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DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL DEPARTMENT ACTIVITY
FORT CARSON, COLORADO 80913-5101

REPLY TO
ATTENTION OF

May 21, 1997

U.S. Nuclear Regulatory Commission
Region IV
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Sir:

Enclosed is a copy of the revised Quality Management Program for Evans Army Community Hospital's (License # 05-26854-01) Nuclear Medicine Department. The QMP was approved by the Radiation Control Committee on March 19, 1997.

Please contact me if you need any further information, at phone # (719) 526-7361.

Sincerely,

Jon D. Satko
First Lieutenant, U.S. Army
Radiation Safety Officer

1 Enclosure

050010

ML40

MCXE-RAD (NM)

22 January 1997

MEMORANDUM FOR Radiation Control Committee

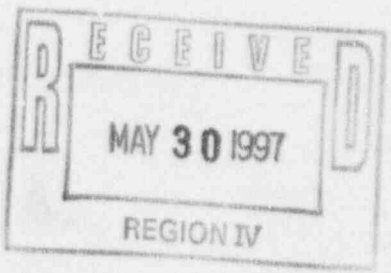
SUBJECT: Revised Nuclear Medicine Quality Management Program

1. Enclosed is a copy of the revised Quality Management Program as is outlined in Title 10, Code of Federal Regulations, Part 34.32 for your approval.

2. Our POC is the undersigned at 6-7350.

Encl

ROYCE K. SOLANO
LTC, MC
Chief, Nuclear Medicine Service



NUCLEAR MEDICINE SERVICE

EVANS ARMY COMMUNITY HOSPITAL
FT. CARSON, CO 80913-5101

QUALITY MANAGEMENT PROGRAM

Na^{125}I & Na^{131}I Doses greater than 30 μCi and all Radiopharmaceutical Therapies

1. Purpose. The objective of the Quality Management Program (QMP) outlined in Title 10, Code of Federal Regulations, Part 35.32 is to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. This document provides guidance to clinic staff in the maintenance and implementation of the QMP. This also certifies that this QMP has been implemented.

2. Scope. This program applies to everyone involved with directing the administration of or directly administering any radiopharmaceutical therapies or Na^{125}I and Na^{131}I in quantities greater than 30 μCi.

3. Procedures.

a. A **written directive** is a written radiopharmaceutical order for a specific patient which is **dated** and **signed** by an **authorized user** prior to the administration of the radiopharmaceutical. The written directive must contain the **radiopharmaceutical**, the **dosage**, and the **route** of **administration**.

b. An authorized user will prepare a written directive (e.g., an order on a nuclear medicine consultation request) prior to the administration of **any radiopharmaceutical therapy dose or any Na^{125}I or Na^{131}I dose greater than 30 μCi.**

c. There are three cases that modify the above.

(1) A **written revision** to a written directive may be made for any diagnostic or therapeutic procedure provided that the revision is signed and dated by an authorized user prior to the administration of the radiopharmaceutical.

(2) An **oral revision** to a written directive may be made if a delay in treatment would adversely affect the patient's health.

(a) The technologist will record the change in the patient's record immediately.

(b) The authorized user will prepare, sign, and date a revised written directive within 48 hours.

(3) An **oral directive** may be acceptable in lieu of a written directive if any delay would adversely affect the patient's health.

(a) The technologist will record the oral directive in the patient's record immediately.

(b) The authorized user will prepare, date, and sign a written directive within 24 hours of the oral directive.

d. Before dose administration, the identity of the patient named in the directive will be verified by at least two methods. Verbal identification, military or civilian ID card, hospital ID bracelet, hospital medical card, and medical insurance card are examples of acceptable methods for identification.

e. Before dose administration, there will also be confirmation of agreement between the written directive and the planned dose to be administered. This includes confirmation of:

(1) the radiopharmaceutical,

(2) the dosage (as measured in a dose calibrator), and

(3) the route of administration.

f. The administering technologist will seek guidance from the NCOIC, Floor Supervisor, or authorized user if he/she does not understand how to carry out the written directive.

g. Dose administration will be documented. This is typically done by filling in the appropriate areas and initialing the nuclear medicine consultation form.

h. At least once every twelve months, the Chief, Nuclear Medicine and at least one other person will review a minimum number of cases (see Table 1) plus all misadministrations and recordable events covered by the QMP. This review is to identify and evaluate any unintended deviations from the written directives. Each reviewer will:

(1) confirm that a written directive was prepared,

(2) verify its agreement with the administered radiopharmaceutical, dose, and route, and

(3) note any deviations found during the review.

Table 1. This outlines the minimum number of randomly selected patient records requiring review. The tabulated values were extracted from 10 CFR 32.110(b), Table (3) and represent a maximum allowable defect rate of 2 percent based on the number of cases within the review period.

Number of Procedures	Sample Size
1 to 75	All
76 to 100	70
101 to 200	85
201 to 300	95
301 to 400	100
401 to 600	105
601 to 800	110

Table 1. QMP Lot Tolerance Percent Defective: 2.0 percent

i. The Chief, Nuclear Medicine in conjunction with the Radiation Protection Officer will evaluate and respond to any recordable event within 30 days after discovery by:

(1) assembling the relevant facts including the cause,

(2) identifying what, if any, corrective action is required to prevent recurrence, and

(3) retaining, for three years, an auditable record of the relevant facts and any corrective action taken.

j. The Chief, Nuclear Medicine will file a summary report of the QMP review with the Radiation Control Committee. This report will include a list and evaluation of any deviations noted and any corrective actions taken.

k. The Chief, Nuclear Medicine will also evaluate the effectiveness of the QMP in meeting its objectives and will make appropriate modifications. This might typically include a review of the numbers, types, and sources of any errors as well as their trends. Any changes in the program will be recorded and furnished to the NRC within 30 days after the change has been made.

l. Records of the written directives, the doses administered, the QMP reviews and evaluations along with the findings and recommendations will be maintained in an auditable form for 3 years.

4. The Chief, Nuclear Medicine Service is the proponent of this document. Address your questions to the Chief, Nuclear Medicine at

ROYCE K. SOLANO, M.D.
LTC, MC
Chief, Nuclear Medicine Service

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DOSE TRACKING LOG

for Iodine-131 and all Radiopharmaceutical Therapies

PATIENT HISTORY: _____

Pregnancy status:

Breast feeding:

PROCEDURE: (Date: _____)

_____
Patient Identification

DOSE REQUESTED:	Type	Amount	Route	Authorized User Signature	Today's Date/Time
Requested					
Revision					

NUCLEAR MEDICINE TECHNOLOGIST: If you are uncertain about how to carry out this directive, you must get help from the floor supervisor, NCOIC, or Authorized User.

PATIENT IDENTIFICATION: (✓ must use at least two)
____ Name verified verbally
____ ID card (military, license, insurance, medical)
____ Hospital arm band
____ Social Security Number
____ Birthdate
____ Address

____ Written consent? (for all therapies)

DOSE GIVEN:

Type	Amount	Route	Administering Tech's Initials	Date	Time

☞ **QUALITY MANAGEMENT PROGRAM REVIEW:**

_____ Written Directive:
____ patient name/ID
____ radiopharmaceutical
____ dosage
____ route
____ signature
____ date

_____ Patient Identification (verified by at least two methods)
_____ Radiopharmaceutical Administered = Radiopharmaceutical Requested
_____ Dose Administered = Dose Requested +/- 10%
_____ Route Administered = Route Requested

SUMMARY:

Reviewer Initials _____

Procedure _____ Deviations: NO YES (describe & report)