Theda Clark Medical Center
United Health Partner

Theda Clark Medical Center
130 Second St.
P.O. Box 2021
Neenah, WI 54957-2021

Phone 414-729-3100

June 11, 1997

Mr. Roy J. Caniano
Acting Director,
Division of Nuclear Materials Safety,
U.S. Nuclear Regulatory Commission,
Region III,
801 Warrenville Road,
Lisle, IL 60532-4351

Reference: Docket No. 030-03463

Dear Mr. Caniano:

This letter is intended to reply to a " Notice of Violation" sent from your office on May 20,1997. The enclosures from that letter indicate that the corrective actions stated are adequate to prevent recurrence .

I have enclosed a copy of all enclosures from that notice with items of personal privacy deleted to be used for the NRC Public Document Room.

I hope this information submitted is satisfactory.

Sincerely,

Paul Macek,
Senior Vice President

cc w/encl: Document Control Desk, Washington D.C.

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.	030-03463
License No.	48-09494-01
Report No.	030-03463/97001(DNMS)
Licensee:	Theda Clark Regional Medical Center Department of Nuclear Medicine
Location:	130 Second Street Neenah, WI 54956
Date of Inspection:	May 6, 1997
Inspector:	D. G. Wiedeman, Senior Health Physicis
Approved By:	John R. Madera, Chief, Nuclear Materials Inspection Branch 1 Division of Nuclear Materials Safety
Attachment A:	Written directive dated 12/19/96 and dose record
Attachment B:	Letter from licensee dated May 7, 1997
Attachment C:	Letter dated May 6, 1997 to the referring physician
Attachment D:	Letter dated May 6, 1997 to the patient

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EXECUTIVE SUMMARY

Theda Clark Regional Medical Center
Neenah, Wisconsin
NRC Inspection Report No. 030-03463/97001(DNMS)

This special inspection was conducted to review the circumstances surrounding a misadministration that was reported by the licensee to the NRC on May 1, 1997, involving a patient treatment on December 20, 1996. The inspection also included a review of selected aspects of the licensee's routine diagnostic and therapeutic nuclear medicine and quality management program (QMP) implementation.

The misadministration event involved the administration of 4.6 millicuries {170 MBq} of sodium iodine I-131 to a patient being treated for hyperthyroidism, a dosage that was about 48% under the amount prescribed by the authorized user physician on the written directive.

The event occurred because the nuclear medicine technologist and physician preparing and administering the dosage failed to observe that the patient took both capsules each containing 4.6 millicuries of iodine-131. During the administration of the dosage, the patient was asked to take the capsules orally and then drink some water, however, the patient took only one of the two prescribed capsules containing the iodine-131. Neither the physician nor the technologist checked the container after the dosage administration and the remaining capsule remained in the plastic container inside a lead shield until it was discovered on May 1, 1997. The technologist and physician assumed that both capsules containing 4.6 millicuries {170 MBq} each for a total dose of 9.2 millicuries {340 MBq} were administered. The root cause of the event was failure to observe that the patient took both capsules, precipitated by the licensee's failure to have adequate procedures in place to ensure that the total dosage was administered to the patient, e.g. visual inspection of the dosage container and/or radiation survey of the dosage container after the administration of the dosage.

One violation associated with the misadministration was identified for failure to have adequate written QMP policies and procedures to ensure that the administered dose was in accordance with the written directive. The inspection disclosed the violation to be isolated and not representative of a programmatic weakness in the implementation of the license's QMP.

The licensee's routine nuclear medicine program and associated QMPs were found to be adequately developed and generally well implemented.

Report Details

1.0 Summary of Licensed Program and Inspection History

NRC License No. 48-09494-01 authorized the licensee to use byproduct material as radiopharmaceuticals in diagnostic and therapeutic nuclear medicine. The license also authorized in-vitro laboratory testing utilizing byproduct material listed in 10 CFR 31.11.

The licensee performed approximately 200 NRC-licensed diagnostic nuclear medicine procedures each month. In addition, the nuclear medicine department performs approximately seven to nine hyperthyroid treatments per year. Additionally, radiopharmaceutical therapy using strontium-89 was used one time in the past.

Previous inspections were performed of the licensee's NRC-licensed activities on September 5, 1991 and June 29, 1995. No violations were identified during either of these two previous inspections.

2.0 Sequence of Events

2.1 Inspection Scope

On December 20, 1996, the licensee administered 4.6 millicuries {170 MBq} of sodium iodine I-131 to a patient being treated for hyperthyroidism, rather than 10 millicuries {370 MBq} as prescribed by the physician in the written directive. The treatment error was initially identified by the licensee on May 1, 1997. On May 1, 1997, the incident was determined to be a misadministration and was reported to the NRC. An inspection was conducted at the licensee's facility on May 6, 1997 to review the circumstances of the event and other aspects of the licensee's program.

2.2 Observations and Findings

On December 19, 1996, [redacted], an authorized user under this license prepared a written directive for the administration of 10 ± 1.0 millicuries {370 ±37 MBq} of I-131 for the treatment of hyperthyroidism. The written directive was approved and the dosage from the two iodine-131 capsules were verified in the licensee's dose calibrator, see attachment A for a copy of the written directive and dose calibrator verification slip.

At approximately 10:30 am on December 20, 1996, a nuclear medicine technologist and an authorized user physician provided the patient with instructions to take and swallow the capsules inside a plastic container located inside a lead shield. According to the statements from licensee representatives involved in the administration of the dosage, they were aware that the total dosage prescribed by Doctor [redacted] (10 ±1.0 millicuries) consisted of two capsules containing 4.6

millicuries/capsule. However, during the administration of the dosage, neither individual directly observed the patient swallow the two capsules and assumed that both capsules were taken.

According to the nuclear medicine technologist (NMT) involved in the patient treatment, dual capsules containing the total prescribed amount of iodine-131 was common and the dosage of 10 millicuries for the treatment of hyperthyroidism was typical. The technologist stated that after the dosage was administered she did not recheck the inner plastic container to ensure that both capsules were taken.

On May 1, 1997, the chief NMT discovered the treatment error during a routine clean-up of used lead containers in the hot laboratory and discovered an iodine-131 capsule inside one of the lead containers. After checking patient records and interviewing the staff it was concluded that the patient treated on December 20, 1996 received only half of the prescribed dosage. On May 1, 1997, the error was confirmed by the radiation safety officer, who determined the incident to be a misadministration and reported it to the NRC.

2.3 Conclusions

The immediate cause of the event was the technologist and physician administering the dosage failed to observe the patient to ensure that both capsules were taken and failed to re-check the capsule container after the dosage was administered. The patient was administered 4.6 millicuries {170 MBq} rather than the prescribed 10 millicuries {370 MBq} because it was assumed that the patient took both capsules.

According to the licensee, the effect on the patient was negligible because followup tests of the patient's thyroid function indicated that the treatment with 4.6 millicuries {170 MBq} decreased the patient's thyroid activity and additional treatment(s) will not be needed and that there would be no anticipated adverse effects. The licensee plans to continue to monitor the patient during follow-up examinations.

3.0 Event Investigation

3.1 Inspection Scope

The inspector reviewed the circumstances of the misadministration event and assessed the root and contributing causes. Licensee staff involved in the incident were interviewed, as were other staff involved in the routine nuclear medicine program. Records and procedures were also reviewed as part of the inspector's assessment.

3.2 Observations and Findings

The licensee's nuclear medicine department has developed an administrative system for requesting and tracking the various studies that are to be performed within the

department. All studies involving the administration of NRC-licensed material must be specifically approved by an authorized user physician, by completing a "requisition slip". The requisition slip includes the patient's name and the requested study. Requisition slips, however, do not usually specify the dosage to be administered. For quantities of radioiodine I-131 in excess of 30 microcuries {1,110 kBq}, a written directive or "prescription slip" must be reviewed and signed by an authorized user physician, see attachment A. Nuclear medicine technologists (NMTs) have been instructed through in-service training not to administer sodium iodine I-131 unless a completed prescription slip is available and the dosage has been verified to be in accordance with that recorded on the prescription slip.

The NMT involved in the misadministration incident had about six years experience as a technologist in the licensee's nuclear medicine department. The individual routinely administered quantities of I-131 in excess of 30 microcuries. Interviews disclosed that the NMTs were well versed in the QMP requirements of 10 CFR 35, all were aware of the licensee's procedures which require a written directive (i.e. prescription slip), signed and dated by an authorized user, that includes the patient's name, radioisotope and dosage.

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive, which is defined in 10 CFR 35.2.

The licensee's quality management program for radiopharmaceuticals dated July 7, 1994, requires that prior to administration, the person(s) administering the dosage must verify that the dosage is in accordance with the written directive.

However, as described above, on December 20, 1996, a technologist and authorized user physician administered 4.6 millicuries {170 MBq} of sodium iodine I-131 to a patient, and failed to verify that the dosage was in accordance with the prescribed dose of 10 millicuries {370 MBq} as requested on the written directive by another authorized user physician.

<u>The failure to have adequate written policies and procedures to verify that the administered dosage is in accordance with the prescribed dosage in the written directive is a violation of 10 CFR 35.32</u>.

Based on inspector review of the licensee's QMP and procedures, interviews of nuclear medicine staff, and review of randomly selected cases involving the administration of sodium iodine I-131, it appears that the QMP violation was isolated. The failure to follow the QMP and implementing procedures established

by the licensee did not appear to be representative of a programmatic weakness in the implementation of the program. This conclusion was supported by previous inspection findings in this area in 1991 and 1995.

3.3 Conclusions

Although a violation of the licensee's QMP was identified and directly resulted in a misadministration, the problem appeared isolated and not indicative of a programmatic weakness in the implementation of the QMP. The nuclear medicine department developed adequate control mechanisms to ensure that the administration of NRC-licensed materials does not take place unless "requisition slips" and, if required, "prescription slips" have been completed by an authorized user that include the patient's name, radioisotope and dosage.

4.0 Event Corrective Actions

4.1 Inspection Scope

The inspector reviewed the immediate and long term corrective actions taken or proposed by the licensee as a result of the misadministration event.

4.2 Observations and Findings

The licensee concluded that the event occurred because the nuclear medicine technologist and authorized user physician did not observe the patient take the capsule(s) containing iodine-131 and did not recheck the capsule container after the dosage was administered. On May 6, 1997, five days after the error was identified, the RSO drafted additional procedures to be appended to its existing QMP which includes the following: (1) add an additional line to the written directive which requires documenting the number of capsules received and number of capsules administered, (2) require that the person(s) administering the dosage to observe the patient during administration of the capsules, (3) recheck the capsule container after administration to ensure that all capsules are administered and (4) in-service training to the NMT staff.

4.3 Conclusions

The licensee's corrective actions appear appropriate and sufficiently comprehensive to address the problem and to prevent recurrence.

5.0 Notifications and Reports

5.1 Inspection Scope

The inspector reviewed the actions taken by the licensee to comply with the notification and reporting requirements of 10 CFR 35.33. The inspector interviewed management representatives, NMTs and the RSO, and reviewed the licensee's "draft" written reports to the NRC and involved patient.

On May 1, 1997, the RSO discovered the incident and determined it to be a misadministration. The NRC Region III Office and Operations Center were notified later that day in accordance with 10 CFR 35.33. The RSO attempted to notify the referring physician of the misadministration on May 1, 1997, but was unable to contact him because he was unavailable, however on the day of the inspection it was confirmed by the licensee that the referring physician was notified on May 2, 1997, see attachment C. In addition, the patient was notified by letter from the licensee dated May 6, 1997, see attachment D.

The licensee submitted its written report of the misadministration to the NRC Region III Office in a letter dated May 7, 1997, see attachment B. The written report satisfied both the timeliness and informational requirements of 10 CFR 35.33. At the time of the on-site inspection the referring physician was not available, however, on May 14, 1997, the inspector contacted him by telephone and confirmed that he was fully aware of the misadministration.

5.3 Conclusions

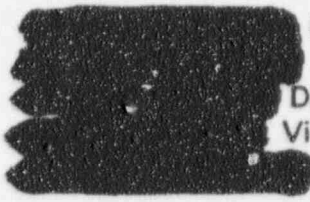
The licensee made all NRC-required notifications and reports associated with the misadministration event in a timely manner. The content of the notifications and reports met all informational requirements of 10 CFR 35.33.

Exit Meeting Summary

The inspector discussed the preliminary inspection findings with licensee management and other representatives during an exit meeting at the licensee's facility on May 6, 1997. The meeting included a discussion of the apparent violation, the causes, and the NRC Enforcement Policy.

The license did not identify any information reviewed during the inspection as proprietary.

PARTIAL LIST OF PERSONS CONTACTED



Radiation Safety Officer
R.T., Nuclear Medicine Technologist
Director of Diagnostic Services
Vice President of Diagnostic Services
, Referring Physician

INSPECTION PROCEDURES & MANAGEMENT DIRECTIVE USED

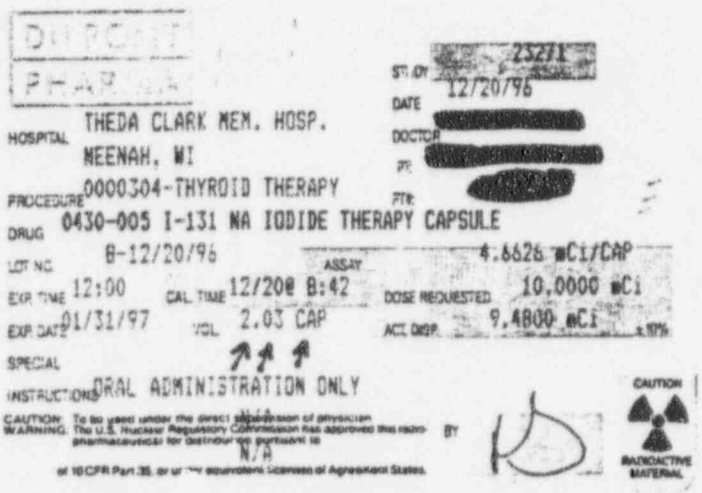
IP 87100	Licensed Materials Programs
IP 87103	Inspection of Incidents at Nuclear Materials Facilities
MD 8.10	NRC Medical Event Assessment

ITEMS OPENED

030-03463/97001(01)	VIO	Failure to have adequate written procedures and policies to ensure that the administered dose is in accordance with the prescribed dose in the written directive.

LIST OF ACRONYMS USED

CFR	Code of Federal Regulations
GBq	Gigabequerel
kBq	Kilobequerel
MBq	Megabequerel
mCi	Millicurie
RSO	Radiation Safety Officer
QMP	Quality Management Program
I-131	iodine-131



DUPONT
PHARMA

HOSPITAL THEDA CLARK MEM. HOSP.
MEENAH, WI

PROCEDURE 0000304-THYROID THERAPY

DRUG 0430-005 I-131 NA IODIDE THERAPY CAPSULE

LOT NO B-12/20/96

EXP TIME 12:00 CAL TIME 12/20@ 8:42 ASSAY 4.6626 mCi/CAP

EXP DATE 01/31/97 VOL 2.03 CAP DOSE REQUESTED 10.0000 mCi

ACT DISP 9.4800 mCi ±10%

SPECIAL INSTRUCTIONS ORAL ADMINISTRATION ONLY

CAUTION: To be used under the direct supervision of physician. The U.S. Nuclear Regulatory Commission has approved this radiopharmaceutical for distribution pursuant to N/A or 10 CFR Part 35, or under equivalent licenses of Agreement States.

BY KD

STUDY 23271

DATE 12/20/96

DOCTOR [redacted]

PT [redacted]

PTR

CAUTION RADIOACTIVE MATERIAL

Copy of dose calibrator slip which is used to verify the total dosage from both capsules

ATTACHMENT A

PAGE 2 of 2 PAGES

REPORT No. 030-03463
97-001

THEDA CLARK
Regional Medical Center

I-131 IODIDE ADMINISTRATION
[For any activity greater than 30uCi I-131 Iodide]

Procedure (check one): ☐ Diagnostic ☒ Therapeutic

I. PRESCRIPTION
(Written Directive)

Patient's Name: [redacted] ;Hosp #: [redacted]

Date to be administered on: 12/20/96 Radiopharmaceutical I-131

Activity to be administered: 10mCi; Radionuclide Form: ☒ Capsule, ☐ Liquid

Route of administration: Oral, Prescribing Physician: [redacted]

Physician's signature: [redacted] Date: 12-19-96

II DOSAGE VERIFICATION

Dosage Received: 9.4 mCi of I-131 _____ In ☒ Capsule, ☐ Liquid, Form

Date Received: 12/20/96; By: [redacted]

Does the dosage received confirm with the written directive? ☒ YES; ☐ NO.
[If the dosage does not confirm with the written directive, notify the RSO immediately].

Signature: _____; Date _____

III PREGNANCY TEST:

Has the pregnancy test been perfromed?

☐ YES; ☒ NO

Results: ____negative; ____ Positive

If the patient is pregnant, inform the authorized user immediately.DO NOT PROCEED FURTHER

Signature: _____

IV NURSING:

Is the patient Nursing a baby?

☐ YES; ☒ NO

If the patient is nursing a baby, inform the authorized user immediately. DO NOT PROCEED FURTHER.

Signature: _____

V ADMINISTRATION VERIFICATION

The patient's identity must be verified by TWO methods:

1. Call the patient by complete name (including middle name); and check below the second method used: ☐ Name on the patient's ID bracelet; ☐ Birth Date; ☒ Social Security Number; ☐ Address

See Attached Sheet 1

Activity measured in the dose calibrator: ____mCi of ___ at _____ on _____

Activity administered 9.4 mCi at 10:30 on 12/20/96

Physician's Signature: [redacted] Date _____

Technologists Signature: [redacted] Date 12/20/96

Form ITH/94

130 Second St. • Neenah, WI 54956 • 414-729-3
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ATTACHMENT A

PAGE 1 of 2 PAGES

REPORT No. 030-03463 97-001

Theda Clark Medical Center
United Health Partner

Theda Clark Medical Center
130 Second St.
P.O. Box 2021
Neenah, WI 54957-2021

Phone 414-729-3100

May 7, 1997

Mr. John Madera,
Chief Nuclear Material Inspection Branch,
U.S. Nuclear Regulatory Commission,
Region III,
801 Warrenville Road,
Lisle, IL 60532

Reference: Byproduct Material License # 48-09494-01

Dear Mr. Madera;

This letter is to inform you of a therapeutic misadministration which took place at our facility on 12/20/1996. The incident was discovered on 5/1/1997 by one of my technologists. I reported the incident in a phone conversation with both Mike Lafranzo from Region III office and to John Mackinnon at the operation center on 5/1/97. I also contacted the referring physician on 5/2/97. The referring physician informed me he would notify the patient himself on 5/2/97.

Description:

A patient was to receive a therapeutic dose of I-131 on 12/20/1996. The prescribed dose of 10 mci was made by [redacted] A dose was received of 9.4 mci comprised of two capsules. Both capsules were assayed together along with an absorbent pad in the vial that they were received in. The administration of apparently one of the capsules took place, with the technologist and the authorized user not realizing that another capsule was also in the vial to be administered as well. It appears that the capsule may have become lodged between the vial and the absorbent pad in the vial. The vial was returned to the lead shield it was shipped in and placed behind some lead bricks in our hot lab for storage. Upon removing the lead shield and vial on 5/1/97 it was noticed that there was one capsule remaining in the vial. I contacted the original shipper to determine the exact strength of each of the two capsules. One Capsule was calibrated to be 4.2 mci and the other 4.9 mci. From this I determined that the patient received a dose of approximately 50% less than the prescribed dose. The lead shield was marked with a prescription indicating that two capsules were contained in the vial. The technologist and the authorized user failed to verify the number of capsules that may have been shipped in the container.

ATTACHMENT B

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97-001

9705160012

Effects to Patient:

The patient was seen in follow up by the referring physician on 5/2/97 to ascertain the efficacy of the treatment to date. On 5/5/97 the referring physician informed me that the patient's thyroid function indicated a hypothyroid state, so that no further intervention was needed by Nuclear Medicine.

Improvements:

We will be adding additional lines of information to our dosage verification forms to indicate the number of capsules received and administered for the prescribed dose. We will also reassay the administered vial to asses that no radioactivity remains in the vial.

Included with this letter is our revised QM plan indicated the above mentioned changes.

Sincerely,

[redacted]

Radiation Safety Officer

Theda Clark Medical Center
United Health Partner

Theda Clark Medical Center
130 Second St.
P.O. Box 2021
Neenah, WI 54957-2021

Phone 414-729-3100

May 6, 1997

[redacted]

Dear Dr. [redacted]

Enclosed is a letter addressed to the NRC describing the misadministration of therapeutic iodine-131 to one of your patients whom we spoke about on 5/2/97. By NRC regulations 10 CFR 35.33 I have also written a notification to your patient indicating the error and that corrective action has been taken to prevent this from happening again. A copy of this letter is also enclosed for your records.

For our records I would appreciate a letter from you documenting your notification to your patient.

I apologize for any concerns this error may have caused you or your patient. If I can be of any further assistance to you, please call me at 729-3179.

Sincerely,

5/9/97

[redacted]
Nuclear Medicine

Dear [redacted],
I have notified
Mrs. [redacted] of the situation described
above. No harm has been done.

[redacted]

ATTACHMENT C

PAGE 1 of 1 PAGES
REPORT No. 030-03463
97-001

Theda Clark Medical Center
United Health Partner

Theda Clark Medical Center
130 Second St.
P.O. Box 2021
Neenah WI 54957-2021

Phone 414-729-3100

May 6, 1997

Ms. [redacted]

Dear [redacted],

This letter is to inform you of some information that I discovered on 5/1/97 pertaining to your thyroid therapy administration on 12/20/96. A physician in Radiology atter consultation with [redacted] prescribed a dosage of Iodine-131 in the amount of 10 mci. The actual amount given to you was 4.6 mci. Dr. [redacted] was informed of this error on 5/2/97, at which time he informed me that he was in the process of performing lab test to asses your thyroid function. He informed me on 5/5/97 the lab tests indicate your thyroid function was below normal which was the desired effect of the therapy.

By Nuclear Regulatory Regulations 10CFR 35.33 I have reported this incident, and a review has taken place with an inspector from the NRC. Corrective action has been taken on our part to prevent this type of error from reoccurring.

I apologize for any concern this error may have caused you. If you have any questions or concerns of me please contact me at [redacted]

Nuclear Medicine

ATTACHMENT D

PAGE 1 1 PAGES

REPORT NO. 030-03463
97-001