DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
2510 WALMER AVENUE
NORFOLK, VIRGINIA 23513-2617

6470
Ser OM/10039
08 AUG 1997

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM INFORMATION NOTICE 97-08, QUALITY MANAGEMENT PROGRAM (QMP)

Ref: (a) 10 CFR 35.32
(b) NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/08687 of 17 Dec 96, Navy Radioactive Material Permit (NRMP) Program Information Notice 96-05

Encl: (1) Annual Review of Quality Management Program (QMP) (Rev. 2, 08/97)
(2) 1997 Navy Environmental Health Center Information Notices Pertaining to the NRMP Program

1. I am issuing this information notice to emphasize the importance of continuing review and evaluation of your nuclear medicine and, if applicable, brachytherapy Quality Management Program (QMP). Your QMP must not be simply a written document which is audited annually, but must be an active, integral component of your daily clinic operations. You should continually monitor your QMP to ensure that (1) the QMP includes written policies and procedures to meet the specific objectives of reference (a), and (2) the procedures actually being used in the clinic are in accordance with your written QMP.

2. Recently, a failure to continually monitor their QMP procedures caused a Navy hospital to implement daily nuclear medicine operations which were in direct violation of their QMP. Failure of the hospital to implement procedures in accordance with their NRMP resulted in the Navy Radiation Safety Committee issuing a severity level III violation against the hospital's NRMP.

3. The scenario of the violation occurred generally as follows. During a period of personnel turnover (radiologists and nuclear medicine technologists), a policy was adopted to not require a written directive for diagnostic radiopharmaceutical administrations. Instead, diagnostic studies were administered using normal dosages listed in an approved clinical standard operations manual - a policy in compliance with federal regulations though not normally used in the Navy. Unfortunately, the revised policy resulted in ten diagnostic administrations of Iodine-131 greater than 30 microcuries without a written

directive, a direct violation of both the hospital's written QMP and 10 CFR 35.32(a)(1)(iv).

4. A contributing factor in this violation was an apparent misunderstanding by the nuclear medicine staff that the QMP pertained only to therapeutic administrations and not to diagnostic administrations, even though the written QMP always contained the requirement for a written directive for all administrations of radioactive iodine greater than 30 microcuries. Fortunately, none of the administrations without written directives resulted in a misadministration or harm to the patient.

5. The fact that the failure to use written directives for diagnostic radioiodine administrations continued for a period of 16 months indicates a lack of staff familiarity with their written QMP, a deficiency in the annual QMP training and QMP audit programs, and thus a substantial failure to implement a portion of the QMP. Although the command had conducted an annual QMP audit, the auditor succumbed to the error of basing the audit on review of studies for which there were written directives and not on review of all radiopharmaceutical administrations covered by the QMP. Therefore, the QMP auditor reviewed only therapeutic radioiodine administrations and failed to review diagnostic administrations of radioiodine greater than 30 microcuries.

6. I request that all hospital Radiation Safety Officers (RSO) take the following action:

a. Closely review your nuclear medicine and, if applicable, brachytherapy QMP to confirm not only that it contains procedures to meet specific objectives for all types of use addressed by reference (a), but that your nuclear medicine and, if applicable, brachytherapy daily policies and practices comply with your written QMP. Ensure that your QMP review uses the revised QMP review checklist of enclosure (1) which replaces the one provided by reference (b).

b. Ensure that all staff personnel involved with the QMP, to include RSO, authorized users, nuclear medicine and radiation oncology technologists, and Radiation Safety Committee members, are familiar with and understand all provisions of your QMP. I encourage you to provide QMP training in a formal manner with records to include date, duration, place, instructor, subjects covered, and names of attendees. The policy of having individuals simply read and sign the SOP manual or QMP document

does not provide adequate assurance that the individual understands the content and requirements of the QMP.

7. Enclosure (2) is a list of all previous NRMP Information Notices issued by NAVENVIRHLTHCEN during calendar year 1997. Copies of letters listed in this enclosure are available from NAVENVIRHLTHCEN.

8. Please contact Mr. Paul Tveten for more information at DSN 864-5584, (757)363-5584 or e-mail at tvetenp@ehc50.med.navy.mil

R. L. BUCK

Distribution:
All Hospital Radiation Safety Officers

Copy to:
CNO (N455)
BUMED (MED-211)
NSHS Bethesda MD (Attn: Clinical Nuclear Medicine School)
NAVUSEAMEDINSTITUTE Groton CT

ANNUAL REVIEW OF QUALITY MANAGEMENT PROGRAM (QMP)

1. COMMAND: _____

   PERMIT NUMBER: _____

2. REVIEWER NAME: _____

   REVIEWER COMMAND: _____

3. DATE OF REVIEW: _____

4. SCOPE OF THE AUDIT:

a.	Review of previous QMP review	YES	NO
b.	Review of the written QMP	YES	NO
c.	Review of records of patient dose administrations	YES	NO
d.	Review of training records	YES	NO
e.	Interviews with personnel	YES	NO
f.	Direct observation of procedures	YES	NO

5. MODALITIES OF USE (Check all that apply)

_____ a. Diagnostic radioiodine > 30 microcuries

_____ b. Therapeutic radioiodine > 30 microcuries

_____ c. Other therapeutic radiopharmaceuticals

_____ d. Brachytherapy

_____ e. Strontium-90 eye applicator use

_____ f. Cobalt-60 teletherapy

6. PREVIOUS ANNUAL REVIEW DATED _____
[10 CFR 35.32(b)]

a.	Less than 12 months ago	YES	NO	
b.	Reviewed a representative sample of administrations	YES	NO	
c.	Reviewed all recordable events	YES	NO	NA
d.	Reviewed all misadministrations	YES	NO	NA
e.	Evaluated by Radiation Safety Committee to determine the effectiveness of the QMP	YES	NO	

7. SAMPLING:

Total written directives	Representative sample
1 to 20	All
20 to 100	20
Over 100	20%

		Total Number Written Direct.	Rep. Sample From Above	Actual Number Records Reviewed
a.	Diagnostic radioiodine > 30 microcuries	_____	_____	_____
b.	Therapeutic radioiodine > 30 microcuries	_____	_____	_____
c.	Other therapeutic radiopharmaceuticals	_____	_____	_____
d.	Brachytherapy	_____	_____	_____
e.	Strontium-90 eye applicator use	_____	_____	_____
f.	Cobalt-60 teletherapy	_____	_____	_____

8. MODIFICATIONS TO QMP
[10 CFR 35.32(e)]

a.	Submitted to NEHC within 30 days	YES	NO	NA

9. TRAINING

a. Supervised individuals have been trained in the QMP [10 CFR 35.25(a)(1)] YES NO

List dates of training:

b. Supervised individuals are knowledgeable in the QMP YES NO

List personnel interviewed:

c. Authorized users are knowledgeable in the QMP YES NO

List personnel interviewed:

10. ALL WRITTEN DIRECTIVES (WD) [10 CFR 35.32(a)(1)] [10 CFR 35.2]

a. WD prepared prior to dose administration YES NO

b. WD signed by authorized user YES NO

c. WD dated by authorized user YES NO

d. WDs are retained in an auditable form for three years YES NO

e. Records of doses administered under WDs retained for 3 years YES NO

f. All administrations are in accordance with the WD YES NO

11. DIAGNOSTIC WRITTEN DIRECTIVES [10 CFR 35.2]

a. WD contains dosage YES NO NA

12. THERAPEUTIC WRITTEN DIRECTIVES [10 CFR 35.2]

a. WD contains route, radiopharmaceutical and dosage YES NO NA

13. BRACHYTHERAPY WRITTEN DIRECTIVES
[10 CFR 35.2]

a. WD prior to implantation contains the radioisotope, # of sources and source strengths — YES NO NA

b. WD after implantation but prior to completion of procedure contains the radioisotope, treatment site, and total source strength and exposure time (or total dose) — YES NO NA

14. TELETHERAPY WRITTEN DIRECTIVES
[10 CFR 35.2]

a. WD contains the total dose, dose per fraction, treatment site and overall treatment period — YES NO NA

15. REVISIONS TO WRITTEN DIRECTIVES
[10 CFR 35.32(a)(1) footnote]

a. Written revisions to WDs are signed and dated by the auth. user prior to administration — YES NO NA

b. Oral revisions to WDs are documented immediately in the patient's record — YES NO NA

c. A revised WD is signed by the authorized user within 48 hours of an oral revision to a WD — YES NO NA

16. ORAL DIRECTIVES
[10 CFR 35.32(a)(1) footnote]

a. Oral directives are documented immediately (emergencies only) — YES NO NA

b. WD prepared within 48 hours of an emergency oral directive — YES NO NA

17. PATIENT IDENTITY VERIFICATION
[10 CFR 35.32(a)(2)]

a. More than one method is used — YES NO

18. UNINTENDED DEVIATIONS
[10 CFR 35.32(a)(5)]

a.	Are identified and evaluated	YES	NO	NA
b.	Any necessary modifications made	YES	NO	NA
c.	Records retained for 3 years	YES	NO	

19. RECORDABLE EVENTS
[10 CFR 35.32(c)]

a.	Evaluated within 30 days	YES	NO	NA
b.	Facts including cause and corrective action identified	YES	NO	NA
c.	Records retained for 3 years	YES	NO	NA

20. MISADMINISTRATIONS
[10 CFR 35.33]

a.	Reported by OPREP-3 Navy Blue	YES	NO	NA
b.	Referring physician notified within 24 hours	YES	NO	NA
c.	Patient notified within 24 hrs	YES	NO	NA
d.	Report to patient within 15 days	YES	NO	NA
e.	Records retained for 5 years	YES	NO	NA

21. SIGNATURES AND DATES

a. _____
Reviewer

b. _____
Radiation Safety Officer

c. _____
Chairman, Radiation Safety Committee

1997
NAVENVIRHLTHCEN INFORMATION NOTICES
NAVY RADIOACTIVE MATERIAL PERMIT PROGRAM

97-01: NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/09393 of 9Apr97
Current 10 CFR Parts 19, 20 and 35
NRC Information Notice 97-03 on defacing RAM labels
Distributed to all hospital RSOs

97-02: NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/09416 of 11Apr97
Description of iodine-125 spill
RAM Shipping Information survey
Distributed to all medical NRMP holders

97-03: NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/09422 of 15Apr97
Revised NRMP Application form
Distributed to all medical NRMP holders

N/A NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/09418 of 15Apr97
Sealed and Unsealed Source Inventory Requirement
Distributed to drug labs and research labs only

97-04: NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/09432 of 16Apr97
Current 10 CFR Parts 19 and 20
Distributed to drug labs and research labs only

N/A NAVENVIRHLTHCEN ltr 6470 Ser OM/09488 of 30Apr97
DOT RAM Transportation and Training Requirements
Distributed to all medical NRMP holders

97-05: NAVENVIRHLTHCEN ltr 6470 Ser OM/09522 of 9May97
Verification of transferee license to receive RAM
Distributed to all medical NRMP holders

97-06: NAVENVIRHLTHCEN ltr 6470 Ser OM/09568 of 16May97
Release of patients administered radioactive materials
Distributed to all hospital RSOs

97-07: NAVENVIRHLTHCEN ltr 6470 Ser OM/09852 of 02Jul97
NEHC Nuclear Medicine Inspection Field Notes
Distributed to all hospital RSOs

N/A NAVENVIRHLTHCEN ltr 6470 Ser OM/09863 of 03Jul97
List of all NEHC Info Notes (1987-97)
Distributed to all medical NRMP holders