UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 29, 2015

EA-15-137
EN 50729
NMED No. 150036 (closed)

Mr. Gregory S. Losasso, President
Elkhart General Hospital
600 East Blvd.
Elkhart, IN 46514

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03017305/2015001(DNMS), AND INVESTIGATION REPORT NO. 3-2015-006 – ELKHART GENERAL HOSPITAL

Dear Mr. Losasso:

On January 13 and 14, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an announced, reactive inspection at your facility in Elkhart, Indiana, with continued in-office review through September 17, 2015. The purpose of the inspection was to review the events surrounding a medical event that was reported to the NRC on January 9, 2015. The NRC Office of Investigations (OI) began an investigation on January 27, 2015, and the investigation report was issued on June 26, 2015. The in-office review included a review of the OI investigation report and related issues. The enclosed inspection report (Enclosure 1) presents the results of the inspection. A factual summary of the investigation is enclosed (Enclosure 2). Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with Mr. William Molen of your staff on September 23, 2015, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as 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, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were 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. Detailed information concerning the violations is in the enclosed inspection report.

The first violation concerned the failure to use only dosages that fall within the prescribed dosage range or within 20 percent of the prescribed dosage unless directed by an authorized user, as required by Title 10 of the *Code of Federal Regulations* (CFR), Section 35.63(d). This non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

The second violation concerned a technologist's deliberate violation of 10 CFR 30.9, in maintaining incomplete and inaccurate documentation of the dosage administered to the patient. The technologist recorded an inaccurate dose into the hospital's recordkeeping system, which is required documentation under 10 CFR 35.63(a) and (e) and 35.2063(a)-(b). The initial entry may have been due to negligence, but by failing to correct the error and engaging in other actions to conceal his mistake, he deliberately failed to maintain accurate information. Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of an individual in a low-level position within the organization, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the enclosed inspection report. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to Inspection Report No. 03017305/2015001(DNMS); EA-15-137" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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's 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.

Please feel free to contact Mr. Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-17305
License No. 13-18879-01

Enclosures:
1. Narrative Report
2. Factual Summary of OI Investigation

cc w/encls: William Molen, Executive Director Radiology
Liang Q. Wang, M.S., Radiation Safety Officer
State of Indiana

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[1] OE concurrence provided via e-mail from K. Norman on October 23, 2015
[2] OGC "no legal objection" provided via e-mail from L. Baer on October 23, 2015

OFFICIAL RECORD COPY

Letter to Gregory S. Losasso from John B. Giessner dated October 29, 2015

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03017305/2015001(DNMS), AND INVESTIGATION REPORT NO. 3-2015-006 – ELKHART GENERAL HOSPITAL

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-17305
License No.	13-18879-01
Report No.	03017305/2015001(DNMS)
EA No. / NMED No.	EA-15-137 / 150036
Licensee:	Elkhart General Hospital
Facility:	600 East Blvd. Elkhart, Indiana
Inspection Dates:	January 13 and 14, 2015, with in-office review through September 17, 2015
Exit Meeting Date:	September 23, 2015
Inspectors:	Geoffrey M. Warren, Senior Health Physicist Zahid M. Sulaiman, Health Physicist
Approved By:	John B. Giessner, Director Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Elkhart General Hospital
NRC Inspection Report 03017305/2015001(DNMS)

This was an announced, reactive inspection, performed in response to the licensee's report on January 9, 2015, of a medical event that had occurred in the nuclear medicine service. The medical event concerned a patient who was administered an estimated 160 millicuries (mCi) of technetium-99m (Tc-99m) pertechnetate instead of the intended 30 mCi of Tc-99m tetrofosmin for a cardiac stress test. After recognizing that he had administered the incorrect dose, the technologist deliberately removed the sticker for the pertechnetate dose from the radiology order and replaced it with the sticker for the tetrofosmin dose and injected the material from the tetrofosmin syringe into the bulk pertechnetate syringe to make it appear that he had administered the intended dose.

The licensee technologist's administration of an estimated 160-mCi dosage of Tc-99m pertechnetate instead of the intended 30-mCi dosage of Tc-99m tetrofosmin is a violation of Title 10 of the *Code of Federal Regulations* (CFR) Section 35.63(d), which states that, unless 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. No authorized user directed the technologist to use the dose. The root cause of the violation was individual error; the technologist was distracted and not paying proper attention to his actions. This non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

Although the technologist's original entry into the hospital's recordkeeping system may have been due to negligence, he failed to correct his error and later took deliberate actions to cover up his mistake. This conduct constituted a violation of 10 CFR 30.9, which requires, in part, that information required by the Commission's regulations to be maintained by the licensee must be complete and accurate in all material respects. This matter is material to the NRC under 10 CFR 35.63(a), which requires licensees to determine and record the activity of dosages of unsealed byproduct material for medical use; 10 CFR 35.63(e), which requires licensees to maintain records of the dosage determination; and 10 CFR 35.2063(a)-(b), which require that records be maintained for three years and to include the following: the radiopharmaceutical, the patient's name, the prescribed dosage and determined dosage, the date and time of the dosage determination, and the name of the individual who determined the dosage. The root cause of this violation was a deliberate act by the technologist to prevent the licensee from identifying the technologist's error. Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. This non-repetitive, licensee-identified, and corrected violation is also being treated as a Non-Citied Violation consistent with the Enforcement Policy.

In addition to terminating the technologist's employment, the licensee took the following corrective actions to prevent recurrence of the violations: (1) nuclear medicine staff were retrained on assaying each dose and checking labels; (2) nuclear medicine staff were notified that falsifying documentation was cause for dismissal; and (3) the licensee contacted the radiopharmacy and requested to have future bulk doses delivered in vials rather than syringes. These activities were completed prior to January 16, 2015.

REPORT DETAILS

1 Program Overview and Inspection History

Elkhart General Hospital was authorized under U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-18879-01 to use licensed material for certain medical activities at a hospital in Elkhart, Indiana. Among these medical activities was diagnostic nuclear medicine. This inspection was an announced, reactive inspection, performed on January 14 and 15, 2015, in response to a reported medical event. At the time of the medical event, the licensee employed three full-time and one part-time nuclear medicine technologists.

2 Sequence of Events

2.1 Inspection Scope

The inspectors interviewed nuclear medicine staff and management personnel and the licensee's radiation safety officer (RSO) concerning the events surrounding a medical event that occurred on January 8, 2015, and reviewed documentation concerning the events leading up to and following the medical event. The medical event involved the administration of a bulk Tc-99m syringe to a patient.

2.2 Observations and Findings

On January 8, 2015, a nuclear medicine technologist in the nuclear medicine hot lab at Elkhart General Hospital was preparing to administer an approximately 30-mCi dose of Tc-99m tetrofosmin to a patient for a cardiac stress test. The technologist had personal issues that day that distracted him from his duties. The dose arrived in a package from the radiopharmacy, and the technologist performed the appropriate receipt surveys on the package. The package also contained two additional syringes – one syringe containing a bulk dose of Tc-99m pertechnetate in case licensee personnel needed to prepare a kit for later use, and one syringe of a bulk dose of Tc-99m microaggregated albumin. The technologist apparently removed the bulk pertechnetate dose from the package and opened the lead pig it was stored in. Upon realizing his error, the technologist removed the correct dose from its pig and measured it in the dose calibrator as 32.4 mCi, documenting this activity on the sticker attached to the pig. However, he then mistakenly took the bulk dose to the treadmill room and administered it to the patient. The licensee in its initial event report to the NRC reported the activity of the pertechnetate bulk dose as unknown, but later estimated with the assistance of the radiopharmacy that the pertechnetate bulk dose contained approximately 160 mCi at the time of administration to the patient. The estimated activity was calculated through decay corrections from the time the administration occurred compared to the radiopharmacy's orginal assay of the dose.

According to the nuclear medicine coordinator, the technologist should have placed the pigs containing the two doses into the rack where doses were organized, then taken the appropriate pig from the rack, rather than taking it directly from the package for administration. In addition, the technologist should have double checked the label with another technologist before administering the dose to confirm it was the correct syringe.

Title 10 CFR 35.63(d) states that, unless 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. Contrary to this requirement, the licensee's technologist administered an estimated 160-mCi dosage of Tc-99m pertechnetate instead of the prescribed 30-mCi dosage of Tc-99m tetrofosmin without direction by an authorized user. No authorized user directed the technologist to use the dosage. The root cause of the violation was individual error; the technologist was not paying proper attention to his actions. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

When the technologist returned to the nuclear medicine hot lab, he placed the label from the bulk dose on the radiology order, a sheet of paper documenting the administration. He apparently noted at this point that he had administered the incorrect dose. Upon realizing this, he appears to have panicked and attempted to cover up the error. He took several actions including removing the bulk sticker from the radiology order, replacing it with the sticker from the tetrofosmin pig, and injecting the material from the tetrofosmin syringe into the bulk syringe to make it appear that he had injected the patient using the correct syringe. He did not tell anyone about the error and lied to supervisors when they asked him directly.

Title 10 CFR 30.9 requires, in part, that information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects. The hospital's recordkeeping system is required documentation under 10 CFR 35.63(a) and (e) and 10 CFR 35.2063(a)-(b). Contrary to this requirement, the technologist recorded that the tetrofosmin dose had been administered, which was not accurate. The initial root cause of this violation may have been due to negligence, but his failure to maintain accurate information and later cover-up activities were deliberate acts to prevent the licensee from identifying the technologist's error. Although this violation is willful, it was brought to the NRC's attention by the licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

The patient returned to the nuclear medicine area and was placed on one of the cameras to be scanned. Following the scan, the technologist began processing the image. The nuclear medicine coordinator observed the image on the computer at this time, and noted that it did not appear to be correct; the image showed mostly stomach and very little if any heart, indicating an issue with the chemical form of the Tc-99m dose. She also observed that the number of counts was very high for a 30-mCi administration. She questioned the technologist, who stated that the procedure had been performed correctly. She then asked to see the radiology order and noted that it indicated that a tetrofosmin dose had been administered. Soon after this, the technologist left the hospital as he had previously been given approval to leave work early. The coordinator contacted her supervisor about her concerns, and the coordinator contacted further management personnel about the issue.

The manager and coordinator contacted the radiopharmacy concerning the dose. Personnel at the pharmacy performed a number of checks, including re-performing the

quality control testing on the tetrofosmin kit, and determined that the kit was good. They also noted another facility associated with Elkhart General Hospital that had received doses from the same kit; the coordinator contacted that facility and they said there were no problems with their images. The coordinator checked the pertechnetate syringe in the dose calibrator and determined that the activity was approximately 40 mCi, far less that it should have been. She returned this syringe to the radiopharmacy, where they ran quality control tests on the material in the syringe, identifying that it appeared to be primarily tetrofosmin with some pertechnetate.

The coordinator and her supervisor discussed what they had found and determined that the only sequence of events that made sense was that the technologist had administered the wrong dose and attempted to cover it up. They also noted that the radiology order showed signs of having a sticker removed, taking some of the paper with it, and that the bulk Tc-99m syringe sticker was missing. They then briefed additional management personnel about the situation as they now understood it.

The following day, January 9, when the technologist arrived for work, he was called into a meeting with the supervisor and other management personnel. He initially restated that the procedure had gone as planned. The manager then confronted him with what they believed had occurred, and he admitted his error in administering the bulk syringe and that he had tried to cover it up. The technologist was then terminated from employment and escorted from the hospital.

That afternoon, the supervisor and the RSO contacted the licensee's physics consultant as to whether the administration constituted a medical event. The consultant performed the calculations and determined that the resulting whole-body dose was 7.81 rem, meeting the criteria specified in 10 CFR 35.3045(a)(2)(i) for a medical event using the wrong radiopharmaceutical. An authorized user physician in nuclear medicine reviewed the case and examined the patient and determined that the patient would likely have no effect from the radiation exposure; the physician also briefed the patient about the medical event.

In addition to terminating the technologist's employment, the licensee took the following corrective actions to prevent recurrence of the violations: (1) nuclear medicine staff were retrained on assaying each dose and checking labels; (2) nuclear medicine staff were notified that falsifying documentation was cause for dismissal; and (3) the licensee contacted the radiopharmacy and requested to have future bulk doses delivered in vials rather than syringes. These activities were completed prior to January 16, 2015.

2.3 Conclusions

The inspectors identified a violation of 10 CFR 35.63(d) concerning the licensee technologist's administration of an estimated 160-mCi dosage of Tc-99m pertechnetate instead of the intended 30-mCi dosage of Tc-99m tetrofosmin. This non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

In addition, the inspectors identified a deliberate violation of 10 CFR 30.9, as the technologist failed to maintain an accurate entry into the hospital's recordkeeping system. Although this violation is willful, it was brought to the NRC's attention by the

licensee, it involved isolated acts of a low-level individual, and it was addressed by appropriate remedial action. Therefore, this non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Citied Violation, consistent with Section 2.3.2.b of the Enforcement Policy.

3 Licensee Notification to the NRC

3.1 Inspection Scope

The inspectors interviewed the radiation safety officer and radiology management personnel concerning the initial notification to the NRC about the medical event and the written report. In addition, the inspectors reviewed the documentation of the notifications for required information.

3.2 Observations and Findings

On January 9, 2015, the licensee identified that the administration of the Tc-99m pertechnetate dose had resulted in a medical event. The licensee notified the NRC's Headquarters Operations Office about the medical event by telephone the same day, meeting the requirement to notify the NRC no later than the next calendar day as specified in 10 CFR 35.3045(c). The report contained all required information. In addition, the licensee notified the referring physician and the patient about the medical event the same day, as required by 10 CFR 35.3045(e).

On January 14, 2015, during the onsite inspection, the licensee provided the inspectors the written report, which contained all required information. This was within the 15 days required by 10 CFR 35.3045(d) to provide the report to the NRC.

3.3 Conclusions

No violations were identified concerning the licensee's reporting of the medical event to the NRC.

4 Exit Meeting Summary

The NRC inspectors presented preliminary inspection findings following the onsite inspection on January 14, 2015. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented. The NRC inspectors presented the final inspection findings during a final inspection exit meeting by telephone on September 23, 2015.

LIST OF PERSONNEL CONTACTED

- # Stephanie Jones, Nuclear Medicine Coordinator
- # Raymond T. Kiendl, Executive Director Radiology (now retired)
- # Gregory S. Losasso, Hospital President
- #* William Molen, Manager Radiology (now Executive Director Radiology)
- # Liang (Larry) Q. Wang, M.S., Radiation Safety Officer

Attended preliminary exit meeting on January 14, 2015
* Participated in final exit meeting on September 23, 2015

FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2015-006

On January 27, 2015, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a Nuclear Medicine Technologist (NMT), willfully failed to provide complete and inaccurate information to the licensee, Elkhart General Hospital, pertaining to misadministration of a medical radiopharmaceutical. The NRC completed its investigation on June 26, 2015.

The licensee notified the NRC that on January 8, 2015, an NMT submitted information to the licensee which he knew to be incomplete and inaccurate. Specifically, the NMT documented on a patient's record that the patient was administered 32.4 millicuries (mCi) of Myoview technetium-99m (Tc-99m) Tetrofosmin (Myoview), although the employee knew that he had mistakenly administered an unknown dosage of technetium-99m Pertechnetate (bulk technetium).

During the OI interview, the NMT described his experience and training an as NMT. He demonstrated knowledge of hospital procedures and protocols in administering radiopharmaceuticals. The day of January 8, 2015, the NMT admitted to being distracted due to personal matters and further stressed by an impatient doctor waiting for the administration of Myoview. After examining the package sent from Cardinal Health, he had placed two pigs, one containing bulk technetium and the other containing Myoview, on the counter near the dose calibrator. He opened both pigs, placed the syringe containing Myoview in the dose calibrator, and recorded the dose of 32.4 mCi on the label affixed to the pig. At this point, the NMT stated that he took what he believed to be the pig with syringe containing 32.4 mCi of Myoview and administered it the patient. The NMT admitted that he did not check the label on the pig nor the syringe before the administration. Next, he took the label from the pig and placed it on the patient's requisition form. He also recorded an inaccurate dose into the licensee's recordkeeping system indicating that he delivered 33 mCi of Myoview to the patient. He noticed the label read bulk Technetium and realized that he had made an error and administered the bulk technetium instead of Myoview. He confessed that he tore the label off the requisition form and replaced it with the label that was affixed to the pig containing Myoview syringe. Next, he emptied the syringe containing Myoview into the syringe that he had used to administer the bulk technetium. Then, he proceeded to image the patient. The patient's images confirmed the NMT's error. The NMT mentioned that he considered disclosing the error to his supervisor who he acknowledged was present at the time when he was viewing the images. At no point did he correct the inaccurate entry in the licensee's recordkeeping system. According to the NMT, after he went home that day, he realized he needed to tell someone, but did not contact anybody. Further, he continued to provide false statements during the licensee's investigation the very next day. Finally, he acknowledged he attempted to conceal the error of administering the incorrect radiopharmaceutical.

Based on the evidence gathered during the OI investigation, it appears that the NMT deliberately violated NRC requirements by failing to maintain complete and accurate information in accordance with Title 10 of the *Code of Federal Regulations* (CFR) Section 30.9 (a).