U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02685/86001(DRSS)

Docket No. 030-02685

License No. 34-01710-05 Category G Priority 3

Licensee: Toledo Hospital
2142 North Cove Blvd.
Toledo, OH 43606

Inspection Conducted: November 25, 1986

Inspector: J. L. Lynch
Radiation Specialist
1-8-87
Date

Reviewed By: D. G. Wiedeman, Chief
Nuclear Materials Safety
Section 1
1-8-87
Date

Approved By: W. L. Axelson, Chief
Nuclear Materials Safety
and Safeguards Branch
1-8-87
Date

Inspection Summary

Inspection on November 25, 1986 (Report No. 030-02685/86001(DRSS))
Areas Inspected: Special, announced inspection to review the circumstances surrounding a reported misadministration to a patient which occurred on November 18, 1986.
Results: No violations of license requirements were identified during the inspection.

DETAILS

1. Persons Contacted

*William Jeffries, M.D., Radiation Safety Officer (RSO)
*James Johnson, Technical Manager
Mervin Green, M.D., Referring Physician
Debbie Kuck, Technologist
Amy Ilconich, Diagnostic Center Receptionist
Mary Jane Carver, Medical Secretary
Reynold Brown, M.D., NRC Consulting Physician

*Attended the exit interview on November 25, 1936.

2. Purpose of Inspection

This was an announced special safety inspection conducted to review the circumstances surrounding a diagnostic misadministration resulting in a therapeutic dose. The misadministration occurred on November 18, 1986 and was reported to the NRC the following day.

3. Licensed Program

License No. 34-01710-05 authorizes the possession and use of byproduct and source material in a nuclear medicine program. Approximately 500-600 nuclear medicine procedures (including therapy) are performed monthly in this 800 bed hospital. Dr. Jeffries, Acting Director of Nuclear Medicine was also acting as the Radiation Safety Officer (RSO) at the time of the incident. He was subsequently approved as RSO by the NRC on December 5, 1986.

4. Inspection History

The last inspection performed at Toledo Hospital was on January 10-11, 1984. Four violations were identified: exceeding license possession limits, failure to perform bioassays and surveys; and failure to properly calibrate survey instruments.

In addition to the subject incident, three misadministration events (all diagnostic) have been reported to the NRC since the last inspection.

July 5, 1984 report - Disofenin administered instead of prescribed MDP. Caused by technologist error.

July 3, 1985 report - Lung scan dose administered instead of prescribed liver scan dose. Physician's written order misread by clerk and technologist.

July 2, 1986 report - Three patients administered improperly prepared bone scan agent. Caused by technologist error.

The violations and misadministrations were discussed with the licensee during this inspection.

5. Incident Chronology

A misadministration resulted from the administration of a 20 millicurie iodine-131 dose to a 62 year old female patient instead of the prescribed 20 millicurie technetium-99m MDP dose. The test was scheduled through the outpatient scheduling system which requires the referring physician's office to contact the hospital Diagnostic Center which in turn writes the request on a calendar and then relays that information to the nuclear medicine department.

November 11, 1986: The referring physician wrote a request for a bone scan on the patient's chart (see Attachment A) and asked his secretary to telephone Toledo Hospital to schedule the request. The secretary telephoned the Diagnostic Center and to the best of her recollection, ordered a bone scan for the patient who had metastatic breast cancer. A record of that conversation was not maintained by the secretary, however, the secretary recalls that she spoke with the Diagnostic Center's receptionist.

When asked by the inspector, the receptionist could not recall the particular telephone call from the referring physician's office and had no mention of a bone (or metastatic breast cancer) scan request on her calendar for that day. Instead, the calendar details the request to read "Total Body Scan, rule out metastases, carcinoma." This information was forwarded to Nuclear Medicine the next day.

November 13, 1986: Nuclear Medicine ordered a 20 millicurie iodine-131 capsule from its radiopharmaceutical vendor. The Nuclear Medicine Department interpreted the telephoned prescription to mean a thyroid metastatic disease scan which is also known as a "total body scan." This procedure is used to search for metastases in patients who have undergone a thyroidectomy, so a large thyroid radiation dose is avoided. Toledo Hospital routinely uses a 20 millicurie dose for this procedure, higher than the usual prescribed dose of ten to 15 millicuries, in an effort to achieve a more complete identification of metastases.

To confirm that his department had the correct information, the Nuclear Medicine technical manager asked the Diagnostic Center receptionist if a thyroid metastatic disease scan was the requested procedure and if all pre-scan tests were satisfactory. The receptionist confirmed that the information she had received indicated that the patient was approved for the total body scan. However, the referring physician's office was not contacted for a true confirmation of the study.

November 17, 1986 - The 20 millicurie iodine-131 capsule was received at the hospital.

November 18, 1986 - At approximately 8:30 a.m., the iodine-131 capsule was administered to the patient in the nuclear medicine department. Prior to the administration, the technologist explained the procedure to the patient but did not question the patient about her medical history. The patient did not provide any information to alert the technologist that a different procedure than the one being performed was appropriate.

November 19, 1986 - The error was discovered when the patient mentioned to the Nuclear Medicine secretary that she was going to have bone scan images taken that day. The secretary knew that a bone scan had not been scheduled, and alerted the technical manager of the discrepancy.

At 12:15 p.m., the NRC was notified of the diagnostic misadministration which resulted in a therapeutic dose to the patient. The referring physician and the patient were also immediately notified of the misadministration.

Region III issued a Preliminary Notification (PN) describing the misadministration (Attachment B).

November 20, 1986 - The NRC informed the licensee by telephone that a Confirmatory Action Letter (CAL) would be issued, effective immediately, to modify nuclear medicine procedure scheduling. The licensee agreed to the modifications.

November 21, 1986 - A CAL was issued, requiring the licensee to assure that all prescriptions for nuclear medicine procedures are in written form and that all prescriptions are reviewed by a nuclear medicine physician and verified by the technologist prior to administration of doses to patients (Attachment C).

The licensee reported, in writing, the misadministration to the NRC. This satisfied the 10 CFR 35 reporting requirement.

The licensee performed, at the NRC's request, a thyroid uptake study on the patient to determine thyroid uptake rates.

November 25, 1986 - The NRC conducted an inspection at Toledo Hospital and at the attending physician's office in Sylvania, Ohio.

6. Medical Status

The patient had been previously diagnosed as having carcinoma of the breast. A thyroid function test, performed in November 1982, indicated that the patient was also mildly hypothyroid. The patient had been receiving exogenous thyroxin to make up for the decreased thyroid function.

According to the licensee's December 22, 1986 report (Attachment D) the patient's thyroid received an estimated dose of 6,760 rads while other organs received relatively small doses. Thyroid uptake rates were

determined with a uptake test performed 72 hours after the misadministration (Attachment E). The patient's thyroid uptake was measured to be only 6.5%, less than the normal range of 15-35%. A normal thyroid would have received between approximately 20,000 and 50,000 rads, as calculated using absorbed radiation dose factors from MIRD Dose Estimate Report, No. 5. The referring physician did not feel that doses of potassium iodide (KI) or diuretics would be beneficial in limiting thyroid uptake after the misadministration so they were not administered. According to the referring physician, the thyroid dose is expected to significantly decrease thyroid function which would necessitate increased thyroxin dosage to the patient. The thyroxin dosage was increased after the incident to three times the previous dosage. Both the hospital and the referring physician plan to continue followup of the patient.

7. Corrective Actions

The misadministration resulted from a communication breakdown in the licensee's outpatient scheduling system. Apparently, the procedure request was not properly communicated between the referring physician's secretary and the Diagnostic Center receptionist. Various other checks in the system also failed to alert Nuclear Medicine personnel of the potential misadministration. During the inspection, methods to improve the scheduling system were discussed with the licensee. Until these or other adequate methods are approved by the NRC, the conditions of the CAL will remain in effect. No violations of NRC requirements or license conditions were identified during this inspection.

The NRC procured the services of Reynold Brown, M.D. of the University of California as a medical consultant for this case (Attachment F). Dr. Brown will evaluate the patient's exposure and determine if the misadministration could cause any significant long term biological effects. A report will be submitted to the NRC which will then be made available to the licensee and referring physician.

8. Exit Interview

An exit interview was conducted on November 25, 1986 at the licensee's facility. Licensee attendance at the meeting is indicated in Section 1 of this report. During the exit interview, the inspector discussed the NRC's concerns, ramifications of the CAL, and licensee corrective actions. The licensee was advised that escalated enforcement action was being considered.

Licensee management stated that the information included in this report was not proprietary in nature.

9. Attachments

A. Referring physician's patient chart
B. Preliminary Notification
C. Confirmatory Action Letter
D. Licensee dose report
E. Thyroid uptake test data
F. NRC request to consultant

ATTACHMENT A

10/13/86 — [illegible] [illegible] x-ray [illegible]
Refer FH — P.T. (OPD) — 3x/wk for 3 [illegible]
[illegible] [illegible] [illegible] [illegible] [illegible]
[illegible] [illegible] MEP

11/11/86 — [illegible] to P.T. [illegible] better, but
[illegible] [illegible] [illegible] [illegible] [illegible] P.T.
[illegible] will get bone scan, TH MEP

11/19/86 Conference @ TH — [illegible] [illegible] [illegible]
[illegible] scan in error (Nuclear [illegible])
[illegible] [illegible] [illegible] to 3x 0.05 [illegible]
[illegible] 10C
Bone scan in 2 wks MEP

11/21/86 - phone: Naprosyn 250 mg #60 bid Rx 1 [illegible] / MEP

A

ATTACHMENT B

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE--PNO-III-86-137 Date November 19, 1986

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region III staff on this date.

Facility: Toledo Hospital
Toledo, OH

License No. 34-01710-05

Licensee Emergency Classification:
____Notification of an Unusual Event
____Alert
____Site Area Emergency
____General Emergency
__X__Not Applicable

Subject: DIAGNOSTIC MISADMINISTRATION RESULTING IN A THERAPEUTIC DOSE

On November 19, 1986, the licensee reported that a patient had been administered the wrong radiopharmaceutical for a diagnostic bone scan. The diagnostic procedure had been prescribed verbally on about November 12, 1986, but was not clearly described on the diagnostic center's calendar. The intended procedure was for a bone scan using 20 millicuries of technetium-99m MDP, but on November 18, 1986, the patient was administered 20 millicuries of iodine-131 for a thyroid scan, which was the technologist's interpretation of the ambiguous test description.

The error was discovered when the patient returned to the hospital on November 19, 1986, for the diagnostic procedure. The principal organ exposure from the incorrect radiopharmaceutical would be to the thyroid. The patient had previously experienced hypothyroidism, and the radiation dose would be expected to further reduce thyroid activity.

The patient's attending physician is monitoring her condition. Region III (Chicago) will have the case reviewed by an NRC medical consultant. An inspection is scheduled for early next week to review the circumstances of the misadministration.

The State of Ohio will be notified.

Region III was notified of this incident by the licensee at 11:30 a.m., November 19, 1986. This information is current as of 3 p.m., November 19, 1986.

CONTACT: J. L. Lynch
FTS 388-5669

for D. G. Weideman
FTS 388-5616

W. L. Axelson
FTS 388-5612

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Region III
Rev. November 1986

B

NOV 21 1986

Toledo Hospital
ATTN: William F. Jeffries, M.D.
Radiation Safety Officer
2142 N. Cove Boulevard
Toledo, OH 43606

License No. 34-01710-05

Gentlemen:

This refers to your conversation with Mr. J. L. Lynch of my staff on November 20, 1986, regarding a recent misadministration which resulted in a therapeutic dose of iodine-131 to a patient.

Based on that conversation, it is our understanding that as of November 20, 1986, you will implement specific procedures to preclude possible future misadministrations caused by miscommunication of physician orders. Specifically, all prescriptions for nuclear medicine procedures will be in written form. Written orders will be reviewed by a nuclear medicine physician and verified by the technologist prior to administration of doses to patients.

If our understanding of the above is not correct, please contact this office by telephone immediately.

Sincerely,

Original signed by
James G. Keppler

James G. Keppler
Regional Administrator

cc: DCS/RSB (RIDS)

bcc: J. G. Partlow, IE
J. Axelrad, IE

~~8612020415~~

RIII	RIII	RIII	RIII	RIII	RIII	RIII	RIII
for Lynch/mm	Wiedeman	Axelson	Hind	Berson	Stapleton	Davis	Keppler
11/20/86			11/21/86	NOT AVAILABLE		11/21	11/21/86