DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5001

27 May 1997

REPLY TO
ATTENTION OF:

Preventive Medicine Services

Nuclear Regulatory Commission, Region I
Medical Licensing Division
Attention: QMP Coordinator
475 Alendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Quality Management Program Coordinator:

Walter Reed Army Medical Center (WRAMC) uses radioactive material authorized by U.S. Nuclear Regulatory Commission (NRC) Byproduct Material License number 08-01738-02 with an expiration date of June 30, 2004. This is a medical broadscope Type A license for medical diagnosis, therapy, and research in humans in accordance with any applicable Food and Drug Administration (FDA) requirements. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; and student instruction.

The revised Nuclear Medicine Quality Management Program dated 2 May 1997 which will supersede 22 March 1994 is included with this request (enclosure 1) as per 10 CFR 35.32(e).

For additional information, please contact COL William B. Johnson, Chief, Health Physics Office or CPT Arthur R. Morton, Chief, Operations Branch, Health Physics Office, Preventive Medicine Services, at (202) 356-0058.

Sincerely,

William B. Johnson
Colonel, U.S. Army
Radiation Protection Officer

Enclosure

Copy Furnished:

Headquarters, United States Army Medical Command

2/75

MAY 30 1997

MCHL-XN 2 May 1997

QUALITY MANAGEMENT

I. Quality Management Program, WRAMC Nuclear Medicine Service

A. The five objectives are:

1. Written directive given prior to administration.
2. Patient I.D. verified by more than one method.
3. Final plans of treatment and calculations are in accordance with written directives.
4. Each administration in accordance with written directives.
5. Any unintended deviation from written directives is I.D.'d, evaluated, and appropriate action is taken.

B. Develop procedures for and conduct a review of the QMP including:

1. All misadministration.
2. All recordable events.
3. A sampling of patient administrations... at intervals no greater than 12 months.
4. Retain records for three years.

II. Radiopharmaceutical QMP

A. For all Radiopharmaceutical Therapies and Diagnostic Iodine 131 & 125; Iodine MIBG NP59; Strontium-89 Chloride, Samarium-153 EDTMP, Yttrium-90 antibodies, and Phosphorus -32 IV.

1. Authorized user - Sign and date written directive (radiopharmaceutical, dosage, route of administration) before administration. (Delays, oral directives and revisions OK under certain circumstances. 10 CFR 35.32 (a) (1).).

2. User and/or Designee verify patient identity by more than one method:

a. Ask patient name, confirm, and
b. Birth date or
c. Social security number or
d. Address or
e. Signature or
f. ID bracelet or
g. Hospital ID card or
h. Military ID card.

3. Person administering dose verify details of administration:
a. Radiopharmaceutical
b. Dose
c. Route of administration

4. Encourage worker to ask questions.

II. Radiopharmaceutical QMP cont.

5. User or supervised person date and sign/initial written record (chart).

See enclosure Radiopharmaceutical Administration Checklist

III. Annual Review

A. At least annually the QMP review will consist of:

1. Random sample of therapies representative of the following patient administrations:

Lot size	Sample size	Acceptance No.
20	ALL	0
21 - 100	20	0
>100	20%	0

2. All misadministration

3. All recordable events.

B. For each patient case, compare administered vs. prescribed for

1. Written directive complete
2. Patient identity verified
3. Radiopharmaceutical
4. Dose
5. Route of administration

ANA A. RODRIGUEZ
COL, MC
Chief, Nuclear Medicine Service

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RADIOPHARMACEUTICAL ADMINISTRATION CHECKLIST

(To be filled out by individuals administering a therapeutic dosage of any radiopharmaceutical other than sodium iodine I-125 or I-131 (SR-89 MIBG, NP-59, P-32), or any dosage greater than 30 microcuries of sodium iodide I-125 or I-131).

PLACE RADIOPHARMACEUTICAL STICKER HERE

DIRECTIONS: Complete the items below in the order listed, and initial each item when completed. If you do not fully understand how to carry out the written directive (PRESCRIPTION/CONSENT FORM) for this administration, halt the procedure and contact the Chief, Nuclear Medicine Service, or other authorized user immediately.

PART I - BEFORE ADMINISTRATION

Attach a copy of the written directive (PRESCRIPTION/CONSENT FORM) for the dosage prepared. _____ initials

The written directive (PRESCRIPTION/CONSENT FORM) is signed and dated by an authorized user. _____ initials

The patient's identity checked verbally and confirmed as the individual named in the written directive (PRESCRIPTION/CONSENT FORM) by comparison with corresponding information in the patient's record using at least two of the following means of identification. _____ initials
(Listed in order of preference. Check applicable means.)

1._____Military ID card
2._____Name on the patient's ID bracelet
3._____Drivers license photo
4._____Other (__SSAN __Birth date __Address __Signature)

The radiopharmaceutical to be administered is the same as that identified on the written directive (PRESCRIPTION/CONSENT FORM). _____ initials

Route of administration (circle): I.V. I.M. P.O. Other _

The dosage to be administered is the same as that identified on the written directive (PRESCRIPTION/CONSENT FORM). _____ initials

Laboratory test results (Beta HCG, TSH, CBC, etc) have been reviewed. _____ initials

Pathology report reviewed by physician (Cancer Therapy) initials

PART II - AFTER ADMINISTRATION

Date and time of dose administration: _____ _____
DATE TIME

Record, date, and initial the administered dosage on the patients's consult, and place in the Nuclear Medicine Folder. _____ initials

REVIEWED BY (AUTHORIZED USER):

_____
SIGNATURE DATE