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

6470
Ser OMSJR/ 01104
25 APR 1995

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM INFORMATION NOTICE 95-04

Ref: (a) NAVENVIRHLTHCEN ltr 6470 Ser 311aj/10164 of 15 Oct 91
(b) Title 10, Code of Federal Regulations, Part 35.32
(c) Title 10, Code of Federal Regulations, Part 21.6

Encl: (1) Section 206, U.S. Energy Reorganization Act of 1974
(2) Revised NRMP Application for Medical Department Activities
(3) Guidelines for Preparation of NRMP Application
(4) List of 1995 NAVENVIRHLTHCEN Information Notices Pertaining to the NRMP Program

1. I need to clarify reference (a) with respect to radioiodine and the Quality Management Program (QMP). Even though reference (b) requires that QMP procedures be used only when handling Iodine-125 and Iodine-131, Navy permittees will continue to include Iodine-123 in their Quality Management Programs. Thus, all radioiodine administered to patients in dosages greater than 30 microcuries by Navy NRMP holders will be subject to the requirements of the QMP.

2. In accordance with reference (c), enclosure (1) is required to be prominently posted at your facility. The content deals with reporting of safety hazards.

3. Enclosure (2) is a revision to the application form which must be submitted to NAVENVIRHLTHCEN whenever a NRMP is to be issued, renewed, amended or terminated. Enclosure (3) provides guidelines for completion of the application package.

4. Enclosure (4) is a list of all NRMP Information Notices previously issued by Navy Environmental Health Center during calendar year 1995. Copies of letters listed in this enclosure are available from NAVENVIRHLTHCEN.

5. You may contact me for more information at DSN 564-4657 or Commercial (804) 444-4657, extension 413.

S. J. Riahi
S. J. RIAHI
By direction

Subj: NAVY RADIOACTIVE MATERIALS PERMIT (NRMP) PROGRAM INFORMATION NOTICE 95-04

Distribution:
NATNAVMEDCEN Bethesda MD
(ATTN: CDR L. F. Parr, MSC, USN)
NAVMEDCEN Oakland CA
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NAVHOSP Charleston SC
(ATTN: LT E. S. Wittenbach, MSC, USN)
NAVHOSP Great Lakes IL
(ATTN: CAPT E. R. Willgress, MC, USN)
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NAVHOSP Jacksonville FL
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NAVHOSP Okinawa JA
(ATTN: LT C. J. Day, MC, USN)
NAVHOSP Pensacola FL
(ATTN: CDR H. G. Herr, MC, USN)

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

Section 206, Energy Reorganization Act, 1974 Noncompliance

Sec. 206.

(a) Any individual director, or responsible officer of a firm constructing, owning, operating, or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or pusuant to this Act, who obtains information reasonably indicating that such facility or activity or basic components supplied to such facility or activity -

(1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to substantial safety hazards, or

(2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate.

shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

(b) Any person who knowingly and consciously fails to provide notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.

(d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section.

Navy Radioactive Material Permit Application for Medical Department Activities

INSTRUCTIONS: OPNAVINST 6470.3 established the Navy Radiation Safety Committee to control and approve the use of radioactive material, with certain exceptions, within the Navy and Marine Corps. Navy Radioactive Material Permits will be issued to authorize the use of radioactive material. This application must be completed as described in the enclosed instructions and submitted to:

Navy Environmental Health Center
2510 Walmer Avenue
Norfolk VA 23513-2617

Point of contact: Radiation Health Department at DSN 564-4657, Commercial (804) 444-4657

NOTE: The information contained in this application will be considered an integral part of your Navy Radioactive Material Permit and will be subject to verification during compliance inspections.

1) **THIS IS AN APPLICATION FOR: (Check one)**

- ☐ New Permit
- ☐ Amendment to Permit Number _____
- ☐ Renewal of Permit Number _____
- ☐ Termination of Permit Number _____

2) **NAME AND MAILING ADDRESS OF COMMAND: (Include nine-digit zip code)**

_____

_____

_____

_____

3) **ADDRESS(ES) WHERE RADIOACTIVE MATERIAL USED OR POSSESSED:**

_____

_____

_____

_____

4) **POINT OF CONTACT ABOUT THIS APPLICATION:**

Name, Rank and Position:

_____

Telephone Numbers: DSN: _____

Commercial: _____

Facsimile: _____

Submit information requested in items 5 through 11 in the space below and/or on separate sheets as needed.. A description of thr type and scope of information required is included in the enclosed instructions.

5) **Radioactive Material**

6) **Purpose(s) for which radioactive material will be used**

7) **Individual responsible for radiation safety program**

8) **Training provided for exposed individuals**

9) **Facilities and equipment**

10) **Radiation Safety Program**

11) **Waste Management**

12) **COMMENTS**

NAME OF COMMANDING OFFICER **SIGNATURE OF COMMANDING OFFICER** **DATE**

GUIDELINES FOR PREPARATION OF NAVY RADIOACTIVE

MATERIAL PERMIT APPLICATION FOR NUCLEAR MEDICINE

1. The enclosed Navy Radioactive Material Permit Application Form should be completed without reference to any documentation submitted previously and should reflect current operating procedures. Retain a copy of your application package which will become an integral part of your permit.

2. The extent of your radiation safety program is dependent on the "Types of Use" of radioactive material as defined in 10 CFR 35.100 through 35.500. The attached table lists the program elements required for each type of use. **NRC Regulatory Guide 10.8, Revision 2** contains details on the program requirements and provides model radiation safety procedures. Follow the guidance in this Regulatory Guide in completing your application, except as modified for the following items of the application form:

a. Items 5 and 6

(1) Prepare your application in the format of Table 1 on Page 7 of the Regulatory Guide for only the types of use for which you have authorized users and the necessary equipment and facilities. Since the scope of compliance inspections will depend on the types of use listed in your permit, it is in your interest to limit your program to only those types of use which you intend to practice at this time. Additional types of use can be added at a later date with a permit amendment.

(a) If you request radioisotopes for use as stated in 10 CFR 31.11 for in vitro laboratory procedures, including carbon- 14 Bactec, state whether each isotope will be used within the limits of 10 CFR 31.11. The NRC Form 483 for a general license as discussed in 10 CFR 31.11 and paragraph 1.4.1 of NRC Regulatory Guide 10.8 is no longer applicable to Navy commands. You may be authorized to use any isotope listed in 10 CFR 31.11 under the provisions of 31.11 if:

(i) Inventory limits of 31.11 are observed.

(ii) In vitro isotope usage is physically and administratively separate from medical isotope use involving internal or external administration to humans or animals.

(b) If you request radioisotopes for use as stated in 10 CFR 35.200, state whether generators, gases, or aerosols will be used by your command.

(c) If you request use of a Sr-90 eye applicator, submit a copy of your rules for safe handling or adopt the NRC's "Rules for Safely Handling a Strontium-90 Eye Applicator", which are provided on page 5 of these guidelines.

(d) Provide information to identify nickel-63 sources used in gas chromatographs, and any other sources which are not addressed in NRC Regulatory Guide 10.8.

(2) Include all naturally occurring and accelerator produced isotopes, such as radium, cobalt-57, gallium-67, indium-111, and thallium-201, that will be used. List either the amount needed or the phrase "as needed" and the purpose for each isotope.

b. Item 7

(1) Submit the name, training and experience of your Radiation Safety Officer, using Supplement A of Regulatory Guide 10.8, Revision 2. Indicate whether the qualification of your Radiation Safety Officer has been reviewed by your Command Radiation Safety Committee to ensure that the person meets the requirements of 10 CFR 35.900.

NOTE: The Radiation Safety Officer must be listed by name on your permit.

(2) If you desire authorization to have your Radiation Safety Committee approve Authorized Users, include the following statement:

"All authorized users will be approved by this command's Radiation Safety Committee using, as a minimum, the training and experience requirements listed in Subpart J of 10 CFR 35 for each type of use authorized."

NOTE: The command's Radiation Safety Committee shall document all training and experience of authorized users on Supplements A and B of the Regulatory Guide 10.8 and maintain copies of documents reviewed during the approval process. A copy of the physician's state license to practice medicine should also be maintained. The approval of authorized users by the Radiation Safety Committee shall be in addition to any action of the Hospital Credentialing Committee and shall specifically state the types of use which the individual is authorized to perform. These documents shall be available for review during compliance inspections.

(3) If you desire the Navy Radiation Safety Committee to approve authorized users, submit Supplements A and B and other documents which confirm that each user meets the training and experience for each type of use requested for that individual. Indicate whether or not the person has been recommended as an authorized user by the command's Radiation Safety Committee.

(4) In cases where an individual does not have the required training or experience under Subpart J of 10 CFR 35 to be an authorized user, that individual may perform procedures under the supervision of an authorized user. Ensure that you comply with the provisions of 10 CFR 35.25 for procedures performed under the supervision of an authorized user.

(5) Specific cases for approval of an individual as an Authorized User, who does not meet the requirements of Subpart J of 10 CFR 35, may be submitted for approval to the Navy Radiation Safety Committee via the Navy Environmental Health Center. Such cases must clearly have merit to justify any waivers from NRC requirements.

c. Items 8, 9 (except 9.2), 10 and 11

You may state that you will follow the Model Procedure in Appendix ( ) of Regulatory Guide 10.8, Revision 2. If you do not follow the model procedure, then submit your procedure for review. Procedures used by your command shall be promulgated in a Standard Operating Procedures (SOP) Manual or equivalent format, as required by 10 CFR 35.21(b)(2), and should also include requirements of or reference to BUMEDINST 6470.20 and OPNAVINST 6470.3. These procedures will be reviewed during inspections to ensure that the command is in compliance with its Navy Radioactive Material Permit. (**Note**: You are reminded that the Navy has implemented the revised 10 CFR 20 effective 1 April 1993. Thus, your program must comply with requirements of 10 CFR 20.1001 - 20.2402 and not 10 CFR 20.1 - 20.602.)

d. Item 9.2

(1) Submit a list of radiation survey instruments. For each instrument, list the manufacturer and model number, the number of instruments available, and the type of use. The manufacturer name need not be submitted for standard Navy RADIACs.

(2) If the command's radiation survey instruments are calibrated by a Navy RADIAC Calibration Facility, then state on the application, "All radiation survey instruments are calibrated by (name of facility)".

RULES FOR SAFELY HANDLING A STRONTIUM-90 EYE APPLICATOR

From NRC Information Notice No. 90-58

*1. Wear your personnel dosimeter(s) whenever you handle the Sr-90 eye applicator. Finger ring-type dosimeters should be worn with the detector on the palm side of the hand.

2. Remove the Sr-90 eye applicator from its secured storage location just before use. Do not leave it out any longer than necessary.

3. After removing the Sr-90 eye applicator from its secured storage location:

   a. Do not touch the treatment end of the applicator with your hands or other portion of your body,

   b. Always hold the applicator by its handle, and

   c. Except during patient treatment, do not point the treatment end of the applicator toward another person, especially toward the eyes.

4. If the applicator is to be sterilized, place on a flat surface, use a cotton swab, sponge, or gauze dampened with a sterilizing agent, then wipe the treatment end of the applicator across the swab, sponge, or gauze. Do not sterilize by holding the swab, or gauze in your hand.

5. During treatment, hold the patient's eye lids open with tape or other device, not with your fingers.

6. Immediately after treatment and/or resterilization, return the Sr-90 eye applicator to its storage container and to its secured location (e.g., locked cabinet).

7. Do not remove any metal or plastic inserts from the manufacturer-supplied storage container. These items are generally a part of the container's shielding. Removal of these items can lead to excessive and unnecessary radiation exposures.

* It is strongly recommended that Thermoluminescent Dosimeter (TLD) ring or film type badges be worn when handling a Sr-90 eye applicator.

(3) If any radiation survey instruments are not calibrated by a Navy RADIAC Calibration Facility, submit information required by the Regulatory Guide for those instruments.

e. Item 10.1

Submit the information required by the Regulatory Guide. Submit a list of current Radiation Safety Committee membership by position. The Radiation Safety Committee's records and minutes shall be sufficient to document its oversight of the use of radioactive material as outlined in 10 CFR 35.22(b). This documentation will be a key item for review during compliance inspections.

f. Quality Management Program

Submit your written Quality Management Program in it's entirety. Reference 10 CFR 35.32.

g. Items 12 - 14 of the Regulatory Guide are not applicable to the Navy Radioactive Material Permit program.

h. The comment section may be used to submit additional information to the Navy Radiation Safety Committee concerning this application.

i. **The application shall be signed by the Commanding Officer or Officer in Charge.**

1995
NAVENVIRHLTHCEN INFORMATION NOTICES
NAVY RADIOACTIVE MATERIALS PERMIT PROGRAM

95-01: NAVENVIRHLTHCEN ltr 6470 Ser 312/00087 of 17Jan95
Brachytherapy misadministration and QMP
Distributed to medical treatment facilities only

95-02: NAVENVIRHLTHCEN ltr 6470 Ser 31/00613 of 23Feb95
Draft regulatory guides and proposed rules
Quality Management Program info
Cardiolite vial breakage warning
List of 1994 NAVENVIRHLTHCEN NRMP Info Notes
Distributed to medical treatment facilities only

95-03 NAVENVIRHLTHCEN ltr Ser 31/00655 of 26 Feb 95
Draft regulatory guides
Distributed to non-hospitals only