Theda Clark Medical Center
United Health Partner

JRM
10CFR35.33

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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
03003463

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 Dr. Forrest Bates. 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.

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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,

Ed Marlewski, CNMT,RT,
Radiation Safety Officer

QUALITY MANAGEMENT PROGRAM (QMP)

All Nuclear Medicine technologists and personnel who handle radio-pharmaceuticals for therapy, including 30 uci or more of I-131 and I125 as Sodium Iodide, must review this Program.

If any individual needs guidance or does not understand this program they must contact the RSO or one of the authorized users.

Before administering a Radio-Pharmaceutical dosage, the identity of the patient must be verified by at least TWO methods:

1. Ask the patient's name and confirm the patient's name,

   and

2. **One** of the following-

   Name on the patient's ID bracelet,

   Birth date,

   Social Security Number,

   Address.

Quality Management Program (QMP) for:

a. Therapeutic dosage,

b. Any dosage greater than 30 microcuries of either sodium iodide I-125 or I-131.

1. Written Directive -

A **written** directive signed and dated by the authorized user (or by a physician under the supervision of an authorized user), will be issued prior to the administration of any therapeutic dosage of a radio-pharmaceutical or any dosage greater than 30 microcuries of I-125 or I-131 as sodium iodide. Form IT/97 will be used to issue the written directive.To meet this requirement, the authorized user will complete the Item # "I. Prescription" part of the attached form **"I-131 IODIDE ADMINISTRATION"** before the dosage is administered to the patient.

A. On rare occasions, if the therapy is delayed because of the absence of a written directive and if this delay would jeopardize the patient's health, an oral directive will be acceptable, provided the following steps are taken:

   a. information provided in the oral directive is documented immediately in the patient's records, and
   b. a written directive is prepared **within 24 hours** of the oral directive.

B. Occasionally a revision to the written directive may be necessary. if a delay occurs in obtaining this revision in writing, and if this delay jeopardizes the patient's health, an oral revision would be acceptable, provided-

   a. The oral revision is documented immediately in the patient's record, **and**
   b. A revised written directive must be signed and dated by an authorized user, or by a physician under the supervision of an authorized user, **within 48 hours** of the oral revision.

C. Written directives may be revised for any diagnostic or therapeutic procedures, however, the revision must be dated and signed by an authorized user prior to the administration of the radio-pharmaceutical dosage.

2. VERIFICATION OF THE WRITTEN DIRECTIVE

A. Before administering the byproduct material, verify the following to assure that the dosage is administered in accordance with the written directive-

a. Patient's identification,
b. Radiopharmaceutical
c. Dosage
d. Number of capsules
e. Route of administration (oral,IV,etc)
Use the revised Form IT/97 to comply with this procedure.

B. The individual administering the dosage should confirm the dosage by measuring it in the dose calibrator. The results must be compared with the prescribed dosage in the written directive. Use the Form IT/97 to log the data.

C. The individual administering the dosage will confirm that the entire dosage was administered by re-assaying the original container in the dose calibrator to verify that **no** radioactivity remains in the container. Use Form IT/97 to log the data.

D. The records for the following must be retained for a minimum of three years after the date of administration:

a. Each written directive
b. Each administered radiopharmaceutical dosage.

E. The authorized user will initial a written directive of the therapeutic dosage administered to the patient. See Form IT/97 to log this information.

3. PERIODIC REVIEWS:

A. The QMP data will be reviewed by the RSO as follows:

a. The first ten cases: each case will be reviewed within four weeks of the completion of the therapy,

b. Annually thereafter.

B. The number of cases reviewed annually will depend upon the number of therapies administered during that time period. The guidelines below will be followed:

Total Therapeutic Cases in the review period	**No. Of Cases reviewed**
20 or less	**All**
21 to 100	**20**
more than 100	**20%**

C. If the periodic review uncovers a misadministration or a recordable event, the review will be performed once every calendar quarter, until the results of the review of two successive quarters reveal no significant deficiencies with the program. Thereafter the review will be performed annually.

3. **RECORDABLE EVENTS:**

A. Each recordable event shall be evaluated within 30 days after the discovery of the event. The evaluation will include:
- assembling the relevant facts including the cause;
- identifying what, if any, corrective action is required to prevent recurrence.

B. Retain the recordable event records, including the evaluation results for three years.

C. The RSO and/or the authorized user will review the QMP with each employee involved with the misadministration or recordable event.

D. The effectiveness of the QMP-

The QMP will be considered as 100% effective when all of the therapeutic procedures performed are in compliance with the regulations.

E. If the QMP program is modified, the modification to the program will be submitted to the NRC with 30 days after the modification has been made.

F. The records of the reviews will be retained for three years.

QMP FOR THERAPEUTIC RADIO-PHARMACEUTICAL

OTHER THAN I-125 or I-131

THE QMP FOR I-125/I-131 WILL BE ADAPTED IN TOTALITY.

THEDA CLARK MEDICAL CENTER
NUCLEAR MEDICINE

I- 131 Iodine Administration

{ For any activity greater than 30 uci I-131 Iodine}

Procedure: (check one) ___Diagnostic ___Therapeutic

I. Prescription (Written Directive)

Patient Name:_____ Hospital ID#:_____
Date to be administered on:_____; Radiopharmaceutical _____
Activity to be administered:_____; Route of administration_____
Prescribing Physician:_____Date:_____

Physician' Signature:_____Date:_____

II. Dosage Verification

Dosage Received:_____mCi of I-131 in Capsule Form ; Number of Capsules:_____
Date Received:_____; Received By:_____
Does the Dosage received correspond with the written directive?_____
(If the dosage does not correspond with the written directive, notify the RSO immediately)

Signature: _____; Date: _____

III. Pregnancy Test

Has the pregnancy test been performed? _____**Yes** _____**NO**
Results: _____**Negative** _____**Positive** (If 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.

V. Administration Verification

The patients 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 ID Bracelet; _____Birth Date;
_____Social Security Number; _____Address;
Activity measured in the dose Calibrator: _____mCi of I-131 At_____on___/___/___;
Activity administered _____mCi I-131 At_____ on ____/____/____, No. of Capsules_____

Physician's Signature:_____ Date:_____

Technologist Signature:_____ Date:_____
Activity of container measured in the dose Calibrator after administration: _____