U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02006/90-001(DRSS)

Docket No. 030-02006

License No. 21-01333-01 Category G Priority 1

Licensee: William Beaumont Hospital
5601 w. 13 Mile Road
Royal Oaks, MI 48072

Inspection Conducted: October 17, 1990

Inspectors:

R. J. Caniano, Chief
Nuclear Materials Safety
Section 2

November 4, 1990
Date

M. F. Kurth
Radiation Specialist

November 2, 1990
Date

Approved By:

J. A. Grobe, Chief, Nuclear
Materials Safety Branch

11-7-90
Date

Inspection Summary:

Inspection on October 17, 1990 (Report No. 030-02006/90-001 (DRSS))
Areas Inspected: This was an announced special inspection conducted to review the circumstances surrounding a therapeutic iodine-131 misadministration which occurred at the licensee's facility on October 15, 1990.
Results: Although no violations of NRC requirements were identified, concerns were expressed over the storage of stock iodine-131 solution with a patient intended dose and the lack of communications between the technologist who prepared the dose and the technologist who administered the dose (Section 5).

DETAILS

1. Persons Contacted

Howard Dworkin, M.D., Chief of Nuclear Medicine
*Ann Forsaith, Radiation Safety Officer
*Larry Randolph, Associate Hospital Director
Robert Gutkowski, Chief Radiopharmacist
Helena Balon, M.D., Authorized User
Stuart Dees, Chief Technologist
Nancy Sawyer, Director Education Program
Cheryl Culver, Medical Physicist
*Joseph Dylag, Senior Assistant Hospital Director
*Darlene Fink, M.D., Chairperson, Radiation Safety Committee

* Denotes those present at exit meeting.

2. Purpose of Inspection

This was a special, announced inspection conducted to review the circumstances surrounding a reported therapeutic misadministration which occurred on October 15, 1990.

3. Licensed Program

NRC License No. 21-01333-01 was originally issued to William Beaumont Hospital on November 1, 1956, and was last renewed in its entirety on August 10, 1987, by Amendment No. 44. This license authorizes any byproduct material with Atomic Nos. 3-83 including those materials referenced in 10 CFR Parts 35.100-35.500. The authorized uses of the licensed materials are for medical research, diagnosis, therapy and laboratory research including animal studies.

This hospital performs on an annual basis approximately 6000 diagnostic procedures, approximately 60 brachytherapy procedures and approximately 60 iodine-131 therapy procedures. The licensee operates their own nuclear pharmacy under the supervision of a radiopharmacist.

4. Inspection History

The last inspection of this licensee was conducted on November 15, 1989 at which time three violations of NRC requirements were identified: (1) failure to heat seal the ends of iodine-125 seeds prior to patient implants, (2) failure to inventory brachytherapy sources promptly after patient explant, and (3) failure to record radiation surveys following implanting of brachytherapy sources. These violations were associated with the loss of six iodine-125 brachytherapy seeds.

Prior inspections conducted in September of 1989 and June and July of 1986 identified no violations of NRC requirements.

5. Incident Summary

In addition to the requirements set forth in 10 CFR Part 35.53 (measurements of radiopharmaceutical dosages), 10 CFR Parts 35.60 and 35.61 (labeling of syringes and vials), and 10 CFR Subpart F, Radiopharmaceuticals for Therapy, the licensee also has established their own procedures for the dispensation of iodine-131 therapy solutions. This procedure is outlined in Item 19 of the licensee's application dated February 27, 1987, referenced in License Condition No. 20 (Attachment A). In addition to describing general safety precautions for the handling of iodine-131 solution, the procedure also requires the use of a dose calculation sheet and requires an assay of the dose prior to administration.

On October 10, 1990, a 60-year-old female patient was referred to the nuclear medicine department for an iodine-131 thyroid ablation therapy after undergoing a thyroidectomy for papillary carcinoma. After reviewing the available clinical data on the patient the authorized physician user prescribed 175 millicuries of iodine-131 solution, to be administered orally on October 15, 1990. This prescription was written by the authorized user and forwarded to the department's nuclear pharmacy for ordering.

On October 15, 1990, the licensee received the oral iodine-131 solution from an authorized distributor for the scheduled therapy procedure. In addition, the licensee also received a vial containing 140 millicuries of iodine-131 solution. This vial is a standing order for the hospital which is received every Monday morning for use during the week. Upon receipt and survey of the packages containing the iodine-131 therapy solutions, the licensee proceeded to assay each of the two vials at approximately 10:00 a.m. and recorded the results. The vial containing the iodine-131 solution for the scheduled therapy patient was assayed at 180 millicuries and the standing order solution was assayed at 140 millicuries. At this time the technologist also prepared the required unit dose record for the patient which contained information including patient name, time of assay and assay data, type of procedure to be performed, and the initials of the technologist assaying the dosage. Noting that the assay of the iodine-131 patient vial was 180 millicuries rather than 175 millicuries as had been prescribed, the technologist proceeded to question the authorized user whether that amount could be administered. Authorization to administer that amount was given by the authorized user, and the technologist affixed a label to the top of the container indicating assay information.

After the dosage assay procedure and associated paperwork was completed, the technologist proceeded to place both vials of iodine-131 solutions in the fume hood located in the nuclear pharmacy. Both vials, which were still in their original leaded shields and labeled as to their contents, were placed side by side along with the unit dose record prepared for the patient.

At approximately 10:30 a.m. the authorized physician user was ready for the administration of the 180 millicurie dose to the patient and called for the material. Since the technologist who had prepared the dosage was not readily available, another technologist, after being informed that the dosage was assayed and ready for patient administration, proceeded to the nuclear pharmacy to get the radiopharmaceutical. The technologist who prepared the dosage, did not indicate to the administering technologist how many vials were to be administered. The administering technologist observed both vials side by side in the fume hood and reviewed the dose record which was under the vials. He then picked up both vials, assuming that both were to be administered to the patient, and proceeded to the patient's private room along with the authorized physician user and physicist to administer the dose. The technologist did not review the labels on the containers assuming that they were the proper doses. The technologist also did not consider the administration of more than one vial of iodine-131 to be unusual since this is a common occurrence at this facility.

Arriving at the patient's room the authorized physician user reviewed the dosage record and instructed the technologist to proceed and administer the dose to the patient. The technologist administered both vials which contained approximately 320 millicuries of iodine-131. The authorized user did not review the labeling on the containers assuming that, since the unit dosage record was complete and indicated a dosage of 180 millicuries, the vials were the proper ones for administration. The authorized user also did not question the multiple vials since, as previously indicated, it is common occurrence at this hospital to administer more than one vial of iodine-131 solution to a patient.

Following the administration of the iodine-131 to the patient the licensee proceeded to post the patient's room and perform radiation surveys in accordance with the requirements set forth in 10 CFR Part 35.315. The survey results indicated levels of 250 milliRoentgen per hour (mR/hr) at the patient's bedside, 36 mR/hr at one meter and 0.1 mR/hr at the patient's doorway and unrestricted areas. While performing the radiation surveys, the physicist noted that, although the surveys were well within the 10 CFR Part 20 limits for unrestricted areas, the results at the patient's bedside and one meter were slightly above what is normally detected with the administration of 180 millicuries of iodine-131. This concern was alleviated once the physicist reviewed the patient's unit dose record which indicated that the 180 millicuries of iodine-131 was administered.

On the following day, October 16, 1990, the nuclear pharmacist received a request for 25 millicuries of iodine-131 from the West Bloomfield site, an authorized place of use for William Beaumont Hospital. Assuming that the material was available from the standing order received the previous day, the nuclear pharmacist acknowledged the order indicating that it would be filled as requested. Later that day the nuclear pharmacist proceeded to fill the order and was unable to locate the standing order vial received on October 15, 1990. Inquiring as to its whereabouts, the licensee

determined that the vial had been erroneously administered on the previous day. Additionally, on October 15, 1990, the licensee, in accordance with 10 CFR Part 35.315(a)(8), conducted a thyroid uptake of the technologist who had administered the iodine-131 dose on the previous day. The results of that bioassay were found within 10 CFR Part 20 limits.

On October 17, 1990, the licensee, after determining that the incident constituted a therapeutic misadministration as defined in 10 CFR Part 35.2, informed the patient and her referring physician of the event. On the same date and as required by 10 CFR Part 35.33 (a), the licensee also telephonically contacted the NRC Region III office. The licensee also held an emergency safety meeting to discuss, amongst other things, the patient's estimated radiation doses (Attachment B) and planned follow-up medical treatment, of the patient. The planned follow-up treatment, at this time, will consist of a complete blood count and differential which will be obtained at three weeks and three months post dose. The licensee also began discussing the root cause of the error and corrective actions to prevent recurrence of a similar event in the future.

Following NRC notification, the NRC Region III office contracted with Frank R. Hendrickson, M.D. to serve as a medical consultant to evaluate and review the circumstances of the event and potential effects on the patient. Dr. Hendrickson's evaluation dated October 23, 1990 (Attachment C), indicated that the misadministration should not have any adverse medical effects on the patient's medical condition. Dr. Hendrickson also indicated that the licensee's corrective actions to prevent recurrence of similar misadministrations are appropriate and that the patient is being well cared for. The NRC also reviewed the licensee's estimated doses to the patient and independently calculated estimated doses. Those calculations were in close agreement to those of the licensee as indicated in Attachment B.

Although this event constituted a therapeutic misadministration as defined in 10 CFR Part 35.2, the factors leading to its occurrence did not represent any violations of NRC requirements. The contributing factors leading to the event appear to be that a stock solution of iodine-131 was being stored in the same area as the patient's dose and that the administering technologist was different than the technologist who prepared the dose. In the latter case, the technologist who prepared the dose failed to inform the administering technologist that there was only one vial to be administered to the patient. These factors were addressed as areas of concern to the licensee during the inspection and were the same factors that had been determined by the licensee in their evaluation of root causes.

In order to prevent recurrence of similar events from occurring at William Beaumont, the licensee, on October 18, 1990, submitted to the NRC Region III office in the form of an amendment request, a modification to their procedures for iodine-131 administrations. This modification which was put into place by the licensee immediately following the misadministration includes the following provisions:

a. Following dose preparation, both the individual dispensing the dose and the individual administering the dose to the patient should assay the dose together if possible. If the individual administering the dose cannot be physically present to assay the dose, then he/she must re-assay the dose and verify the correct activity prior to administration. Both individuals are required to record the assayed activity and their initials on the dose sheet indicating the number of vials that comprise the prescribed dose.

b. Just prior to administration of a cancer therapy dose to the patient, the physician will verify the assay dose activity with the prescribed dose and initial the dose sheet.

c. The standing order of therapeutic iodine-131 will be stored in the hot locker after being checked in and only placed in the fume hood when needed for dispensing.

On October 29, 1990, these procedures were incorporated into William Beaumont's NRC License via Amendment No. 53. Since two contributing factors to this misadministration involved: (1) the storage of stock solution of iodine-131 with the patient's solution and (2) the fact that the technologist who administered the dose was a different technologist that had prepared the dose, the licensee's submitted procedure modifications should significantly decrease the likelihood of a similar event from occurring.

A random review of other iodine-131 therapy procedures performed at William Beaumont from the period May 1990 to the date of this inspection revealed no violations or deficiencies.

On October 24, 1990, in accordance with 10 CFR Part 35.33(b) the licensee submitted a written report to the NRC Region III office detailing the misadministration.

No violations of NRC requirements were identified.

6. Exit Meeting

At the conclusion of the on-site inspection on October 17, 1990, the inspectors met with the individuals identified in Section 1 of this report. The preliminary results of the inspection were discussed along with the licensee's planned corrective actions. The licensee did not indicate that any information discussed or reviewed during the inspection was proprietary in nature.

Attachments:

A. Instructions for Dispensing Iodine-131
B. Dose Estimates
C. Medical Consultant's Report Dated October 23, 1990

ATTACHMENT A

PROCEDURE FOR DISPENSING SODIUM IODIDE I-131 THERAPY SOLUTIONS

ALL SODIUM IODIDE I-131 THERAPY SOLUTIONS MUST BE ORDERED BY THE RADIOPHARMACY. AT LEAST 24 HOURS NOTICE IS NEEDED FOR ORDERING.

A PATIENT DOSE CALCULATION SHEET MUST BE PRESENTED TO THE RADIOPHARMACY TO OBTAIN ANY THERAPY SOLUTIONS.

Precautions

Disposable gloves must be worn throughout the dispensing procedure.

Pipette bulb must be used to pipette. NO PIPETTING BY MOUTH.

Remote handling tools must be used to transfer dose bottles from lead shielding to dose calibrator.

Work in the exhaust hood while preparing I-131 therapy solutions.

Dispensing Procedures

1. Upon obtaining patient's dose calculation sheet, check calculation and patient for accuracy. Check lot number on dose bottle against lot number on dose sheet.

2. Transfer sodium iodide I-131 solution in its shielding to the exhaust hood in the hot lab of the radiopharmacy.

3. Using tool supplied by Mallinckrodt, remove cap from the bottle containing the I-131 solution and allow it to stand opened in the hood. (This will allow any volatile I-131 to be dispersed up the hood.)

4. Fill out all dispensing forms at this time.

5. Determine if any transfer of solution is necessary. Transfers should be made so that the amount of radioactivity being pipetted is minimized. Example: If 3 mCi is needed from a 10 mCi source, pipette 3 mCi from the 10 mCi vial and transfer to a shielded dispensing vial. If 140 mCi is needed from a 150 mCi source, pipette 10 mCi from the 150 mCi vial and transfer to a shielded, pre-labeled vial, and use the remaining 140 mCi as the dose container.

6. Working in the exhaust hood, prepare the dose.

7. Cap the dose bottle and transfer to the dose calibrator. Remote handling tools must be used to remove the dose bottle from the shielding and transferring to the dose calibrator. Dose calibrator reading must be within 10% of required radioactivity.

.....continued

Dispensing Procedures...continued

8. After the dose is prepared and calibrated, inform the assigned technologist that the dose is ready for administration.

9. The sodium iodide I-131 therapy solution is transfered in a shielded container to the administration area just prior to patient administration.

10. All personnel involved in the preparation and dispensing of sodium iodide I-131 therapy solutions are required to have a bioassay performed in accordance with USNRC Regulatory Guide 8.23.

ATTACHMENT B

I-131 Iodide 5% Uptake
Dose: 320 mCi I-131
Thyroid CA Ablation

Organ	Absorbed Dose
* Adrenals	38.7 Rads
* Bladder Wall	687
Bone Surface	38
Breast	37
GI Tract	
* Stomach Wall	533
* Small Intestine	332
* ULI Wall	70
LLI Wall	51
* Kidneys	75
Liver	35
Lungs	40
Ovaries	52
Pancreas	59
Red Marrow	45
Spleen	46
Testes	34
Thyroid	85,248
Uterus	65

Reference: ANNALS OF THE ICRP ICRP Publication 53
"Radiation Dose to Patients from Radiopharmaceuticals"

Total Body 76.8 Rads

Reference: MIRD DOSE ESTIMATE REPORT No. 5

* Critical Organ

ATTACHMENT C

RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER 1653 WEST CONGRESS PARKWAY, CHICAGO, ILLINOIS 60612 312/942-5751

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October 23, 1990

A. Bert Davis
Regional Administrator, Nuclear Regulatory Commission
799 Roosevelt Rd.
Glen Ellyn, IL 60137

Re: Preliminary Notification (PNO-III-90-70)

Dear Mr. Davis:

I have followed up on the above notification of a misadministration in Michigan. As you were notified, the patient received not only the intended vial of 180 millicuries of I-131, but an additional vial of 140 millicuries that was their regular weekly delivery and intended to be divided into smaller doses for other patients. The patient was a 60 year old female with papillary thyroid cancer that had invaded into the trachea with tumor having been left behind. Mr. Roy Caniano has visited the institution and discussed the situation with Ms. Ann Forsith and the two have seemed to work out a reasonable program to avoid such a misadministration in the future. I have reviewed the clinical situation with Dr. Howard Dworkin. The patient had a residual uptake in the neck of about three per cent. Following the administration, less than thirty per cent of the administered dose remained in the body forty eight hours later. The patient has subsequently been discharged from the hospital and follow up blood counts have been entirely normal. An estimate of the bone marrow dose received from the administration is between forty and fifty rads, which should be quite well tolerated. The patient and patients husband have been informed of the increased dose that she has received, and appropriate follow up measures are planned.

In view of the fact that the treatment of thyroid cancer with radioactive iodine can be done with quite varied administered doses and dose schedules, the actual dose that the patient received is not beyond the reasonable range for treatment of her condition. I feel that the misadministration will have no adverse effects on the patients status and in fact, may have a greater therapeutic benefit on her cancer.

It would appear that appropriate measures have been taken both to minimize the likelihood of a repetition of this particular problem and that the patient is being well cared for.

Sincerely:

Frank R. Hendrickson, M.D.

Frank R. Hendrickson, M.D.

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