U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-08523/94001(DRSS)

Docket No. 030-08523

License No. 34-12100-03 Category G Priority III

Licensee: St. Rita's Medical Center
730 W. Market St.
Lima, OH 45801-4667

Inspection At: St. Rita's Medical Center

Inspection Conducted: February 23, 1994

Inspector: Toye L. Simmons 4/7/94
Toye L. Simmons
Radiation Specialist
Date

Reviewed By: B. J. Holt 4/7/94
B. J. Holt, Chief
Nuclear Materials Safety
Section 1
Date

Inspection Summary

Inspection on February 23, 1994 (Report No. 030-08523/94001(DRSS))
Areas Inspected: This special, safety inspection was conducted in response to a radiopharmaceutical therapy misadministration reported by the licensee to NRC on January 20, 1994. The inspection included a review of the circumstances surrounding the misadministration, components of the radiopharmaceutical therapy Quality Management Program, and interviews with personnel.
Results: Of the areas inspected, no violations of NRC requirements were identified.

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DETAILS

1. Persons Contacted

*Brian Nye, Acting Manager of Radiology
*Holly Watters, Coordinator of Nuclear Medicine
Grace Bailey, Nuclear Medicine Technologist

*Indicates those present at the exit meeting held on February 23, 1994.

2. Inspection History and Licensed Program Review

A routine NRC inspection was conducted on December 3, 1992, to review the adequacy of the overall implementation of the radiation safety program. No violations of NRC requirements were identified.

License No. 34-12100-03 was last renewed in its entirety on March 9, 1994. The authorization to possess and use radioactive materials identified in 10 CFR 35.100, 200, 300, 400, 10 CFR 31.11, and depleted uranium, has not changed since the previous license renewal in 1988.

3. Radiopharmaceutical Misadministration Event Summary

A 41 year old male outpatient diagnosed with hyperthyroidism was scheduled to receive 15 millicuries (0.6 GBq) of iodine-131 on January 19, 1994. The licensee received one vial which contained two I-131 capsules from a local radiopharmacy. The technologist assayed the vial in the dose calibrator prior to administration and determined the activity to be 15.8 millicuries. At 2:30 p.m. EST, the patient was given the vial and told to self administer the contents. The vial was recapped and returned to its lead container. The lead container was then smeared, surveyed, and placed in the pharmacy shipping container which was returned to the pharmacy. On January 20, 1994, at approximately 11:00 a.m., a pharmacist called the licensee and questioned why one capsule remained in the vial. 10 CFR 35.2 defines a misadministration of a radiopharmaceutical involving iodine as when the administered dosage differs from the prescribed dosage by more than 20 percent and the difference between the administrated dosage and the prescribed dosage exceeds 30 microcuries (1.1 MBq). Based upon the assay of the returned capsule, it was determined that the patient had received 9.1 (0.34 GBq) millicuries which was approximately 39 percent less than the prescribed dose.

Upon discovery of the misadministration, the appropriate notifications required by 10 CFR 35.33 were made by the licensee on January 20, 1994. The patient returned to the licensee's facility on the morning of January 21, 1994, and received an additional 7.4 millicuries (0.27 GBq)

of I-131 in capsule form for a total dosage of 16.5 millicuries (0.61 GBq). While at the licensee's facility for the second dosage the patient was given a copy of the licensee's written report of the event. (See attachment A - licensee's report received 2/3/94). The original written directive was revised by the treating physician to reflect the dosage administered.

4. Brachytherapy Misadministration Evaluation

There are primarily two reasons for the occurrence of this event. First, the licensee historically obtained byproduct material from a nuclear pharmacy located in Toledo. Whenever I-131 was ordered for hyperthyroid therapies, the Toledo pharmacy would send one capsule. In June 1993, the Toledo pharmacy transferred some of its clients to a new pharmacy located in Fort Wayne, Indiana. The licensee was one of those clients transferred. From June 1993 until January 19, 1994, no therapies were performed, therefore, no I-131 capsules were ordered from the Fort Wayne pharmacy. When the order was placed for the case in question, two capsules were dispensed. Although the label indicated that two capsules had been dispensed, the licensee's technologist assumed, based on her experience with the Toledo pharmacy, that one capsule was present. Secondly, both capsules were contained in one small vial. A packet of silicate was placed between them and the label identifying the product obscured one capsule from visual identification. When the vial was assayed, the correct dosage was confirmed. However, since the licensee normally received only one capsule, the patient was administered one capsule.

The apparent root cause of this misadministration was the technologist's assumption that the nuclear pharmacy delivered one I-131 capsule, as had been done in the past. The failure of the technologist to fully read the product label and the packing of the I-131 capsules are contributing factors to this event.

Following the misadministration the licensee instituted two procedures to preclude such an incident from recurring. Capsules are to be physically counted prior to dosing the patient and the vial is to be assayed in the dose calibrator following administration. Since the misadministration occurred, at least one other iodine therapy has been performed without incident. The licensee's corrective actions appear to be adequate.

Because the total dosage was delivered within a short period, no adverse affects to the patient are expected. The facts of this misadministration were discussed with an NRC medical consultant who determined that further review was not warranted.

No violations of NRC requirements were identified.

5. Implementation of the Licensee's Quality Management Program (QMP)

The inspection included a review of the licensee's implementation of its QMP with regard to administrations of I-125 and I-131 in quantities greater than 30 microcuries.

In accordance with 10 CFR 35.32 (f)(2), the licensee submitted a written QMP to the NRC with a letter dated January 3, 1992, and provided a statement that the program had been implemented. A revised QMP was submitted to NRC with a letter dated October 1, 1993, to include therapeutic administrations of radiopharmaceutical other than sodium iodides. The program appears to meet the objectives outlined in 10 CFR 35.32.

In the case of the misadministration, it appears that the licensee adequately implemented its QMP based upon the following: (a) a written directive was generated for this therapy by the treating physician; (b) the patient's identity was verified by two methods, social security number and date of birth; (c) the dose was assayed in the dose calibrator prior to administration; (d) an unintended deviation from the written directive was identified, evaluated, and appropriate action was taken to assure that the patient was properly dosed.

Based on NRC inspector interviews with members of the licensee's staff, QMP training has been provided as required.

On December 14, 1993, the licensee conducted a review to verify compliance with and to determine the effectiveness of all aspects of its QMP. No deficiencies were noted. (see attachment B - QMP annual review)

No violations of NRC requirements were identified.

6. Exit Meeting

At the conclusion of the inspection on February 23, 1994, the inspector met with those individuals identified in Section 1 of this report. The inspector summarized the scope and findings of the inspection and discussed NRC's enforcement options.

The licensee discussed the actions taken to preclude such an event from recurring. These actions are discussed in the body of this report. The licensee did not identify any of the information addressed as proprietary.

Attachments:
A. Licensee's rpt rec'd 2/3/94
B. QMP annual review 12/14/93

U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, Illinois
60532-4351

NOTICE OF MISADMINISTRATION

SECTION I- Licensee

St. Rita's Medical Center
730 W. Market St.
Lima, Ohio 45801
License #34-12100-03

SECTION II- Prescribing Physician

Dr. Thomas Church
St. Rita's Medical Center
Lima, Ohio 45801

SECTION III- Brief Description

A 41 year old male patient received an oral dose of I131 sodium iodide, , in capsule form for the treatment of Hyperthyroidism on 1/19/94. His prescribed dose of 15mCi. of 131I sodium iodide : in capsule form.
Upon the patient's arrival, Dr. Church provided this patient with a very thorough explanation of the procedure and precautions needed to be followed. The dose was verified by assaying the vial in the dose calibrator by Holly Watters, R.T.,(R), C.N.M.T., and Florence McNall R.T.,(R),(N),R.D.M.S. This was done by verifying the written directive, the prescription number on the package receipt and on the vial itself, the calibration assay of the dose from the dose calibrator. (The capsule(s) in this vial were not removed from the glass vial for the assay, to avoid unnecessary handling of the capsule and to avoid undo exposure). This male patient was given the capsule for self administration at 1430 on 1/19/94. The vial was then recapped, placed back in lead container, wiped, surveyed, then placed in the stroage box for return shipment to Syncor. Surface readings were 0.01 mr/hr, so this did not indicate that another capsule was in the container.
On Tuesday, 1/20/94 at 11:00AM., our Syncor pharmacists called and asked us why we only gave one capsule! I told her that I did not see any other capsule in the vial and only one capsule came out of the vial when administered to the patient. This is when it was realized a misadministration had occurred. I asked how much was in the remaining capsule and we were able to back figure the actual activity of the non-ingested capsule to be 6.7 mCi. as of 1/19/94, which means this patient received 9.1 mCi. of 131 I sodium iodide. . This was approximately 39% LESS than prescribed and assayed dose of 15.8 mCi.

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ATTACHMENT A

SECTION IV.- Why this event occurred.

There was a salt type package,also in this small vial which apparently was in front of the other capsule. I truely did not see the second capsule and prevented the other capsule from coming out of the vial when fed to this patient. Neither Dr. Church nor myself even questioned the fact of one capsule vs. two capsules for the 15 mCi dose usually comes in one capsule from Syncor. We are used to recieving only one capsule for these types of treatment.

SECTION V.- Effect on the Patient

I notified Dr. Church at 11:30A.M. on 1/20/94 and he determined we should give the remainder part of his treatment as soon as possible and that this would not alter the effect of his treatment. Also after talking with the referring physician, Dr. George Herman at 1448 on 1/20/94, he also stated that it was close enough together that the treatment effects would be the same. This patient was to return at 7:30 A.M. on 1/21/94 for the remainder of the dose.

SECTION VI- Improvements that are needed to prevent recurrence.

To be more observant to the number of capsules in the vial and to match the number actually given to the patient.

SECTION VII- Corrective action taken to prevent recurrence

After talking with Wayne Sawinski (1-708-829-9820), it was decided that in order for this to never happen again, we are implementing the practice to assay the empty vial before shipping back to Syncor. Also to note the number of capsules in these vials vs the number of capsules given to the patients.
These two items will be recorded and placed in the patient's chart.

SECTION VIII.- Licensee Notification to the Patient

Once I realized what had happened after talking with Syncor at 11 A.M. EST. on 1/20/94.

#1- Notified Dr. Eric V.Bostick,RSO,Chief Radiologist at 11:15 A.M. on 1/20/94.

#2- Called the patient's house and talked with patient's wife at 11:20A.M. I informed to her what had happened about her husband, only recieving one capsule. That he needed to return for completion of his dose. She informed me that she would call her husband at work and would make arrangements for him to come in on 1/21/94.

#3- Talked with Dr. Church at 11:30A.M., The prescribing doctor, and he asked to have the patient return as soon as possible.

#4- I talked with Tracey King, MPC consultant, at 11:45A.M. on 1/20/94, who in turned said she would call the NRC. She talked with Wayne Sawinski at approximately 12:00 EST. on 1/20/94. I also talked with Mr. Sawinski on this same date.

#5- At 1448 on 1/20/94, I talked with the referring physician, Dr. George Herman. Explained to him what had happened, about giving his patient LESS than the prescribed amount and that his patient had been asked to return on 1/21/94. He was very understanding and was very knowledgable to the fact that no harm was brought to his patient.

#6- I then again called the patient's home and reaffirmed with the patient's wife that she had infact talked with her husband. I once again reassured her that there would be no adverse affect on him and that once again what had happened was that he was only given one capsule (which is what we usually get in from our supplier instead of two). She was very understanding and said that her husband would return to our department at 7:30 AM. on 1/21/94.

#7- At 1430 on 1/20/94, I also talked with Wayne Sawinski ,from NRC, We discussed what had happened, who was notified, what was to be done to prevent recurrence, and what would be in his report and that a physician might call the referring physician and or RSO.

#8- At 7:45 A.M. on 1/21/94. this gentleman did in fact return to our department. He did receive and additional 7.4mCi. of Na 131 I in capsule form. There were two capsules given and two capsules in the vial came in. He therefore, received a total 16.4 mCi of Na131 I The empty vial measured 0.01 uCi. with background reading 0.1 mCi. from our dose calibrator. Dr. Church did reassure this patient that there would be no ill affects for his treatment

SECTION IX- Information to be prvided to the Patient

This gentleman was notified by phone on 1/20/94 with his wife answering, in person on at 7:30 A.M. on 1/21/94 and is being sent a copy of this report.

Dr. Eric V. Bostick, RSO Chief Of Radiology	Dr. Thomas Church Prescribing Doctor	Holly Watters,R.T.,(R),C.N.M.T. Coordinator of Nuc. Med. Person preparing report

Medical Physics Consultants, Inc.

St. Rita's Medical Center

QUALITY MANAGEMENT PROGRAM ANNUAL REVIEW

12/14/93

License No.: 34-12100-03

Date of last review or implementation: 12/22/92

Conducted by: Holly Waters, Coordinator
Tracy King, Physicist

Reviewer's summary of effectiveness of existing Quality Management Program

Good.

Review

1.	Number of administrations of greater than 30 uCi of NaI-125 or NaI-131 or NaI-131 and therapeutic radiopharmaceuticals made since the last review	9
2.	Sample size used for review	9
3.	Compliance rate of having written directives for administrations of greater than 30 uCi of NaI-125 or NaI-131 and therapeutic radiopharmaceuticals	9/9
4.	Compliance rate of required contents included in written directive	9/9
5.	Percentage of supervised individuals properly instructed in written quality management program and requirement of following authorized user instructions	in process
6.	Compliance rate of verification of patient's identity by more than one method.	9/9

ATTACHMENT B

7. Compliance rate of verification methods matching those stated in written quality management program 9/9

8. Compliance rate of administrations of radiopharmaceuticals in accordance with written directive 9/9

9. Number of unintended deviations from written directive identified by staff 0

10. Number of those identified which were properly evaluated and for which appropriate corrective action was taken N/A

11. Number of recordable events which occurred since last review 0

12. Compliance rate of responding as required to recordable events N/A

13. Number of misadministrations which occurred since last review 0

14. Compliance rate of notifying and reporting misadministrations as required N/A

15. Compliance rate of keeping appropriate records:
    - written directives 9/9
    - radiopharmaceutical dosages 9/9
    - recordable events N/A
    - misadministrations N/A
    - annual reviews 1/1

16. Number of unintended deviations from quality management program identified during this review 0

    Types of deviations:

17. Corrective action recommended:

    change in procedure: N/A

    documenting recordable events:

    reporting misadministrations: