

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

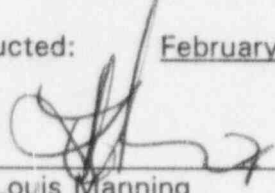
Report No. 030-08184/97-001 Program Code 02120
Docket No. 030-08184
License No. 37-14870-01 Priority 3 Category G
Licensee: Monsour Medical Center
70 Lincoln Way
Jeannette, Pennsylvania 15644

Facility Name: Monsour Medical Center

Inspection At: 70 Lincoln Way
Jeannette, Pennsylvania

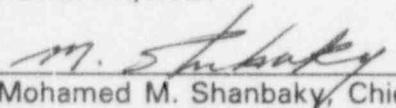
Inspection Conducted: February 20 and 21, 1997

Inspectors:


Louis Manning
Health Physicist

3/31/97
date

Approved By:


Mohamed M. Shanbaky, Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

3/31/97
date

Executive Summary: Special announced inspection to review a reported diagnostic misadministration of sodium iodide iodine-131 (I-131) which occurred on February 12, 1997 (Inspection Report No. 030-08184/97-001). Areas reviewed during this inspection include: (1) Program Scope; (2) Procedures for Nuclear Medicine Thyroid Uptake and Scan; (3) Incident Chronology; (4) Notification of Incident; (5) Corrective and Preventive Actions; (6) Review of Incident; (7) Medical Evaluation of the Misadministration; and (8) Quality Management Program.

Results: One apparent violation was identified; failure to have a written directive for sodium iodide I-131 in quantities greater than 30 microcuries (uCi) (Section 7).

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DETAILS

1. Persons Contacted

- * Jerry A. Joseph, Chief Executive Officer
- * Shanteri U. Nayak, M.D., Radiation Safety Officer
- * Joseph Rolek, Nuclear Medicine Technologist (Staff Technologist)
- * Robert Einwachter, Nuclear Medicine Technologist (Temporary Technologist)
- * Joseph Och, M.S., Consulting Health Physicist
- Lonna Paterline, Director of Nursing

- * Attended Exit Meeting

2. Program Scope

The Nuclear Medicine Department at Monsour Medical Center (MMC) is a small department. There are approximately 50 patient studies performed per month. Of this volume, approximately 50% of the studies performed are cardiac (50% using technetium-99m (Tc-99m) labeled Myoview, and 50% using thallium-201 for stress studies). Other studies include 35% bone, 3-5% thyroid uptake and scan using I-131 for the uptake and Tc-99m pertechnetate for the scan. The remaining studies consist of biliary, lung, indium-111, and I-123 uptake and scan. The staff includes one staff nuclear medicine technologist (NMT) and three temporary technologists. Two of the temporary technologists take call, while the other technologist covers for the staff NMT. There are six authorized users (AU) listed on the license, including, the Radiation Safety Officer (RSO). The RSO is the primary physician who reads the nuclear medicine scans.

3. Procedures for Nuclear Medicine Thyroid Uptake and Scan

The inspector reviewed the licensee's procedures for nuclear medicine thyroid uptake and scan studies. The inspector noted that the licensee maintains a nuclear medicine patient procedures manual, which outlines the doses and radiopharmaceuticals used for a thyroid uptake and scan study. A thyroid uptake study could be performed using either a 10 to 30 uCi I-131 capsule or a 100 to 300 uCi I-123 capsule. The scan could be performed with either 10 to 20 millicuries (mCi) of Tc 99m pertechnetate, 200 to 300 uCi of I-131, or 200 to 500 uCi of I-123. The licensee routinely uses I-131 for the thyroid uptake and Tc-99m pertechnetate for the scan. When a physician orders a thyroid uptake and scan, the staff NMT places the order with the pharmacy a day before the study is to be performed. The order is verified with the pharmacy to ensure that the proper dose and radiopharmaceutical will be shipped. When the dose arrives the next day, the NMT verifies that the proper materials were received. Should there be a discrepancy, the NMT has been instructed to seek guidance from an AU. The dose will be verified by examination of the packing slip, label, and assay in the dose calibrator. Once the proper dose, radiopharmaceutical, and patient are verified, the dose is administered to the patient. The thyroid uptake and scan

study is a two part procedure. The thyroid uptake is performed first, and the patient returns within twenty-four hours for the scan.

4. Incident Chronology

On February 11, 1997 the staff NMT placed an order to Mallinckrodt Medical for a diagnostic I-131 capsule for an uptake. The order was placed and checked by the pharmacist for a 12 uCi capsule of sodium iodide I-131.

On February 12, the staff NMT was out of the office, as a result, a temporary NMT was present to provide coverage. The temporary NMT was a former employee of MMC and has worked at the facility for 11.5 years. He retired in February 1996, and has provided coverage for the staff NMT 4 to 5 times since his retirement. At approximately 8:00 am, the temporary NMT arrived at the department. After he performed all the necessary quality control procedures, the temporary NMT checked in the radiopharmaceuticals. Two patients studies were scheduled for the day, with the first study being the thyroid uptake. The temporary NMT checked the packing slip and observed that the dose received was 84.2 uCi calibrated for 12:00 pm. He assayed the dose in the dose calibrator to verify that the dose was in agreement with the packing slip. The dose was verified to be 88 uCi. At this point, the temporary NMT questioned whether this dose was proper for the procedure. After reviewing the request form, he verified that the study was for a thyroid uptake and scan. The temporary NMT believed that the dose was too high for an uptake, but too low for a scan. He then focused on the word "scan". Believing, at the time, that the required study was a thyroid scan, he administered the dose to the patient at approximately 8:30 am. Later that day, the temporary NMT realized that he did not have a written directive, and a written directive was required, since the dose administered was greater than 30 uCi.

On February 13, the temporary NMT informed the staff NMT, via the telephone, that he administered the dose without a written directive. The staff NMT then realized that there was potentially another problem, and informed the RSO that a misadministration may have occurred. After consultation with the RSO, and the consulting Health Physicist on February 14, it was determined that a misadministration occurred; because, the study involved the administration of a radiopharmaceutical dosage of greater than 30 uCi of sodium iodide I-131; the administered dosage differed from the prescribed dosage by more than 20 percent of the prescribed dosage; and the difference between the administered dosage and the prescribed dosage exceeded 30 uCi. The misadministration was subsequently reported to the NRC Operations Center at 3:40 p.m. on February 14, 1997 (event number 31786).

The licensee informed the inspector that the referring physician and patient were notified of the misadministration on February 14. The licensee's consulting Health Physicist calculated the dose using the following methods based upon a patient uptake of 15%:

Package Insert:

	Intended Dose	Actual Dose	Difference
Thyroid	9.6 rem	70.4 rem	60.8 rem
Ovaries	0.002 rem	0.015 rem	0.013 rem
Whole Body	0.006 rem	0.044 rem	0.038 rem

CRC Handbook of Radiation Doses in Nuclear Medicine and Diagnostic X-ray:

	Intended Dose	Actual Dose	Difference
Thyroid	9.6 rem	70.4 rem	60.8 rem
Ovaries	0.003 rem	0.022 rem	0.019 rem
Whole Body	0.004 rem	0.030 rem	0.026 rem

It should be noted that the actual patient uptake measured 12%. The licensee's preliminary medical assessment of the incident indicated that there would be no alteration in thyroid function.

5. Notification of Incident

The licensee notified the NRC Operations Center on February 14, 1997 that a misadministration occurred on February 12, 1997 per 10 CFR 35.2. The inspector verified that the licensee notified the referring physician and the patient. The inspector determined, based upon the information provided by the licensee during the inspection, that the licensee complied with the notification requirements of 10 CFR 35.33.

6. Corrective and Preventive Actions

In the licensee's report of misadministration, received March 3, 1997, the licensee described the reason the misadministration occurred, and their corrective actions. The licensee concluded that the misadministration occurred because of the following:

- 1) Failure of Mallinckrodt Medical to supply the correct dose as ordered.

- 2) The staff NMT did not leave explicit details of the doses ordered for the covering NMT for the following day.
- 3) Failure of the covering NMT to seek guidance from the RSO regarding the questionable dose.

The licensee's corrective actions are as follows:

- 1) The staff NMT will maintain a written log of all doses ordered from the supplier for the covering NMT.
- 2) The staff NMT will include the specific test ordered in the same log.
- 3) The staff NMT will communicate with the covering NMT regarding the doses ordered and the tests to be performed the day before coverage is needed.
- 4) The on call NMT will be provided training to familiarize them with the department protocols and procedures on a periodic basis.

7. Review of Incident

The inspector concluded that two primary factors may have contributed to the misadministration. The first factor was that the temporary NMT failed to ensure that a written directive was prepared, after he verified that the dose on hand was 88 uCi. The second factor was that the temporary NMT did not seek guidance, when there was a question regarding the dose for the procedure requested. The 88 uCi capsule of sodium iodide I-131 was neither within the procedural range for a sodium iodide I-131 thyroid uptake (10 to 30 uCi), nor within the range for a sodium iodide I-131 scan (200 to 300 uCi). The licensee's Quality Management Program (QMP) and the regulations require a written directive for sodium iodide I-131 in quantities greater than 30 uCi.

10 CFR 35.32(a)(1)(iv) requires, in part, that prior to administration, a written directive is prepared for any administration of quantities greater than 30 uCi of sodium iodide I-131.

Failure to have a written directive for administration of doses greater than 30 uCi of sodium iodide I-131 is an apparent violation of 10 CFR 35.32(a)(1)(iv).

8. Medical Evaluation of the Misadministration

In accordance with the NRC's Medical Event Assessment Program, the NRC has contracted a physician consultant to review the misadministration, and report on the probable deterministic effects of the increased dose to the patient's thyroid. The consultant's report concluded that the patient received 61 rem to the thyroid, based upon a 12.7% uptake. The consultant determined that this case was a misadministration, and that the dose would not have any biologic sequelae.

9. Quality Management Program

The licensee's QMP for the administration of sodium iodide in quantities greater than 30 uCi was submitted to the NRC by a letter received January 23, 1992. The licensee's revised QMP was received August 11, 1994.

The inspector reviewed the revised QMP and determined that the QMP contained the required written policies and procedures in accordance with the regulations. The inspector reviewed all I-131 patient administrations from January 9, 1991 to February 20, 1997. The inspector determined that the licensee performed 61 I-131 procedures during this period, and identified no other cases where a recordable event or misadministration occurred. Out of this total, only three cases required a written directive. Two out of the three cases requiring a written directive, were administered in accordance with the licensee's written QMP. That is, a written directive was prepared and used for these two cases. The third case, this misadministration, did not have a completed written directive. The inspector concluded that the misadministration was an isolated event and did not represent a programmatic weakness.

10. Exit Meeting

An exit meeting was conducted on February 21, 1997 with the individuals identified in Section 1 of the report. The inspection findings and licensee's proposed corrective actions were discussed with the licensee.