July 18, 2006

NMED No. 060387

Gerrie K. Baarson, Director
Outpatient & Ambulatory Services
Battle Creek Health System
300 North Avenue
Battle Creek, Michigan 49016

SUBJECT: NRC SPECIAL INSPECTION REPORT NO 030-13899/06-001(DNMS) - BATTLE CREEK HEALTH SYSTEM

Dear Ms. Baarson:

This refers to the inspection conducted on June 15, 2006, at Battle Creek Health System, Battle Creek, Michigan. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions regarding an unintentional iodine-131 therapy treatment which occurred on June 12, 2006. The enclosed report presents the results of this inspection. An exit meeting was conducted on June 23, 2006, via telephone conference, with you and other members of your staff.

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 a 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 no violations of NRC requirements occurred. However, we are concerned that your procedures for scheduling patients for medical studies involving NRC licensed material failed to ensure that the requested study was scheduled for a patient. Specifically, a whole body metastatic thyroid scan, typically scheduled for patients without a functional thyroid gland, was erroneously scheduled. The patient's attending physician intended for the patient to receive a thyroid uptake and scan for thyroid function. A written directive was developed by nuclear medicine staff and signed by the physician authorized user based on the erroneously scheduled scan. The procedural errors resulted in the administration of a 2.2 millicurie dosage of iodine-131 to the patient rather than the 100 microcurie dosage intended for a thyroid gland function study. Although the written directive was followed, the patient did not receive the thyroid gland function study requested by the attending physician. Therefore, we request that you respond to our concerns by describing your corrective actions taken to avoid future errors in scheduling patient studies, including your process/procedures for developing and authorizing written directives.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's

document system is 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,

/Samson S. Lee for RA/

Steven A. Reynolds, Director
Division of Nuclear Material Safety

Docket No. 030-13899
License No. 21-01354-04

Enclosure:
Inspection Report No. 030-13899/06-001(DNMS)

cc w/encl: S. Smiley, M.D., Referring Physician

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NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-13899
License No.:	21-01354-04
Report No.:	030-13899/06-001(DNMS)
Licensee:	Battle Creek Health System
Location:	300 North Avenue Battle Creek, MI 49016
Date of Inspection:	June 15, 2006
Date of Final Exit Meeting:	June 23, 2006
Inspector:	Robert P. Hays, Health Physicist
Reviewed By:	John R. Madera, Chief Materials Inspection Branch

EXECUTIVE SUMMARY

Battle Creek Health System
Battle Creek, Michigan
Inspection Report No. 03013899/06-001(DNMS)

The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to the licensee's notification of an unintended iodine-131 therapy treatment that occurred on June 12, 2006. The treatment involved an oral administration of 2.2 millicuries of iodine-131 which was administered to a 64 year-old male outpatient. The patient's referring physician oncologist ordered an iodine-131 thyroid scan to evaluate an enlarged thyroid lobe related to B-cell lymphoma. The licensee's protocol for a thyroid scan is to routinely administer 100 microcuries of iodine-131 to a patient with an intact thyroid gland. However, in this case, the written order from the referring physican oncologist's office incorrectly indicated the patient should receive a metastatic thyroid scan, implying the patient did not have an intact thyroid.

The licensee's protocol for a metastatic thyroid scan requires 2.0 millicuries of iodine-131 to be administered to a patient without a thyroid gland. The written order from the patient's referring physician requested a metastatic thyroid scan which conflicted with the patient's symptoms as indicated on the order. The nuclear medicine technologist (NMT) and/or authorized user physician should have questioned the referring physician's order prior to developing a written directive and ordering 2.0 millicuries of iodine-131 from the nuclear pharmacy. On June 12, 2006, the patient was administered a 2.2 millicurie dosage of iodine-131, in accordance with an authorized user approved written directive.

The patient was instructed to return on June 14, 2006, to complete the scan. On June 14, 2006, another NMT conducting the whole body scan noticed the patient had an intact thyroid gland with significant iodine-131 uptake. The NMT notified the lead NMT. The lead NMT discovered that the patient had received the wrong procedure. The licensee concluded that the 2.2 millicuries of iodine-131 would not result in adverse health consequences for the patient.

To reduce the likelihood of a similar event, the licensee's proposed corrective actions were to counsel the NMT who ordered the 2.2 millicurie iodine-131 dosage and included: (1) to excuse the NMT from administering any radiopharmaceutical followed by a reorientation on administering isotopes; and (2) repeat competencies with a focus on administering isotopes. Other proposed corrective actions included: (1) requiring an additional peer review of orders and patient assessment for any patient receiving iodine-131; and (2) provide Central Scheduling with instructions to confirm the status of the patient's thyroid with the following questions: (1) does the patient still have their thyroid?; (2) any prior surgeries involving the thyroid?; and (3) any prior treatment or care relating to cancer of the thyroid?

No violations of NRC requirements were identified by the inspector.

Report Details

1 Program Scope and Inspection History

License number 21-01354-04 authorizes Battle Creek Health Systems (licensee) to use byproduct materials in 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.500. Licensed activities included nuclear medicine and brachytherapy procedures. The licensee routinely performs an average of 500 administrations per month for routine diagnostic and imaging procedures with the majority of diagnostic procedures being cardiac studies. Therapeutic procedures including occasional administrations of strontium-89 are performed by the oncology department. Thyroid carcinoma patients administered I-131 are released from the hospital in accordance with 10 CFR 35.75. The oncology department also performs cesium-137 implant therapy and permanent seed implant treatments on an average of 10 patients per month.

No violations were identified during the last and previous NRC inspections conducted on May 27, 2004, and October 29, 1998, respectively.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the licensee's investigation of the iodine-131 over dosage. The inspector also interviewed selected licensee personnel, and reviewed selected pertinent records.

2.2 Observations and Findings

The patient's referring physician oncologist ordered the patient to receive an iodine-131 thyroid scan to evaluate an enlarged thyroid lobe related to B-cell lymphoma. The oncologist's nurse completed a written order for the patient to receive a thyroid scan examination in the licensee's nuclear medicine department. The written order also indicated the patient had an enlarged thyroid lobe as a symptom for the exam. The nurse contacted the hospital's Central Scheduling department to schedule the thyroid scan. Central Scheduling staff instructed the nurse to indicate a "metastatic" thyroid scan on the order. The licensee's protocol for a thyroid scan is to administer 100 microcuries of iodine-131 to a patient with an intact thyroid gland. If the patient does not have a thyroid, the protocol is to perform a metastatic thyroid scan with 2.0 millicuries of iodine-131. When the written order from the referring physician oncologist's office was received in the nuclear medicine department, it indicated the patient was to have a metastatic thyroid scan.

The patient was scheduled for a metastatic thyroid scan on June 12, 2006. Prior to the patient study, one staff nuclear medicine technologist (NMT) contacted the nuclear pharmacy and ordered 2 millicuries of iodine-131, based upon the written order for a metastatic thyroid scan. A written directive to administer the 2 millicuries of iodine-131 was initiated. The written directive included the treatment prescription signed by an authorized user, the activity, date ordered, and name of the NMT ordering the dosage. A short time later, the dosage was delivered to the nuclear medicine department. The written directive was completed by another NMT, which included the patient's identity being verified by two different methods, actual assayed activity administered, and the

signature of the authorized user approving the actual 2.2 millicuries of iodine-131 to be administered. The dosage was administered orally to the patient without incident and the patient was instructed to return on June 14, 2006, for a followup whole body scan to complete the study. The patient returned to the nuclear medicine department on June 14, 2006 for the scan. The NMT conducting the scan observed more iodine-131 uptake in the patient's thyroid than what was expected. The NMT then notified the lead NMT. The lead NMT reviewed the image and identified there was problem because the patient had thyroid tissue and the exam protocol was for patients without a thyroid. A review of the thyroid scan determined that the patient had received the wrong procedure. The lead NMT subsequently notified the radiation safety officer and the licensee's consultant.

The licensee's investigation of the incident determined the written order for a metastatic thyroid scan was in conflict with the patient's symptoms as indicated on the order and should have been questioned by the NMT and/or authorized user physician prior to ordering the 2 millicurie iodine-131 dosage. The root cause was human error involving a failure to verify the status of the patient's thyroid prior to the administration. As part of the investigation, the licensee performed a thyroid count on the patient which determined a 90% uptake of the iodine in the patient's thyroid. The licensee staff estimated the dose to the patient's thyroid to be 3300 rem. The licensee's medical staff evaluated the potential adverse effects on the patient and concluded that the unintended dose to the patient's thyroid would not cause an adverse biological effect.

2.3 Conclusions

The NRC staff concluded that a medical event had not occurred because the licensee followed their protocol for the type of exam that had been scheduled and the written directive was followed. No violations of NRC requirements were identified.

3 Licensee Corrective Actions

3.1 Inspection Scope

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

3.2 Observations and Findings

On June 14, 2006, the licensee identified that a written order from a referring physician for a patient to receive a thyroid scan examination in the licensee's nuclear medicine department had been modified by the hospital's Central Scheduling staff to indicate a "metastatic" thyroid scan on the order. The written order also indicated the patient had an enlarged thyroid lobe as a symptom for the study. The written order for a metastatic thyroid scan conflicted with the patient's symptoms as indicated on the order and should have been questioned by the NMT and/or authorized user physician prior to ordering 2.0 millicuries of iodine-131 from the nuclear pharmacy. The licensee's corrective actions to reduce the likelihood of a similar event was to counsel the NMT who ordered the iodine-131 dosage which included: (1) to excuse the NMT from administering any radiopharmaceutical followed by a reorientation on administering isotopes; and (2) repeat competencies with a focus on administering isotopes. Other proposed corrective actions included: (1) requiring an additional peer review of orders and patient

assessment for any patient receiving iodine-131; and (2) provide the hospital's Central Scheduling staff with instructions to confirm on iodine-131 orders the status of the patient's thyroid with the following questions: (a) does the patient still have their thyroid?; (b) any prior surgeries involving the thyroid?; and (c) any prior treatment or care relating to cancer of the thyroid?

3.3 Conclusions

The inspector determined that the licensee implemented corrective actions to address the root cause of the unintended therapy incident. Corrective actions to address the root cause of the incident and to prevent similar incidents will be reviewed during a future NRC inspection.

4 Exit Meetings

At the completion of the onsite inspection, the inspector conducted a preliminary exit meeting with licensee management and staff. The inspector discussed the sequence of events, the root and contributing causes of the unintended therapy incident, 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 June 23, 2006, with Ms. Gerrie K. Baarson, and included a discussion of the licensee's corrective actions.

Partial List of Persons Contacted

#* Gerrie K. Baarson, Director Outpatient & Ambulatory Services
#* Earl Monks, Technical Manager, Radiology
#* T. Kelley Allen, Lead Nuclear Medicine Technologist
#* Rob Sieffert, Radiation Safety Officer
Stephen Smiley, M.D., Referring Physician
Charles O'Dell, Jr., M.D., Authorized User

* Denotes individuals who participated in the onsite preliminary meeting on June 15, 2006.
#* Denotes individuals who participated in the final exit meeting conducted via telephone on June 23, 2006.