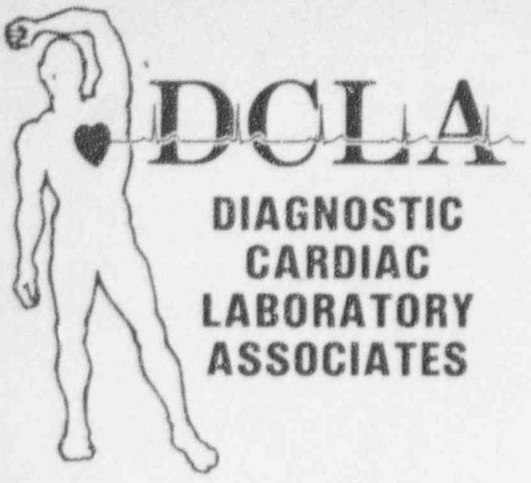

DCLA

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License No. 37-28074-01
9/10/93

To Whom It May Concern

Please note that I, Surendra Pawar, MD am not using using any radiopharmaceutical containing radioactive iodine.

I am not planning to use any in the near future.

In the event that I will happen to use I-131 or I-125, I will submit a Quality Management Program to the US NRC for their review and approval prior to this use.

Surendra Pawar, MD

ML 10

SEP 16 1993

PAWAR, SURENDRA V. (M.D.)

37-28074-01
030-30131

North Hills Passavant Hospital
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Quality Management Program for Nuclear Medicine

The Objective of the Quality Management Program is the reduction of the likelihood of the misadministration of by-product materials to patients undergoing diagnosis and therapy. The Quality Management Program is applicable to the following by-product materials and uses:

1. Iodine 131 and Iodine 125 in excess of 30uci for diagnostic or therapeutic purposes
2. All radiopharmaceuticals used for therapeutic purposes

The objective of the Quality Management Program will be fulfilled by adhering to the following policies and procedures as established by the Department of Nuclear Medicine.

1. The patient's identity will be verified by more than one method.
2. A written directive will be prepared before the administration of radiopharmaceuticals.
3. Each administration of the radiopharmaceutical will be in accordance with the written directive.
4. Any unintended deviation from the written directive will be identified and evaluated and the appropriate action taken.

The intent of the Quality Management Program is to provide high confidence to the staff and patients that by-product materials or radiation from by-product materials are used only as directed by authorized users.

ML 10 FAX RECD MAY 25 1993

January 24, 1992

To: Nuclear Medicine Staff

From: Robert A. Erbstein, M.D.
Chairman, Department of Radiology

Re: Procedures Involving More than 30 uci of Iodine

Before any diagnostic procedure or any therapeutic procedure using more than 30 uci of I-125 or I-131 is performed, a written order must be made by one of the following physicians:

Anne V. Tessaro, M.D.
Surendra V. Pawar, M.D.
Peter J. Fedyshin, M.D.
Roja V. Kodali, M.D.

Other procedures for Nuclear Medicine involving less than 30uci of iodine do not require written authorization from these physicians. However, written authorization from the attending physician for all other Nuclear Medicine procedures must be obtained.

Please indicate you have been made aware of this memo by initialing below.

TECHNOLOGIST'S INITIALS:

Betty J Green CNMT
Allan L. Colvert CNMT
Donald A. Ashton-J CNMT
Karen M. Stiebel CNMT
Michael Dimilla CNMT

POLICES AND PROCEDURES FOR RADIOPHARMACEUTICAL USE

Diagnostic Procedures

All diagnostic radionuclides shall be administered in accordance with the provisions outlined in the Nuclear Medicine Procedure Manual.

For diagnostic procedures, patients will not be asked to give written consent. For in-patients the request for a procedure is written in the chart by the referring physician. For out-patients a written script is provided by the referring physician.

For diagnostic procedures the following technologists may under the direction of the radiologist, administer radiopharmaceuticals intravenously, orally, though inhalation, and or via indwelling catheter:

Betty J. Greer, MS, CNMT, Supervisor
Alan L. Cabot, CNMT
Carl Cavallere., CNMT
Karen Gelbel, CNMT
Michael Dinello, BS, CNMT

These technologists may also give CCK, Pentagastrin, Vitamin B12, lugols and small amounts of heparin used for flushing syringes whenever a radiology nurse is unavailable.

Second year students in the CCAC Nuclear Medicine Technology Program will be allowed to inject radionuclides **only** under the direct supervision of Nuclear Medicine personnel.

Therapeutic Procedures

The radiologist who is an authorized user will date and sign a written directive prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

The written script will include the patients' name, the radiopharmaceutical, dosage, the route of administration, the date, and the authorized physicians' signature.

Before administration, the technologist and the authorized physician will confirm that the radiopharmaceutical, dosage, and route of administration is in accordance with his or her written directive.

All therapeutic doses will be administered in the presence of the authorized physician.

For therapeutic procedures, a written consent must be signed by the patient and witnessed prior to administration.

Radiopharmaceutical Administration

A. The Nuclear Medicine Department has established the following Policy to verify Patient Identification:

1. Before administering a radiopharmaceutical the technologist will ask the patient (Inpatient or Outpatient) to state his/her name to compare with the name printed on the procedure requisition.

2. On In-patients, and Emergency room patients the doctor's order sheet on the chart is to be checked by the technologist to be sure that the requested procedure is the same procedure ordered on the requisition. The technologist will also compare the first and last name on the front of the chart with the first and last name on the patients' identification band before administering a radiopharmaceutical. If the name does not agree or the patient does not have an identification band the technologist will request that the Nursing Unit check the information and provide a corrected ID band.

3. An Out-patient must have a requisition from the doctor with the patient's name and the procedure ordered. The technologist will check the doctor's order and confirm the procedure to done with the patient by asking the following: "Doctor (Referring Physician) has ordered a procedure (ie bone scan), is that correct?" The technologist will also confirm any of the following corresponding information against the physicians prescription and the procedure requisition: name, sex, age, and address. If there is any doubt as to the patient's identity a drivers license or insurance card must be used.

4. Small children, elderly and disoriented patients will be verified by an accompanying party (e.g. relative, attendant, friend, etc).

B. The Nuclear Medicine department has established the following policies for Radiopharmaceutical Administration:

1. All procedures are checked for authorization by a physician prior to administration of a radionuclide.(i.e. written order on the chart or referral slip).

2. The radiopharmaceutical, dosage, and route of administration is confirmed by the technologist administering the radiopharmaceutical to verify agreement

with the written order and is in accordance with the provisions outlined in the Nuclear Medicine Manual.

3. All doses are checked for content and are measured in the dose calibrator by the technologist prior to administration. The results are compared with the prescribed dosage as outlined in the Nuclear Medicine Manual.

4. Should the technologist not understand how to carry out the written directive, he/she must ask the nuclear medicine supervisor or the radiologist if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

5. Women of childbearing age will be asked prior to administration if they are pregnant or nursing. If the answer is yes, the technologist will notify the radiologist. The physician ordering the procedure will decide if the diagnosis outweighs the hazard. If the answer is no the technologist will mark the requisition and have the patient initial her response.

6. Doses are calculated and adjusted for children under 16 years of age.

7. The technologist will administer the radionuclide according to the policy: Venipuncture and intravenous injection of contrast medium.

8. Department policy limits the number of venipuncture attempts to no more than two by a single technologist. After two attempts have failed, another technologist will attempt the injection. If unsuccessful, the radiology nurse or the IV team will be asked to insert an IV line thur which the technologist may inject the radiopharmaceutical.

9. After administering a radiopharmaceutical the technologist will make, date, and sign or initial a written record that documents the administered dosage, in the patient's chart, on the procedure requisition, and the clinical data sheet.

Verbal Orders and Revisions to Written Directives

1. For diagnostic and therapeutic procedures using radiopharmaceuticals, the initial written directive may be provided by the referring physician. This directive will then be confirmed by the Nuclear Medicine physician. Based on the Nuclear Medicine physician's evaluation of the case the original directive of the referring physician may be modified. Such changes in the original directive will be conveyed to the referring physician either orally or in writing by the Nuclear Medicine physician. If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours or the oral revision.

2. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

3. If, because of the emergent nature of the patient's medical condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

Periodic Reviews

1. Semi-annually, reviews of radiopharmaceutical administrations (diagnostic and therapeutic) will be conducted to include a representative sample of patient administrations, all recordable events and all misadministrations. For I-131 or I-125 administrations charts of any four patients will be selected. A record of this review will be maintained as in Attachment B.

2. The patient cases to be reviewed will be selected randomly, and a comparison will be made between what was administered versus what was prescribed in the written directive or procedure manual. If the difference between what was administered and what was prescribed exceeds the criteria for either a recordable event or a misadministration, that comparison is unacceptable.

3. For each patient case reviewed, the reviewer will identify deviations from the written directive or procedure manual, the cause of each deviation, and the action required to prevent recurrence. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.

4. If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. The Radiation Safety Officer or designee will regularly review the findings of the periodic reviews and report the findings to the Radiation Safety Committee.

Corrective Actions and Conclusions:

1. All recordable events in misadministrations will be evaluated. Steps will be taken to prevent the recurrence of such events and misadministration. Necessary changes in policies and procedures will be made only after discussion at the Radiation Safety Committee and with approval of the Radiation Safety Committee.

2. A re-evaluation of the QM program's policies and procedures after an annual review will determine whether the program is still effective or to identify actions required to make the program more effective.

3. Program review results will be documented and will be distributed to the appropriate management and departments. Corrective actions for deficient conditions will be implemented within a reasonable time after identification of the deficiency.

MISADMINISTRATION

I. *Iodine*- If greater than 30 uCi of I-131 or I-125 is given

a. to the wrong patient or
b. the wrong pharmaceutical is given or
c. the administered dose differs from the prescribed dose by greater than 20% of the prescribed dosage and the difference between the amount given and the amount prescribed is greater than 30 uCi.

II. *Diagnostic procedures*- Giving any diagnostic radiopharmaceutical, (including less than 30 uCi of I-131 or I-125)

a. to the wrong patient or
b. by the wrong route or
c. which is the wrong radiopharmaceutical or
d. where the administered dosage differs from the prescribed dosage (amount unspecified by NRC)

AND

a. the dose to the patient is greater than 5 rems or
b. the dose to any individual organ is greater than 50 rems

III. *Therapeutic procedures*- Giving any therapeutic radiopharmaceutical dosage (other than I-131 or I-125)

a. to the wrong patient or
b. which is the wrong radiopharmaceutical or
c. by the wrong route or
d. when the administered dosage differs from the prescribed dosage by greater than 20%

RECORDABLE EVENT

1. Giving a radipharmaceutical or radiation without a written order when one is needed, (i.e. for greater than 30 uCi or I-131 or I-125 and all therapies).

2. Giving a radiopharmaceutical or radiation which was given because of a written directive and not recording daily each administred dose or dosage.

3. Giving a radiopharmaceutical dosage greater than 30 uCi of I-131 or I-125 when the administered dosage differs from that prescribed by greater than 10%

   and

   the difference between that prescribed and that given is greater than 15 uCi

4. Giving a therapeutic dosage, other than I-131 or I-125, when the therapeutic dosage differs from that prescribed by greater than 10%

**Note: A written directive is required for all I-131 I-125 administrations greater than 30 uCi and for all therapy procedures. The written directive is to contain:

1. For I-131 or I-125 greather than 30 uCi

   a. the dosage

2. For all radiopharmaceutical therapies other than with iodine

   a. the radiopharmaceutical
   b. the dosage
   c. and the route of administration

I-131 Quality Management Report Form

PATIENT NAME: _____ AGE: _____ SEX: _____

PATIENT #: _____

REFERRING MD: _____

(Check One)

Two forms of identification obtained	☐ Yes	☐ No
Is patient pregnant?	☐ Yes	☐ No
Is patient nursing?	☐ Yes	☐ No
Consent signed?	☐ Yes	☐ No
Referring MD order present?	☐ Yes	☐ No
Authorized User order present?	☐ Yes	☐ No

Drug ordered: _____ Route of administration: _____

Dose ordered: _____ Dose Admin.: _____ %Difference: _____

Recordable Event? ☐ Yes ☐ No

_____ _____ _____

Authorized User Signature Technologist Signature Date

**Recordable event: No written directive, directive does not contain dosage, and the dosage given differs from the prescribed dose by greater than 10% and greater than 15 uCi.

I-131/I-125 QUALITY MANAGEMENT AUDIT
YEAR_____

MEDICAL RECORD #	DATE OF ADMIN.	REFERRING MD ORDER PRESENT	N.M. MD ORDER PRESENT	mCi ORDER mCi ADMIN.	& DIFF	PHARMACEUTICAL WRITTEN	ROUTE OF ADMINISTRAT.	TECH INITIALS PRESENT	RECORDABLE EVENT
1.									
2.									
3.									
4.									

COMMENTS: