Reichhold

NUCLEAR MEDICINE CENTER
R. S. MANOLI, M.D.
(IN VIVO, IN VITRO AND NUCLEAR CARDIOLOGY)

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(414) 453-6565
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January 10, 1994

Nuclear Regulatory Commission
799 Roosevelt Rd.
Glen Ellyn, IL 60137

To Whom It May Concern,

This is in regard to your letter dated Dec 30 1993 regarding our Radiopharmaceutical quality management program. I have enclosed a few copies of the procedures for radioiodine administration that we follow in our clinic. The efficiency of the Spectrometer (Canberra model 2600) was 62.3%, and the instrument is capable of detecting 2000 disintegrations per minute for the contamination involved.

I hope this is proper procedure and we can continue doing the same. If you have any further questions please call this office 453-6565.

Thank You,

R S Manoli

R.S. Manoli, M.D.

JAN 19 1994

NUCLEAR MEDICINE CENTER
RADIOIODINE ADMINISTRATION RECORD

ORDERING INFORMATION

Name of Patient (Print) Diagnosis

Name of Procedure Radiopharmaceutical, Assay, Form and Route of Administration

Prescribing Physician Date Date of Administration

ASSAY AND ADMINISTRATION:

THE CLINICAL PROCEDURE NAMED ABOVE IS DOCUMENTED IN THE CLINICAL PROCEDURE MANUAL AND THAT THE PERSON ADMINISTERING THE PRESCRIBED DOSE HAS READ AND UNDERSTANDS THAT PROCEDURE:

Radiopharmaceutical, Assay, Date, Time, Adminis. Physician/Tech

Dose calibrator used for Assay:
Model: CRC-7 ADMINIS. PHYSICIAN/TECHNOLOGIST
Manufac: CAPINTEC (Witness)
SERIAL: 71441
CALIBRATION DATE:

PATIENT IDENTIFICATION:

I HAVE HAD THE ABOVE NAMED PROCEDURE EXPLAINED TO ME AND I UNDERSTAND THAT I WILL RECEIVE A PRESCRIBED DOSE OF RADIOACTIVE IODINE. I AFFIRM THAT TO MY KNOWLEDGE, I AM NOT PREGNANT, NOR AM I BREAST FEEDING AT THIS TIME.

SIGNATURE OF PATIENT DATE

SIGNATURE OF PERSON ADMINSIT. DOSE DATE

WITNESS DATE

IN THE EVENT THE PATIENT IS NOT ABLE TO IDENTIFY THEMSELVES, A WITNESS IS REQUIRED TO CONFIRM VERIFICATION OF THE PATIENTS IDENTITY BY THE PATIENTS ARM BAND:

SIGNATURE OF WITNESS DATE

Quality Management Program

Radiopharmaceutical Use Worksheet

Prior to administration, this form is to be prepared for:
A. any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; and
B. any therapeutic administration of a radiopharmaceutical.

If there is any question or confusion concerning any aspect of the procedure, the individual shall contact the authorized user for clarification.

Written Directive

Radiopharmaceutical Prescription

Patient Name			
MRN		Radiopharmaceutical	
Patient Status	Inpatient Outpatient	Route of admin	
Type of Procedure		Prescribed Dose	
Patient ID Verified by		Admin Dose	

Authorized User's Signature _____ Date _____

Patient Identification

Each patient's identity shall be verified by more than one means prior to administration of the radiopharmaceutical. Check all methods used to verify patient's identity.

___ 1. Verbal confirmation of patient's name.
___ 2. Verbal confirmation of patient's SSN
___ 3. Verbal confirmation of patient's address
___ 4. Verbal confirmation of patient's birth date
___ 5. Verbal confirmation by family member.
___ 6. Confirmation by wrist band. *(For inpatients only)*
___ 7. Photographic identification
___ 8. other (identify)._____

QMP Review

Review of this record is being performed as part of:

___ 1. the result of a recordable event, or
___ 2. the result of a misadministration, or
___ 3. a random sample for periodic review.

Review

Yes No The administered dose was within ± 10 % of the prescribed dose.
Yes No The administered radiopharmaceutical and route of administration were the same as prescribed.
Yes No Documentation of procedure recorded in patient's file.

Reviewer _____ Date of review _____

QUALITY MANAGEMENT PROGRAM
Policy and Procedure

Purpose To clearly communicate instructions to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

Policy

Training and Instruction
All persons involved with the administration of radiation for which a written directive is required shall be instructed as appropriate to their involvement with the administration of the radiation.

Written Directive
An authorized user shall sign and date a written directive for each patient which shall be prepared prior to administration of:

1) any teletherapy radiation dose;
2) any brachytherapy radiation dose;
3) any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or
4) any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131.

Patient Identification
Prior to each administration, the patient's identity is to be verified by more than one method as the patient named on the written directive.

Treatment Plans and Administration
The final plans of treatment and calculations for brachytherapy and teletherapy are to be in accordance with the respective written directives.

Administration
Prior to each administration confirmation of radiopharmaceutical, dosage and route of administration shall be made to verify the procedure is in accordance with the written directive.

Guidance
Any individual involved with the procedure who does not understand how to carry out the written directive shall seek guidance from the authorized user and/or their supervisor. Under no circumstances shall the procedure be carried out until the individual completely understands the written directive.

Written Record
A written record of the procedure shall be made after the administration of the radiation dose to document the administration of the radiopharmaceutical.

Deviation from Written Directive
Any unintended deviation from the written directive is to be identified and evaluated, and appropriate action is to be taken.

Evaluation of Recordable Events
Within 30 days after the discovery of a recordable event an evaluation shall be made. The evaluation shall include assembling the relevant facts including the cause and corrective action required to prevent recurrence.

Evaluation of Quality Management Program (QMP)
A review of the QMP is to performed at intervals no greater than twelve months from the previous evaluation. The evaluation is to include a representative sample of patient administrations, all recordable events and all misadministrations

Modification of Quality Management Program
Modifications to the QMP may be made to increase the efficiency provided the programs effectiveness is not decreased.

Procedure

Radiopharmaceutical Use

Authorized User

1. Shall date and sign a written directive prior to the administration of any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 or any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131. The written directive will include the patient's name, the date, the total dose, the dose per fraction, and the overall treatment period. Procedures for oral directives and revisions to written directives include:

   a. 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 of the oral revision.

   b. A written revision to an existing written directive may be made for any teletherapy procedure provided that the revision is dated and signed by an authorized user prior to administration of the teletherapy dose or next teletherapy fractional dose.

   c. If, because of the emergent nature of the patient's medical condition, a delay on order to provide a written directive would jeopardize the patient's health, an oral revision 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 of the oral directive.

2. Will assure that a written record documenting the administered dose is made and placed in the patient's records.

Therapist

1. Before administering the radiopharmaceutical dose, ask the patient his or her name and confirm the name by at least one other method such as having the patient state his or her birth date, address,or social security number; or check the name on the patient's ID bracelet for inpatients; or compare with a photograph of the patient's face; or confirmation from a family member.

2. Confirm, before administering the radiopharmaceutical, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage and route of administration are to verified.

3. If the person administering the radiopharmaceutical does not understand how to carry out the written directive, he or she will ask an authorized user or other knowledgeable persons any questions about what to do or how it should be done rather than continuing the procedure when there is any doubt.

4. After administering the radiopharmaceutical, a written record will be made, dated, and signed or initialed. The written record will contain the administered dose and the procedure and be incorporated in the patient's records.

Dept QA Committee

1. Review the QM program periodically as part of the normal QA review within the department. Reviews should be conducted at intervals no greater than 12 months. Program reviews shall include an evaluation of a representative sample of all patient administrations, all recordable events and misadministrations. The representative sample shall be selected by including, at a minimum, 20% of the cases if the number of cases 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.

SPECIAL INSTRUCTIONS FOR PATIENTS

You have been given a dose of radioactive iodine. Although you present no health hazard to your family or friends, the suggestions listed below are recommended in order to reduce the possibility of radiation exposure or accidental transfer of radioactive iodine to others.

1. Radioactive iodine can be transfered to others through contact with your saliva. Therefore, avoid close contact and kissing for one week.

2. Cooking and eating utensils which come in contact with your saliva can transfer radioactive iodine to other family members. For example, if you sample a sauce with a spoon, do not return the spoon to the sauce because radioactive iodine may be introduced into the food that will be eaten by others. For one week, the dishes and utensils which you use should be washed and dried separately. After your dishes are washed, the sink should be rinsed thoroughly.

3. Your toothbrush, toothpaste, and bathroom glass should be kept separate from those used by the rest of the family for one week.

4. For one week, your urine and feces also can transfer radioactive iodine to other people. Therefore, the toilet should be flushed at least twice after use. Any articles contaminated with urine or feces should be disposed of.

5. For one week, you should avoid contact closer than six feet for extended periods of time with infants, children, and pregnant women. For example, when watching television do not sit next to a child. Similar contact for extended periods might occur during long car trips.

These suggestions are not meant to cause undue concern or lead to extraordinary measures to avoid contact with family, friends, or fellow employees. Many patients find it convenient to tell friends and fellow employees that they are coming down with a bad cold thereby encouraging people to keep a short distance from them. If you follow the guidelines described above, the exposure to your family, friends, and fellow employees will be less than the radiation exposure which they receive from naturally occuring background radiation in the Milwaukee area.

INSTRUCTIONS TO BE GIVEN ORALLY TO RADIOIODINE

THERAPY PATIENTS

TO BE OBSERVED FOR WHEN THEY GO HOME

1. You do not represent a significant danger to others, but others receive absolutely no benefit from your radiation and the precautions are to absolutely minimize their exposure.

2. Flush the toilet 3 times each time it is used. Use care not to contaminate the bathroom with urine.

3. Use a separate drinking glass.

4. Avoid kissing on the lips, especially children.

5. Avoid tasting food, if you cook, and placing the spoon back into the food; thus contaminating it with your saliva.

6. Avoid prolonged, close contact with young children and pregnant women.

7. Secretions from the breast may be radioactive, thus nursing is forbidden.

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CONSENT FOR RADIOISOTOPE THERAPY

NAME: _____ ADDRESS: _____

PHONE: _____

NEXT OF KIN: _____ ADDRESS: _____

I hereby authorize Dr. _____ to administer the following radioisotope therapy _____ as treatment for my _____.

The nature of this treatment has been fully explained to me by Dr. _____, and I have been advised of its possible risks, consequences; no warranty, or guarantee, or other assurance has been made concerning any results or cure.

I have been informed of the following possible side effects:

- transient hyperthyroidism (thyroid storm)
- hypothyroidism requiring lifelong medication for thyroid hormone replacement
- transient neck swelling/pain/dysphasia

I hereby authorize Dr. _____ to administer this treatment.

PATIENT_____

DATE AND TIME _____

If the patient is a minor or is unable to sign, complete the following:

Patient is a minor: _____ years of age.

Patient is unable to sign because _____

_____ _____
SIGNATURE OF WITNESS PERSON SIGNING IN BEHALF OF THE PATIENT

_____ _____
SIGNATURE OF PHYSICIAN RELATIONSHIP TO PATIENT

WHEN ADMINISTERING THE DOSE:

1. Only those persons needed for medical, safety, or training purposes should be present during the administration.

2. Brief the patient on Radiation Safety procedures for the dosage administration, visitor control, toilet use, radioactive waste and the use of linen and trash disposal.

   Identification of the patient will be confirmed by any of the following:
   consent form / ID bracelet / witness

3. Following administration of the dosage, measure the exposure rate in mR/hr at the bedside, at one (1) meter from the bedside, at the visitor safe line, and in the surrounding hallways and rooms. The surrounding hallways and rooms should not exceed two (2) mR/hr or the exposure should not exceed one hundred (100) mR/seven (7) days.

4. Post the room door with a "RADIOACTIVE MATERIALS" SIGN.

5. The patient will be monitored daily at bedside, three (3) feet from the bed, six (6) foot safe line, door, and documented on Exhibit 17 form.

6. For patient's treated with liquid or gelatin - capsuled I 131, one (1) day after the dosage administration, do a bioassay of the thyroid gland of all personnel who were present for the administration.

7. Call Nuclear Medicine to pick up waste as needed (for monitoring and storage or disposal).

8. The patient may be released from the Hospital when the exposure rate from the patient is less than five (5) mR/hr as measured at one (1) meter from the umbilicus with the patient standing or one (1) meter from the bedside with the patient supine if the patient is not ambulatory.

DISCHARGE INSTRUCTIONS:

1. When the exposure rate from the patient is less than five (5) mR/hr but more than (2.2) mR/hr, give these instructions:

ALL HOUSEHOLD MEMBERS OVER 45 Y.O. MAINTAIN A DISTANCE GREATER THAN THREE (3) FEET FOR FIRST TWO (2) WEEKS. VISITS BY CHILDREN NOT RECOMMENDED (MAINTAIN DISTANCE OF NINE (9) FEET IF BRIEF VISITS ARE NECESSARY).

ALL HOUSEHOLD MEMBERS UNDER 45 Y.O. MAINTAIN DISTANCE GREATER THAN SIX (6) FEET FOR THE FIRST WEEK. MAINTAIN DISTANCE OF SIX (6) FEET FOR THE NEXT WEEK WITH ONE (1) PERIOD OF 1/2 HOUR AT THREE (3) FEET PERMITTED.

2. When the exposure rate from the patient is less tha (2.2) mR/hr. there are no restrictions.

DECONTAMINATION:

1. Remove all absorbent paper and plastic covers and place in the appropriate container.

2. Place all linen in the appropriate container.

3. Transfer all containers to the Nuclear Medicine "Decay-In-Storage" area for monitoring and storage.

4. Use the GM survey meter and monitor the room for contamination.

   All areas or surfaces above room background will be decontaminated and a wipe test done until the removable contamination is less than 200 dpm/100 cm squared.

5. Inform the nursing unit when decontamination procedures are complete so the room may be prepared by housekeeping for occupancy.