February 15, 2008

NMED No. 080024

Mr. Michael T. Baker
Director, Operations
Hackley Hospital
1700 Clinton Street
Muskegon, MI 49443-3302

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-02044/2008-001(DNMS) AND NOTICE OF VIOLATION – HACKLEY HOSPITAL

Dear Mr. Baker:

This refers to the reactive inspection conducted on January 17, 2008, at the Muskegon, Michigan facility (Inspection Report No. 030-02044/2008-001, enclosed). 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 13, 2007. The enclosed report presents the results of this inspection.

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

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in the Notice because they have more than minor safety significance. The circumstances surrounding the violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you and members of your staff at the exit meeting on January 17, 2008.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/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/

John R. Madera, Chief
Materials Inspection Branch

Docket No.: 030-02044
License No.: 21-04125-01

Enclosures:
1. Notice of Violation
2. NRC Inspection Report 03002044/2008001(DNMS)
3. Excerpt from NRC Information Notice 96-28

cc w/encls: Carlo Santa Ana, Radiation Safety Officer
State of Michigan

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NOTICE OF VIOLATION

Hackley Hospital
Muskegon, Michigan

Docket No. 030-02044
License No. 21-04125-01

During an NRC inspection conducted on January 17, 2008, two violations of NRC requirements were identified. In accordance with the "NRC Enforcement Policy, the violations are listed below:

1. 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to 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. Procedures must meet the requirements described in 10 CFR 35.41(b).

   Contrary to the above, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that the procedures did not require a step to verify that the number of iodine-131 therapy capsules received for administration of a prescribed dosage is as indicated on the dosage vial label, to ensure that the correct number of capsules are administered to a patient in accordance with the written directive.

   This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

   49 CFR 173.421 excepts limited quantities of radioactive material, specified as radioactive material whose activity per package does not exceed the limits in 49 CFR 173.425 and its packaging, from the specification marking, and labeling requirements (except the UN identification number marking described in 49 CFR 173.422(a), and if not a hazardous substance or hazardous waste), the shipping paper and certification requirements of 49 CFR Parts 171-177, and the requirements of Subpart I of 49 CFR 173, provided among other things, that: (a) the radiation level at any point on any external surface of the package does not exceed 0.005 millisievert per hour (0.5 millirem per hour) and (b) the nonfixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a).

   Contrary to the above, on December 14, 2007, the licensee delivered to a carrier for transport, more than 70 millicuries of iodine-131, as an excepted package-limited quantity of material, but the package was not prepared for shipment, as required, in accordance with 49 CFR 173.421. Specifically, the licensee failed to verify by radiological surveys that the external surface radiation level was less than 0.005 millisieverts per hour and that the removable contamination level does not exceed the limits specified in 49 CFR 173.443(a).

   This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Hackley Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator and the Enforcement Officer, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action, as may be proper, should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 15th day of February 2008

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.	030-02044
License No.	21-04125-01
Report:	03002044/2008-001(DNMS)
Licensee:	Hackley Hospital
Location Inspected:	1700 Clinton Street, Muskegon, Michigan
Date:	January 17, 2008
Exit Meeting:	January 17, 2008
Inspector:	Robert P. Hays, Health Physicist
Approved by:	John R. Madera, Chief Materials Inspection Branch

NMED No. 08002

Enclosure 2

EXECUTIVE SUMMARY

Hackley Hospital
Muskegon, Michigan
Inspection Report No. 030-02044/2008-001(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 at Hackley Hospital (licensee) on December 13, 2007, involving an oral administration of 100 millicuries of iodine-131. The dosage was prepared by a nuclear pharmacy in three capsules. The licensee administered only one of the three iodine-131 capsules on December 13, 2007. The error was discovered the next morning by the nuclear pharmacy staff, when they found the remaining two iodine-131 capsules in a shipping container received from the licensee. The nuclear pharmacy staff returned the two iodine-131 capsules to the hospital and the licensee subsequently administered the remaining dosage to the patient on December 14, 2007.

The licensee concluded that the medical event would not result in adverse consequences to the patient because the patient received the remaining intended dosage the following day (within 24 hours). The root cause of the medical event was the licensee's failure to read the vial label to verify the number of iodine-131 capsules received in the pharmacy package. A contributing factor of the medical event was the failure of the nuclear medicine technologist to survey the package prior to return shipment to the nuclear pharmacy. If a radiation survey had been performed on the package prior to return shipment, the survey would have indicated that additional iodine-131 capsules remained in the vial.

The inspector identified a violation of Title 10 Code of Federal Regulations (CFR) 35.41(a) involving a failure to develop and implement adequate written procedures to provide high confidence that each administration requiring a written directive is in accordance with the prescribed dosage in the written directive. Specifically, the licensee's procedures did not include a step to verify that the number of iodine-131 capsules received for administration of a prescribed dosage was as indicated on the dosage vial label to ensure that the correct number of iodine-131 capsules are administered to a patient in accordance with the written directive. In addition, the inspector identified that the licensee did not prepare the package containing the two remaining iodine-131 capsules for return shipment to the pharmacy as required in 49 CFR 173.421.

To reduce the likelihood of a similar event, the licensee's proposed corrective actions included: (1) revising its procedures to include a step to verify the number of iodine-131 capsules received prior to dose administration; (2) retraining the nuclear medicine technologists administering iodine-131 therapy capsules to verify the written directive, patient information, and the number of capsules to be given; (3) two technologists will verify the original dose in the dose calibrator with the written directive; (4) after the dose is administered, two technologists will verify the vial activity in the dose calibrator prior to releasing the patient; (5) modify procedures to include documentation of dose verification by a second technologist on a checklist; (6) adding a procedure which requires that the Authorized User, Radiation Safety Officer, and licensee consultant

make a joint decision on how to address incidents which may cause a deviation from the written directive; (7) retraining the nuclear medicine technologists on the requirements to survey and wipe test packages prior to any shipment or return shipment to the nuclear pharmacy; and (8) any future shipment not surveyed and wipe tested will result in disciplinary action.

Report Details

1 Program Scope and Inspection History

License Number 21-04125-01 authorizes Hackley Hospital (licensee) to use a variety of byproduct materials for medical purposes, including diagnostic and therapeutic nuclear medicine, and sealed sources used for carcinoma therapy. The licensee routinely performs an average of 600 to 700 diagnostic nuclear medicine studies per month. Therapeutic iodine-131 administrations average one to two patients per month. No recent administrations of either samarium-153 or strontium-89 have been performed. The nuclear medicine staff includes four nuclear medicine technologists.

An inspection conducted on January 11 and 12, 2007, identified one violation of 10 CFR 35.41, involving the licensee's failure to develop adequate written procedures, which would ensure that brachytherapy sources were positioned in the patient in accordance with the written directive and treatment plan. No violations were identified during a prior inspection on September 16, 2005.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspector reviewed the sequence of events that resulted in the medical event and the licensee's investigation of the event. In addition, the inspector interviewed selected licensee personnel, reviewed related records, procedures, and equipment associated with the medical event.

2.2 Observations and Findings

A patient was scheduled for a thyroid ablation procedure at 1:30 pm on December 13, 2007. A written directive was prepared prescribing a dosage of 100 millicuries of iodine-131 for the patient and was signed by the authorized user. The iodine-131 dosage was ordered for the patient through a local nuclear pharmacy. The nuclear pharmacy prepared the dosage in three capsules and placed the capsules into a single vial which was delivered to the licensee's nuclear medicine hot lab. The patient arrived in the nuclear medicine area as scheduled and two nuclear medicine technologists (NMT) initiated the ablation procedure. The procedure was explained to the patient who then signed the consent forms. One of the NMTs verified that the activity of the iodine-131 dosage was within 10 percent of the prescribed dosage as specified on the signed written directive. The iodine-131 dosage measurement indicated 97.2 millicuries.

Following licensee procedures, the NMT that administered the dose verified the patient's identity by two methods and re-assayed the iodine-131 dosage in the vial. After assaying the dosage, the NMT gave only one of the three capsules to the patient. The NMT thought that only one capsule was in the dosage vial because the two capsules remaining in the vial were hidden by the desiccant material shipped with the vial. In addition, the NMT did not read the dosage vial label to verify the number of iodine-131 capsules that were contained in the vial. Reading the dosage vial label to verify the number of iodine-131 capsules received for administration of the prescribed dosage was

not included in the licensee's procedures for administering therapeutic iodine-131. The licensee's failure to develop and implement adequate written procedures to provide high confidence that each administration requiring a written directive is in accordance with the prescribed dosage in the written directive is a violation of 10 CFR 35.41(a).

After the patient was given one iodine-131 capsule, the patient was scheduled for a follow-up scan, and then allowed to leave the nuclear medicine department. The NMT placed the dosage vial back in the shipping container (package). The package was prepared for pick up by the pharmacy early the next morning as a limited quantity package (UN 2910); however, the NMT did not survey the package for radiation levels or contamination (wipe test) to verify that the package did not exceed the limits for a limited quantity shipment after placing the vial inside the package. The licensee's failure to survey and wipe test the package is a violation of 49 CFR 173.421.

The following morning, December 14, 2007, the nuclear pharmacy courier arrived at the hospital and took the package back to the pharmacy before any NMT staff arrived for work. Later that same morning, a staff NMT contacted the nuclear pharmacy to place an order and was informed at that time, that two iodine-131 capsules had been found in the package that was returned to the nuclear pharmacy. After being notified of the situation, the prescribing authorized user requested that the patient return to the nuclear medicine department. The patient and the referring physician were notified of the error. The two iodine-131 capsules were subsequently returned to the hospital by the nuclear pharmacy and the patient was administered the two remaining iodine-131 capsules around 11 a.m. on December 14, 2007.

The licensee determined this issue to be a medical event as defined in 10 CFR 35.3045(a)(1)(ii), because the total dosage administered differed from the prescribed dosage by more than 20 percent. In this case, the patient initially received only a nominal 22 millicuries of iodine-131, rather than the prescribed 100 millicuries specified in the written directive. The licensee does not believe that the medical event will have a negative effect on the patient because the patient received the remainder of the prescribed dosage within 24 hours. The total iodine-131 dosage delivered to the patient was approximately 91.1 millicuries.

The inspector determined that the root cause of the medical event was the NMT's failure to read the pharmacy vial label to verify that three iodine-131 capsules were sent by the nuclear pharmacy prior to administering the dosage. The NMT involved with the administration did not realize that the nuclear pharmacy had prepared the dosage in three capsules and assumed that the dosage was prepared in only one capsule, since only one capsule was observed in the vial and the assayed iodine-131 dosage was within 10 percent of the prescribed dosage. The licensee's written procedures to provide high confidence that each administration is in accordance with the written directive did not include a step to read the dosage vial label to verify the number of iodine-131 capsules received in the vial prior to dose administration.

A contributing factor of the medical event was the licensee's failure to survey the package prior to return shipment to the nuclear pharmacy. If a radiation survey had been performed on the package prior to return shipment, the survey would have indicated that additional iodine-131 capsules remained in the vial.

2.3 Conclusion

The inspector determined that a medical event occurred because the licensee failed to read the pharmacy dosage vial label prior to dosage administration, to verify the number of iodine-131 capsules received for administration of the prescribed dosage. A violation of 10 CFR 35.41(a) was identified involving a failure to develop and implement adequate written procedures to provide high confidence that each administration requiring a written directive is in accordance with the prescribed dosage in the written directive. A violation of 49 CFR 173.421 was also identified for failure to verify radiation levels and contamination on an excepted package prior to return shipment to the nuclear pharmacy.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar events. The inspector reviewed the licensee's report of the medical event dated January 10, 2008, and associated written procedures. The inspector also interviewed selected licensee personnel.

3.2 Observations and Findings

The licensee's written procedures for administering therapeutic iodine-131 did not include a step to verify that the number of iodine-131 capsules received for administration of a prescribed iodine-131 dosage agrees with the number of capsules indicated on the pharmacy vial label. To reduce the likelihood of a similar event, the licensee's proposed corrective actions included: (1) revising its procedures to include a step to verify the number of iodine-131 capsules received prior to dose administration; (2) retraining the nuclear medicine technologists administering iodine-131 therapy capsules to verify the written directive, patient information, and the number of capsules to be given; (3) two technologists will verify the original dose in the dose calibrator with the written directive; (4) after the dose is administered, two technologists will verify the vial activity in the dose calibrator prior to releasing the patient; (5) modify procedures to include documentation of dose verification by a second technologist on a checklist; (6) adding a procedure which requires that the Authorized User, Radiation Safety Officer, and licensee consultant make a joint decision on how to address incidents which may cause a deviation from the written directive; (7) retraining the nuclear medicine technologists on the requirements to survey and wipe test packages prior to any shipment or return shipment to the nuclear pharmacy; and (8) any future shipment not surveyed and wipe tested will result in disciplinary action.

3.3 Conclusions

The inspector determined that the licensee implemented 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 15-day report that was submitted to the NRC.

4.2 Observations and Findings

The licensee staff did not initially believe the iodine-131 misadministration was a medical event because the patient received the intended dosage of iodine-131. The nuclear medicine staff discussed the incident with the RSO who, subsequently, determined that the incident constituted a medical event. Once the RSO discovered that the incident was a medical event on January 4, 2008, the licensee made all of the required notifications and reports of the medical event to the NRC.

The licensee notified the NRC Operations Center, the patient, and the patient's referring physician of the medical event. The licensee notified the NRC Operations Center on January 4, 2008, and provided its written report of the medical event to the NRC in a letter dated January 10, 2008. 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 Exit Meeting

At the completion of the onsite inspection, the inspector conducted an exit meeting with licensee management and staff. The inspector discussed the sequence of events that led to the medical event, the root and contributing causes of the medical event, and the potential violations 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.

Partial List of Persons Contacted

* Sara Crain, Lead Nuclear Medicine Technologist
* Carlo Santa Ana, Radiation Safety Officer
* Michael Baker, Director, Operations

* attended exit meeting on January 17, 2008