CPC #

DMB

Central Plains Clinic

December 5, 1995

Lic: 40-26865-01

U.S. Nuclear Regulatory Commission
Region 4
Attn: Mr. Ross A. Scarano, Director
Division of Nuclear Material Safety
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

RE: Response to an apparent violation inspection report No. 030-29708/95-02

Dear Mr. Scarano:

We are writing in response to NRC inspection report 030-29708/95-02, which was a reactive inspection conducted at Central Plains Clinic in response to misadministrations reported on September 28, 1995. We will specifically address those items that you recommend we include for this apparent violation.

1. Reason for apparent violation: Central Plains Clinic Quality Management Program was not fully adequate to prevent a decreased (lower than ordered) I-131 scan dose. The QMP, at the time of the apparent violation, did not absolutely assure that the number of I-131 capsules to be given as a dose was verified at the time of administration.

2. Corrective steps:

   a. The events were reviewed with all nuclear medicine staff members.
   b. The department software system has been changed so that the number of I-131 capsules per dose, as reported on the manufacturer's label, must be entered (previously would default to 1 capsule if not entered).
   c. Hence forth, I-131 vials will be assayed with documentation immediately after administration to ensure patient has received full dose.
   d. These corrective procedures have been reviewed with the nuclear medicine staff and are documented in our QMP.

96-0389

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IE-07

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Executive Director
David R. Rossing, M.D.
Medical Director

3. The above corrective actions were initiated shortly after discovery of the misadministration. The above procedures have now been formalized and finalized as of November 21, 1995. To date, there have been no recurrences of the apparent violation in question.

Enclosed please find copies of the appropriate documents concerning the above procedures and QMP.

Thank you very much for your assistance in helping us to identify and correct this problem. Please do not hesitate to contact us if you require any further information.

Sincerely,

T.A. Schultz, M.D.
Radiation Safety Officer
Chairman, Board of Directors

D. Garry Belton
Executive Director

TAS/kk

ENC.

Central Plains Clinic
Nuclear Medicine Department

Quality Management Program
Radiopharmaceuticals

Purpose of this Quality Management Program is to avoid misadministrations of radioactive materials and to provide confidence that the radioactive pharmaceuticals will be administered in accordance with the written direction of the authorized user.

This Quality Management Program contains the essential elements of the Quality Management Program outlined in 10 CFR Part 35 of the USNRC rules and regulations.

Polices and procedures have been written to meet the USNRC regulations governing the diagnostic and therapeutic administration of radiopharmaceuticals.

The following operating procedures are established in order to comply with these regulations.

I. Regarding I-125 and/or I-131 greater than 30 microcuries.

A. Prior to administration, an authorized user will sign and date a written order for diagnostic or therapeutic doses. Written order will contain the name of the specific patient and date of birth, the dosage to be administered and the route of administration.

B. An oral revision of a written directive is allowed if the patients condition or a delay to provide a written revision to an existing written directive would jeopardize the patients health. Oral revisions will be documented immediately in the patients record and a revised written directive will be signed and dated by an authorized user within 48 hours of the oral revision.

C. An oral directive will be acceptable if there is an emergent nature of the patients condition and a delay in order to provide a written directive would jeopardize the patients health. This oral directive will be documented immediately in the patients record and a written directive prepared within 24 hours of the oral directive.

D. If in the event a written directive is revised, the revision will be dated and signed by the authorized user prior to the administration of the radiopharmaceutical dosage. Unless the revision meets criteria as outlined in paragraph I-B, above.

E. Records of written directives and of each administered pharmaceutical dosage will be maintained for at least 3 years after the date of administration. After the administration of a radiopharmaceutical, the event will be documented by personnel under the supervision of an authorized user or an authorized user by initialing or signing the document of the administered dose which contains the date of the administration.

F. When administering a dosage of I-125 or I-131 greater than 30 microcuries (diagnostic or therapeutic) or any other radiopharmaceutical for therapeutic reasons, the patient will be verified by more than one method. Both of the following are acceptable methods; name of patient and date of birth.

After the dose has been administered, the I-131 container will be measured in the dose calibrator. This will be done to verity that the dose administered is in accordance with the written directive.

G. In the event an unintended deviation of a written order for a greater than 30 microcurie dose of I-125 or I-131 is discovered, it is to be reported immediately to the radiation safety officer. The circumstances will be investigated and evaluated. Evaluation will be made by the radiation safety officer and the department supervisor if any corrective actions are necessary.

H. If it is determined a recordable event has occurred, the licensee shall investigate and evaluate within 30 days. The following information will be needed.

1. Facts and cause of the event.
2. Any corrective action necessary to prevent a recurrence.
3. Retain a record of the relevant facts and action taken for three years.

I. Review of the program will be done annually. Number of patients to be reviewed will be based upon the number of cases performed during the year. The following minimum cases will be evaluated: 20% if the number of cases is performed is greater than 100. 20 cases if the number of cases is between 20 and 100, and all if the number of cases is less than 20.

J. In the event a previously unnoted misadministration or recordable event is uncovered during the periodic review of our QMP, the number of cases to be reviewed will be doubled. These additional cases will be selected randomly.

K. The effectiveness of this Quality Management Program will be evaluated at least on an annual basis. The effectiveness will be reflected by the number of reportable cases and/or misadministrations. The goal of this Quality Management Program is to eliminate all reportable cases of misadministrations.

L. Any modifications to our Quality Management Program will be submitted to the NRC within 30 days after modification.

II. Regarding therapeutic radiopharmaceutical other than I-125 and/or I-131.

A. The written directive or order must contain the following information: name of the specific patient and date of birth, the radiopharmaceutical, dosage, and the route of administration. This order will be signed and dated by an authorized user prior to administration.

B. If the patients condition is such that a delay in a written order revision would jeopardize the patients health an oral revision will be acceptable. Oral revisions must be documented immediately in the patients record and a revised written directive must be signed and dated by the authorized user or physician under the supervision of authorized user within 48 hours of the oral revision.

C. An oral directive will be acceptable if there is an emergent nature to the patients condition such as a delay in order to provide a written directive would jeopardize the patients health. This oral directive will be documented immediately in the patients record and a written directive prepared within 24 hours of the oral directive.

D. In the event a written directive is revised, the revision will be dated and signed by an authorized user prior to administration of the radiopharmaceutical, unless revision meets criteria as outlined in II-B, above.

E. Each written directive and a record of each administered pharmaceutical dose will be maintained for a minimum of three years. After the administration of the radiopharmaceutical, the event will be documented by personnel under the supervision of an authorized user or an authorized user by initialing or signing the document of the administered dose which contains the date of administration.

F. When administering a therapeutic radiopharmaceutical dose, the patient will be identified by both of the following two methods; patient name and date of birth.

G. In the event an unintended deviation of a written order for any therapeutic radiopharmaceutical other than I-125 or I-131 is discovered, it will be reported immediately to the radiation safety officer. Circumstances will be investigated and evaluated. Evaluation will be made by the radiation safety officer and the department supervisor if any corrective actions are necessary.

H. If it is determined a recordable event has occurred, the licensee shall investigate and evaluate within 30 days. The following information will be needed.

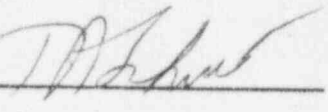
1. Facts and cause of the event.
2. Any corrective action necessary to prevent a recurrence.
3. Retain a record of the fact and action taken for three years.

I. A review of the program will be done annually. The number of cases to be reviewed will be dependent upon the total number of cases during the year in question. 20% of the cases will be reviewed if the total number is greater than 100. 20 cases if the number is between 20 - 100 and all if the number of cases is less than 20.

J. The number of cases to be reviewed will double in the event that a misadministration or recordable event is uncovered during a periodic review of our QMP.

K. Our QMP will be reviewed on a regular basis. The effectiveness of the QMP will be determined by the number of recordable events or misadministrations. Our goal is to eliminate all such events.

L. In the event that modifications to our QMP should occur, they will be submitted to the NRC within 30 days after modification.

Radiation Safety Officer 

Revision Date Nov 21, 1995

CENTRAL PLAINS CLINIC
Nuclear Medicine Department

NAME OF STUDY:
I-131 Thyroid Therapy

INDICATION FOR STUDY:
Radioactive Sodium Iodide-131 is administered with the intent to ablate the thyroid gland.

RADIOPHARMACEUTICAL AND DOSE:
Sodium Iodide-131 (Capsule form)

Individual dosage to be determined by the Nuclear Medicine physician. Not to exceed + 10% 29.9 mCi.

PATIENT PREPARATION:
The patient should remain NPO for a minimum of 4 hours prior to the administration of the I131 capsule(s).

ADMINISTRATION:

a. Prior to administration patient will be instructed to read the written precaution instructions.
b. The Ancillary order must have the patient's name, birth date, the dose, radiopharmaceutical, route of administration, signature of the Nuclear Medicine physician, and date of signature. A check mark will be made by the patient's birthdate and signature on the patient questionaire as they are verified with the order. The dose will be verified in the dose calibrator by two technologists.
c. The capsule(s) will be administered orally to the patient.
d. The I-131 vial will be measured in the dose calibrator after administration of the dose. This will be done to verify that no activity remains in the vial. This will be documented on the Cerner system requisition.
e. Instruct patient to wait 1/2 hour after the administration prior to leaving.
f. Patients should be instructed to notify the Nuclear Medicine Dept. or their physician if they have any questions or problems.

The Nuclear Medicine Department of Central Plains Clinic does not administer I-131 therapeutic doses exceeding + 10% of 29.9 mCi.

rev.10/95 ks

Nov 21, 1995

CENTRAL PLAINS CLINIC
NUCLEAR MEDCINE DEPARTMENT

NAME OF STUDY:
I-131 Whole Body Scan

INDICATION FOR STUDY:
I-131 whole body scan is performed to localize residual thyroid tissue and metastatic thyroid cancer tissue.

PATIENT PREPARATION:
Patient is to drink only clear liquids after midnight the evening before the capsule(s) is given. Patient is not to eat or drink anything 4 hours before the capsule(s) is given. The patient should be off thyroid medications as directed by their physician. (Off cytomel for 2 weeks and off synthroid for 6 weeks.) No iodine contrast material for 6 weeks. Patient should be off iodine containing VITAMINS.

RADIOPHARMACEUTICAL AND DOSE:
5 mCi I-131 PO

TECHNIQUE:
TIME DELAY: The scan is done 3 days after the I131 is given.
DURATION OF SCAN: 1 1/2 hours

EQUIPMENT: Gamma camera, high energy colimator

PROCEDURE:
1. A thyroid uptake is performed using the I-131 capsule(s). The capsule(s) is to be counted using the Starcam camera prior to administering it to the patient. The capsule(s) will be counted for one minute. Place the capsule(s) in the thyroid phantom and place on the imaging table. The camera should be 5 inches from the phantom. Acquire a one minute background count also.

2. The Ancillary order must have the patient's name, birth date, the dose, radiopharmaceutical, route of administration, signature of the Nuclear Medicine physician, and date of signature. A checkmark will be made by the patient's birthdate and signature on the patient questionaire as they are verified with the order. Two technologists must verify the dose as measured in the dose calibrator.

3. Check the to be sure the patient has followed the preparation instructions. If there are any questions about any medications the patient has taken, check with the Nuclear Medicine coordinator or the Nuclear Medicine physician. Then proceed to administer the I-131 capsule(s) to the patient. Instruct the patient that they may eat on the morning that they come for the scan.

TA Schultz MD
Nov 21, 1995

4. The vial containing the I-131 capsule(s) will be measured in the dose calibrator after administering the dose to the patient. This will be done to verify there is no activity left in the vial. This will be documented on the Cerner system requisition.

5. Prior to starting the whole body scan have the patient void. Start the scan by lying the patient supine on the table with a band around their feet. Using velcro straps hold their arms by their sides. Move the table as high as it will go and center the patient horizontally. Position the patient's head just outside the field of view, lock the table, and start the camera. On the 3200iStarcam start the camera with the patient's head underneath the camera.

6. For the posterior whole body view put the camera at 180 degrees and move the table down as far as it will go. Start the patient in the same position as the anterior pass.

7. For the 15 min. anterior neck view place the Co-57 marker on the suprasternal notch. Postion the camera anteriorly and mark the Co-57 with the computer curser. Remove the Co-57 marker and start the camera.

8. The uptake view is taken anteriorly over the patient's neck. The camera should be 5 inches from the neck. Background image is taken over the patient's thigh. Again 5 inches between the patient's leg and the camera.

COMPUTER:
Acquire study using I131METSURVEY protocol. This will set up for an anterior and posterior whole body pass(ABDY) in a 256x1024 matrix, word mode, 2 meters at 12.57 min/meter, 1x.8 zoom. A 15 minute anterior neck view in a 256x256 matrix, a 1 minute uptake view in a 256x256 matrix, and a 1 minute background view.
Process the uptake using I131UPTAKE protocol. This calculates a 72 hour uptake using the I131 capsule.

Reviewed [signature] MD
Date Nov 21, 1995

Rev. 10/95 ks