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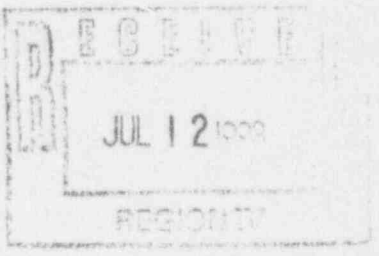
Veterans Administration

In Reply Refer To:



July 6, 1993

U.S. Nuclear Regulatory Commission
Region IV
Parkway Central Plaza Building
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Subject: QA Program

In accordance with 10 CFR 35.32(e), we are submitting our revised quality management program as described in the attachment. This was primarily done because of the anticipated use of Sr-89.

Lynn McGuire, RSO

Encl.

P O L I C Y

Therapeutic Radionuclide Administrations (e.g. Sr-89,P-32)

or

Administration of Greater Than 30 microcuries (μCi) of I-131

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1. INTRODUCTION

Because of the potential for large absorbed doses to patients as a result of the misadministration of therapetic radionuclides and/or administrations of I-125 or I-131 for diagnostic purposes, the following procedure is hereby adopted. No I-125 shall be used for human studies prior to review by the Radiation Safety Committee.

2. PROCEDURES

a. Prior to any I-131 administration greater than 30 microcuries (μCi) or any amount of another therapeutic radionuclide (hereafter usually simply called "dose"), assure that the attached form entitled "RADIOPHARMACEUTICAL DOSE PRESCRIPTION" is completed.

b. If the dose to be administered is greater than 30 millicuries (mCi), the patient must be hospitalized. Contact the RSO for instructions and observe the "Health Physics Checklist: I-131 Metastatic Therapy" attached.

c. *At any point in the procedure, if any of the details seem suspect or if there is any uncertainty about how the procedure is to be carried out, stop immediately. A supervisor or nuclear medicine physician should be contacted.*

d. Before administering the dose, the patient's identity must be verified by more than one method. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

f. Before administering the dose, the radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the prescription, as given in the "RADIOPHARMACEUTICAL DOSE PRESCRIPTION" form attached.

For I-131, the dosage must be measured in the dose calibrator. For other beta-emitting radionuclides, the dose, if possible or meaningful, should be measured in the dose calibrator.

For all radionuclides, the supplier's stated activity will compared with the prescribed amount, and the patient name, nuclide, and dosage must be confirmed on the dose container.

g. After administration of the radiopharmaceutical, the "RADIOPHARMACEUTICAL DOSE PRESCRIPTION" form must be signed and filed in the patient's records. Then the data must be entered into the hospital nuclear medicine computer database in the normal manner.

3. EMERGENCY PROCEDURES

a. If, because of the patient's medical condition, a delay in order to provide a written revision to an existing "RADIOPHARMACEUTICAL DOSE PRESCRIPTION" form 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 form is dated and signed by a staff nuclear medicine physician within 48 hours of the oral revision.

b. Also, a written revision to an existing written directive i.e. "RADIOPHARMACEUTICAL DOSE PRESCRIPTION" form, 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.

c. If, because of the amergent 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.

4. PERIODIC REVIEWS

a. The adequacy of the quality management program to avoid misadaministrations as described above will be monitored through our Service Quality Assurance program, as described in the attachment.

b. During each meeting or QA review, all studies involving radiopharmaceuticals as described above will be reviewed. The cases will be selected via the hospital DHCP database system. All recordable events and all misadministrations

will be scrutinized to determine causes and actions to prevent recurrences will be as described in our QA program.

c. Specifically, for each patient case reviewed, we will determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the written directive. For example, was the following correct: the radiopharmaceutical, dosage, and route of administration.

d. The QA program's policies and procedures will be annually reviewed to determine whether the program is still effective or to identify actions required to make the program more effective.

e. QA results will be documented as described in the attachments. The results of the QA program and reviews are distributed to the Hospital QA coordinator and reviewed by the QA Committee. Corrective actions for deficient conditions will be identified to the QA Committee in order that corrective actions will be implemented within a reasonable time after identification of the deficiency.

RADIOPHARMACEUTICAL DOSE PRESCRIPTION
ADMINISTRATION OF I-131 AS SODIUM IODIDE OR SR-89

For Diagnosis or Therapy
(30 microcuries or more)

1. Patient Identification:

Patient Name _____

SSN: _____ **WARD / CLINIC:** _____

2. Procedure Information and radiopharmaceutical dose prescription:

Procedure: _____

Radionuclide: _____ Radiopharmaceutical: _____

Prescribed Dose: _____ (uCi) (mCi) Route of administration: (IV) (oral)

Prescribed/approved by: _____ MD. Date: _____

3. Review of prescription by the dose administrant (technologist):

The above dose prescription has been reviewed. The prescribed radiopharmaceutical, the amount to be administered and the instructions concerning the route of administration are fully understood.

(1) _____ _____ _____
Dose Administrant | Position | Date

(2) _____ _____ _____
Second Reviewer | Position | Date

4. Patient identity verification (check at least 2 items) and dose administration:

( )Ask patient his/her name
( )Address by patient matches record
( )In-patient ID bracelet
( )SSN by patient matches record
( )DOB by patient matches record
( )Patient is non-responsive, provide ID data:

( )The patient named above has been correctly identified.
( )The radiopharmaceutical has been correctly identified.
( )The dose, as counted, is within 10% of the prescribed amount and recorded.
( )The dose was administered to patient according to prescription directions.

(1) _____ _____ _____
Dose Administrant | Position | Date

(2) _____ _____ _____
Witness | Position | Date

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* SPECIAL PRECAUTIONS *
* Determine if patient can be treated as an outpatient (hyperthyroid) *
* If inpatient: Inform nurses to red bag waste (I-131) *
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HEALTH PHYSICS CHECKLIST - ^{131}I METASTATIC THERAPY
Little Rock AR VAMC

Preoperational	
1.Prescription	1.Approval by NM MD (written Rx)&RSO
2.Contact Nursing Service	2.Schedule private room (4D-40)- rooms on either side to be vacant
3.Order dose	3.Make sure pt can swallow caps. Order high SpA. activity caps (Mall.<=2 caps
4.Review training requirements	4.Depends on nurses and time between nurses prev. inst.
1-Day Prior	
1.Prepare room	1. Floor with paper; toilet; remove/cover chairs
2.Brief and remind nurses	2. Use remind. form & Inst to nurses
3.Dispense filmbadges	3. ~10 needed & sign-up sheet.
Receipt of Dose	
1. Survey package	1. -ion chamber @ surface & @1m mR/h : YII YIII surf 50 200 1m 1 10 -wipe pkg surface: <2.22E4/100cm^2 -Open pkg in hood. Wipe via],inner surface -Record readings, receipt
2. Assay	2. Use tongs;record mCi&time. Notify if > +/- 10%.
Administer Dose	
1. Dispense dose	1. Pt to be dosed in room
2. Survey Pt & environs	2. Initial DR @ 1m. Environs <.6mR/h Use ion chamber survey meter.
3. Complete posting	3. CRM;CRA;Do Not Enter(adj. rooms);Nurse inst. on door and in chart;Caution -Internal Dose. Record survey reading on forms.
Post Administration	
1. Survey pt @ 1m each day	1. Discharge @ 30 mCi or 5 mR/h. DR(30)= (30/mCi admin) * DR(init).
2. Thyroid uptake	2. 24 hr post admin. for those who prepare or admin dose. Use Ba133 or I-131 for std.
Discharge	
1. Advice to patients	1. Use SNM guidelines.Depends on family status.
2. Survey room	2. Use GM pancake to detect hot spots. Also wipe selected areas (200dpm). Attempt decon for removable contam. If difficult, seal room for decay.
3. Collect waste	3. Remove all waste>bkd if necessary. Store for decay.
4. File all records	

Supplies needed:
Cart - Abs paper - Tape - Cups for water - Ion chamber survey meter -Gloves - Meter stick - filmbadges
Forms: CRA;CRM:Caution Int Dose;Do not enter; Nurse inst; sign up forms

QUALITY ASSURANCE PROGRAM
NUCLEAR MEDICINE SERVICE
JOHN L. McCLELLAN VETERANS ADMINISTRATION MEDICAL CENTER
4300 WEST SEVENTH STREET
LITTLE ROCK, ARKANSAS 72205

1) THE OVERALL RESPONSIBILITY OF THE QUALITY ASSURANCE PLAN IS ASSIGNED TO:

a) THE ACTING CHIEF OF NUCLEAR MEDICINE AND/OR b) HIS DESIGNEE OR DESIGNEES.

2) THE NUCLEAR MEDICINE DEPARTMENT PERSONNEL PERFORM

a) DIAGNOSTIC IMAGING PROCEDURES AS WELL AS b) RADIO-NUCLIDE THERAPY ON BOTH AN IN-PATIENT AND AN OUT-PATIENT BASIS. c) EACH PATIENT IS REFERRED TO NUCLEAR MEDICINE BY ATTENDING PHYSICIAN. d) EACH EXAM IS PERFORMED ON PREMISES OF VETERANS ADMINISTRATION LITTLE ROCK DIVISION FROM 0730 -1800 MONDAY THRU THURSDAY AND 0730 -1630 ON FRIDAY. EMERGENCY PROCEDURES MAY BE PERFORMED AFTER HOURS BY NUCLEAR MEDICINE TECHNOLOGIST ON CALL. ON CALL COVERAGE IS PROVIDED FOR THE TIME NOT COVERED BY ROUTINE DUTY HOURS.

3). THE FOLLOWING ASPECTS OF CARE ARE IDENTIFIED:

a) NUCLEAR MEDICINE/PATHOLOGY DIAGNOSIS CORRELATION MALIGNANCIES AS ASSOCIATED WITH METASTASES (HIGH VOLUME)
b) CORRELATION OF SINGLE PHOTON EMISSION COMPUTED TOMOGRAPHY IMAGING INTERPRETATION CAPABILITY (PROBLEM-PRONE) AND RESULTS IN COMPUTER PROCESSED GATED STUDIES (HIGH VOLUME)
c) PATIENT NO SHOW (PROBLEM-PRONE)
d) APPROPRIATE STUDY REQUESTED BASED ON DIAGNOSIS (PROBLEM-PRONE)
e) RADIATION INCIDENTS AND SPILLS (HIGH-RISK)
f) NON-COMPLIANCE WITH MISADMINISTRATION QUALITY MANAGEMENT PROGRAM (HIGH-RISK)

4) THE FOLLOWING THRESHOLDS HAVE BEEN ESTABLISHED:

INDICATOR	THRESHOLD FOR EVALUATION
PERCENTAGE OF SCANS CONFIRMING PATHOLOGY	7%

CORRELATION OF OUTCOMES BETWEEN CARDIOLOGIST AND NUCLEAR STAFF PHYSICIANS ON RESULTS OF MYOCARDIAL PERFUSION STUDIES AND GATED CARDIACS (EJECTION FRACTIONS)	MORE THAN TWO STANDARD DEVIATIONS FROM THE MEAN FOR INDIVIDUAL CARDIOLOGIST
PERCENTAGE OF NO SHOW PATIENTS	5%
INCIDENCE OF INAPPROPRIATE STUDY ORDERED BY ATTENDING PHYSICIAN	7%
INCIDENCE OF RADIATION SPILL OR INCIDENT	0%
INCIDENCE OF MIS-ADMINISTRATION OF RADIO-PHARMACEUTICAL	1 IN 2000

5) THE FOLLOWING INDICATORS HAVE BEEN IDENTIFIED

a) PERCENTAGE OF RADIO-NUCLIDE SCANS CONFIRMING PATHOLOGY DIAGNOSIS
b) CORRELATION OF SPECT IMAGE INTERPRETATION WITH CARDIAC CATHETHERIZATIONS AND GATED CARDIAC RESULTS (EJECTION FRACTIONS)
c) PERCENTAGE OF TOTAL PATIENTS THAT ARE NO-SHOW
d) INCIDENCE OF INAPPROPRIATE STUDY BEING ORDERED BY ATTENDING PHYSICIAN.
e) INCIDENCE OF RADIATION SPILL OR INCIDENT
f) INCIDENCE OF MIS-ADMINISTRATION OF RADIO-PHARMACEUTICAL

6) THE FOLLOWING GUIDELINES ARE TO BE USED TO COLLECT AND ORGANIZE DATA :

a) THE PERSON OR PERSONS RESPONSIBLE FOR MONITORING AND EVALUATION ACTIVITIES ARE THE CHIEF NUCLEAR MEDICINE TECHNOLOGIST, THE RADIATION SAFETY OFFICER AND THE QA NUCLEAR MEDICINE TECHNOLOGIST.
b) DATA COLLECTION WILL BE ACCOMPLISHED BY THE NUCLEAR MEDICINE STAFF TECHNOLOGIST ON A DAILY BASIS.
c) FORMS WILL BE PROVIDED FOR EACH AREA OF SAMPLING AND ENTERED INTO A DATABASE FOR FURTHER ANALYSIS.
d) DATA WILL ANALYZED AND/OR MONITORED BY THE PERSON DESIGNATED THAT RESPONSIBILITY ON A WEEKLY BASIS.
e) RESULTS WILL BE TABULATED MONTHLY AND REPORTED AT THE MONTHLY QA MEETING.

f) MONTHLY QA MEETING WILL TAKE PLACE ON THE SECOND FRIDAY OF EACH MONTH IN THE ACTING DIRECTORS' OFFICE WITH THE FOLLOWING MEMBERS: THE ACTING DIRECTOR, THE CHIEF NUCLEAR MEDICINE TECHNOLOGIST , THE RADIATION SAFETY OFFICER AND THE QA NUCLEAR MEDICINE TECHNOLOGIST .

7) THE EVALUATION OF CARE WILL INCLUDE THE FOLLOWING:

a) ANALYSIS OF CUMULATIVE DATA BY THE DEPARTMENT QA COMMITTEE WILL DETERMINE IF PROBLEM OR PROBLEMS EXIST.
b) TRENDS AND PATTERNS WILL BE IDENTIFIED BY ANALYSIS OF DATA SHEETS.
c) WITH REGARD TO NON-COMPLIANCE WITH MISADMINISTRATION QUALITY MANAGEMENT PROGRAM, ALL IODINE-131 ADMINISTRATION FORMS AND WRITTEN DIRECTIVES WILL BE REVIEWED.
d) SHOULD IT BE DETERMINED FROM THE ANALYSIS OF DATA SHEETS AN INTENSIVE REVIEW OF CARE BY AN INDIVIDUAL PRACTITIONER AND/OR TO AN INDIVIDUAL PATIENT, PEER REVIEW IS UNDERTAKEN.
e) WHEN QUALITY AND APPROPRIATENESS OF CARE ARE FOUND TO BE ACCEPTABLE - OPPORTUNITIES TO IMPROVE CAN STILL BE IDENTIFIED

8) THE FOLLOWING ACTIONS WILL BE TAKEN TO SOLVE IDENTIFIED PROBLEMS:

a) SHOULD THRESHOLDS FOR EVALUATION NOT BE REACHED, MONITORING AND EVALUATION WILL ACTIVELY CONTINUE FOR 2 YEARS. AT THAT POINT ASPECT OF CARE MONITORS AND THRESHOLDS WILL BE RE-EVALUATED.
b) SHOULD PROBLEMS BE IDENTIFIED NUCLEAR MEDICINE STAFF WILL DECIDE WHAT CORRECTIVE ACTION SHOULD BE IMPLEMENTED (SEE FORM)

9) TO ASSESS THE ACTIONS IMPLEMENTED THE FOLLOWING WILL BE ACHIEVED:

a) WAS THE ACTION SUCCESSFUL? THIS ANSWER WILL BE ABLE TO BE DETERMINED BY CONTINUED MONITORING.
b) MONITORING AND EVALUATION ACTIVITIES WILL BE DOCUMENTED TO PROVIDE A RECORD OF THE EFFICIENCY OF THE ACTIONS TAKEN
c) SHOULD ACTIONS TAKEN NOT SOLVE OR IMPROVE THE PROBLEM OR PROBLEMS IDENTIFIED, THEY SHOULD BE RE-ASSESSED

10) THE COMMUNICATION OF RELEVANT INFORMATION TO THE ORGANIZATIONAL QA PROGRAM WILL BE CONVEYED IN THE FOLLOWING MANNER:

a) COPIES OF THE MONTHLY NUCLEAR MEDICINE STAFF QA MEETING MINUTES AND ACTIVITIES
b) QA MEETING ON REGULARLY ASSIGNED SCHEDULE

THE ABOVE PLAN HAS BEEN REVISED AND APPROVED FOR 1991-1992

ACTING CHIEF, NUCLEAR MEDICINE SERVICE	DATE
RADIATION SAFETY OFFICER	DATE
CHIEF TECHNOLOGIST, NUCLEAR MEDICINE	DATE
QUALITY ASSURANCE TECHNOLOGIST NUCLEAR MEDICINE SERVICE	DATE

SUMMARY OF QUALITY ASSURANCE EVALUATION

NUCLEAR MEDICINE SERVICE

JOHN L. McCLELLAN VAMC, L.R., AR 72205

IMAGING SECTION SUMMARY PERIOD_____

INDICATOR	NUMBER OF VARIANCES	% OF TOTAL
1: PERCENTAGE OF SCANS CONFIRMING PATHOLOGY		
2: CORRELATION OF SPECT & EJECTION FRACTIONS		
3: PERCENTAGE OF TOTAL NO-SHOW PATIENTS		
4: INCIDENCE OF INAPPROPRIATE STUDY ORDERED		
5: INCIDENCE OF RADIATION SPILL OR INCIDENT		
6: INCIDENCE OF NON-COMPLIANCE WITH MISAD-MINISTRATION QUALITY MANAGEMPNT PROGRAM		

SUBMITTED BY: _____ DATE:_____
QA TECHNOLOGIST

REVIEWED BY: _____ DATE:_____
CHIEF NUCLEAR MEDICINE