the Myoview™, the technologist assayed the unit dosage, inserted the syringe in a syringe shield, and placed the dosage on the hot lab counter behind the bench shield. The technologist placed the unit dose next to the shielded syringe containing the bulk Tc-99m. At approximately 10:30 a.m., the technologist, intending to retrieve the Myoview™ unit dose, inadvertently selected the shielded syringe containing the bulk Tc-99m. He injected the material into the patient and instructed the patient to return to the department for imaging at approximately 11:00 a.m. As the staff acquired the patient images, the technologist, along with another assisting technologist, discovered that the region of interest, the heart, was not visible.

The technologist recognized that he probably administered the wrong radiopharmaceutical, informed the patient that her exam would need to be rescheduled, and notified his management. Although the licensee staff determined that the technologist inadvertently administered approximately 100 millicuries of bulk Tc-99m, they initially believed that this quantity did not result in a dose to the patient which would require reporting to the NRC. Further estimations by the licensee determined that approximately 124.5 millicuries of the bulk Tc-99m was injected into the patient.

On December 6, 2010, the licensee's consulting physicist calculated that the dose to the upper lower intestine from the administration of 124.5 millicuries as approximately 27 rads and the whole body equivalent as approximately 6 rem. The consultant advised the licensee that the event was a reportable medical event in accordance with 10 CFR 35.3045 (a)(1), because the dose delivered to the patient differed from that of the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) to the whole body and the total dosage delivered differed from the prescribed dosage by 20 percent or more.

The nuclear medicine technologist, who administered the bulk Tc-99m, indicated that he failed to check the label and to assay the syringe containing the bulk Tc-99m just prior to injection, because he was in a hurry to appease the patient who complained of waiting. Although he had previously assayed the syringe containing the unit dose, approximately 30 minutes prior to the injection time, he placed the unit dose next to the syringe containing the bulk pertechnetate behind the L-shield. The two syringes in their shields lay side-by-side behind the L-shield and were identical in appearance. The respective labels were obscured by the syringe shields. When the technologist was ready to inject the dosage, he selected the syringe containing the bulk pertechnetate without verifying the label or assaying the dosage in the dose calibrator.

Title 10 CFR Part 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range, or if the dosage differs from the prescribed dosage by more than 20 percent. The licensee's administration of bulk Tc-99m to the patient differed from the prescribed diagnostic dosage of Tc-99m Myoview™ by more than 20 percent, is an apparent violation of 10 CFR 35.63(d).

License Condition No. 15.A. of NRC License No. 21-11457-02 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 8, 2000. Item 10.3 of this application lists the licensee's Laboratory Safety Rules. Item 18 states, "assayed dispensed doses must be within ±10 percent of the prescribed activity or within the prescribed activity range, unless approved by the authorized user." Item 19 states, "always check the patient's name, identification, the prescribed radiopharmaceutical and dosage prior to administration." The licensee administration of material in a syringe containing Tc-99m and its failure to verify that the assayed dosage was within ±10 percent of the prescribed activity and that dispensed dose was approved by the authorized user is an apparent violation of License Condition 15.A. Furthermore, the licensee failed to check the prescribed radiopharmaceutical and dosage prior to administration which in another example of an apparent violation of License Condition 15.A.

The root cause regarding the apparent violations was human error by the nuclear medicine technologist. The technologist initially assayed the Tc-99m Myoview™ dose and placed it behind a radiological shield, along with a syringe containing a bulk pharmaceutical of Tc-99m sodium pertechnetate. The technologist indicated that he experienced difficulties managing a prior patient which delayed his other patient cases and those patients expressed their discontent about the delays, upsetting the technologist. Because the technologist was upset and in a hurry, he selected the wrong syringe of the two identical syringes behind the radiological shield. A contributing factor was that the bulk pertechnetate was received from the nuclear pharmacy in a syringe identical to that of a unit dose. The technologist also became distracted by another hospital staff member who asked questions about the meaning of certain laboratory results, unrelated to the cardiac study, while the technologist prepared for the patient's study. However, the technologist failed to follow the licensee's procedures to verify the prescribed radiopharmaceutical and dosage prior to administering the dosage to the patient. The licensee's medical staff evaluated the potential adverse effects on the patient and concluded that the unintended dose to the patient would not cause an adverse health effects.

2.3 Conclusions

The inspector determined that a medical event occurred because the licensee failed to verify the radionuclide, chemical form, and dosage prior to administering the dosage. In addition, the method which the licensee received its bulk Tc-99m from the nuclear pharmacy contributed to the event because it was identical to the unit dose intended for the patient. The inspector identified an apparent violation of 10 CFR 35.63(d) involving the licensee's administration of a dosage that differed from the prescribed dose by more than 20 percent. The inspector also identified an apparent violation of License Condition No. 15.A. involving the licensee's failure to check the prescribed radiopharmaceutical and dosage before administering the dosage to the patient.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to prevent similar events. The inspector also interviewed selected licensee personnel.

3.2 Observations and Findings

The licensee took immediate corrective actions which included increased supervision of the technologist directly involved with the medical event. The licensee provided instruction to the nuclear medicine staff on the hospital's policies and procedures for handling doses prior to administration which included documentation of competency training. The department management implemented a process to conduct random audits of staff to evaluate performance including assays of doses prior of administration.

On December 8, 2010, the licensee contacted the nuclear pharmacy and requested the pharmacy to dispense the hospital's standing orders of bulk Tc-99m in vials only. In addition, the licensee changed its hot lab configuration to physically separate and color-code its bulk quantities of material.

3.3 Conclusions

The inspector determined that the licensee implemented adequate corrective actions to address the root cause of the medical event.

4 Notifications and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notifications to the NRC Operations Center, the referring physician, and the patient. In addition, the inspector reviewed the licensee's written report describing the medical event.

4.2 Observations and Findings

On December 6, 2010, the licensee notified the NRC Operations Center of the medical event once it became aware of the whole body dose from the medical event. The licensee notified the patient, the patient's son and the patient's referring physician. In addition, the licensee provided the referring physician a copy of its written report on the medical event. The licensee provided its written report of the medical event to the NRC in a letter dated December 20, 2010, with an addendum dated January 14, 2011. The report included the information required by 10 CFR 35.3045(d)(1).

4.3 Conclusions

The licensee made all of the notifications and reports as required by 10 CFR 35.3045 within the specified time period. The licensee's written report included all of the required information.

5 Other Areas Inspected

5.1 Inspection Scope

The inspector reviewed other aspects of the licensee's radiation protection program which included the prostate brachytherapy activities, security of licensed material, personnel monitoring, training, physical inventory and leak testing of sealed sources, labeling of containers, and postings. The inspector interviewed selected individuals, toured the licensee's facilities, examined the licensee's containers and reviewed selected records.

5.2 Observations and Findings

The inspector observed the licensee personnel prepare, assay and administer two unit doses for cardiac testing procedures (one stress and one resting). The inspector noted all technologists wore their assigned dosimeters while working with licensed material. A review of dosimetry reports revealed that all personnel exposures were below 10 CFR Part 20 limits.

The inspector observed that licensee personnel maintained constant surveillance of its licensed material. In addition the nuclear medicine hot lab remained secured.

The inspector determined that the consultant provided annual training to all staff working with or in the vicinity of licensed material. Through interviews, the inspector determined that the licensee staff understood security requirements for licensed material.

The inspector examined the sealed sources in the licensee's possession. Each source container was noted to bear a clearly visible label identifying the radionuclides and source activities. The licensee's consultant performed inventories and leak tests of the sealed sources and documented the results in his reports.

The inspector observed that the licensee posted a copy of NRC Form 3. The inspector also observed that the areas where licensed material was used and stored were appropriately posted with "CAUTION-RADIOACTIVE MATERIALS" signs. The hot lab was also posted with emergency/decontamination procedures and an approved "dosage chart."

The inspector reviewed a selected sample of 15 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. The inspector identified six patient prostate brachytherapy post-treatment plans, for implants administered in 2009, where the administered dose appeared to exceed the prescribed dose by more than 20 percent. All written directives specified a prescribed dose to the prostate of "125 Gray." The dose to 90 percent of the treatment site (also known as the D90) ranged between 120.9 to 140.7 percent. The prescribing authorized user for these cases departed the hospital and was not available for interview. This issue is considered an Open Item and continues to be under NRC review.

5.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspector determined that no violations of NRC requirements were identified. The inspector identified six patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. This issue is considered an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

6 Exit Meetings

The inspector discussed the sequence of events that led to the medical event, the root and contributing causes of the medical event, and the licensee's proposed corrective actions. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. The final exit meeting was subsequently conducted via telephone on January 11, 2011, and included a discussion of the apparent violations and the licensee's corrective actions.

Partial List of Persons Contacted

*#Dawn Baker, RT(R), Manager, Radiology
Jessica Castmore, CNMT
*Ashok B. Jain, M.D., Radiation Safety Officer and Authorized User
*Piyush Pandya, CNMT, Lead Nuclear Medicine Technologist
Jerry Pinkston, CNMT
Roy Taylor, M.S., Medical Physicist
Taljit S. Sandhu, Ph.D., Medical Physicist
Dorian Soper, CNMT
Kelly Van Daele, CNMT
*Eric Widner, MBA, President and Chief Executive Officer
Thomas Kompuris, M.S., Medical Physics Consultants
Kristin M. Anson, CNMT, Radiation Safety Officer, Medi-Physics, Inc.

*Individuals who participated in the on-site preliminary meeting on December 14, 2010.
#*Denotes individuals who participated in the final exit meeting conducted via telephone on January 11, 2011.