DEPARTMENT OF THE NAVY
NAVY ENVIRONMENTAL HEALTH CENTER
620 JOHN PAUL JONES CIRCLE SUITE 1100
PORTSMOUTH VA 23708-2103

6470
Ser OEM/ 001280
13 SEP 2005

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVAL RADIOACTIVE MATERIALS PERMIT (NRMP) INFORMATION NOTICE 2005-02: MEDICAL USE OF BYPRODUCT MATERIAL – RECOGNITION OF SPECIALTY BOARDS; FINAL RULE

Ref: (a) Title 10, Code of Federal Regulations, Part 35
(b) Office of Nuclear Material Safety and Safeguards (NMSS) Quarterly Newsletter; NUREG/BR-0117, No. 05-02, July 2005

1. The Nuclear Regulatory Commission (NRC) recently published a Final Rule to amend its requirements for "Medical Use of Byproduct Material", 10 CFR Part 35 (reference (a)), in the Federal Register on March 30, 2005 (70 FR 16335). The rule amends the regulations to change requirements for recognition of certain specialty boards' certification processes. These "board certifications" may be used for demonstrating the adequacy of the training and experience of individuals to serve as Radiation Safety Officers (RSOs), Authorized Users (AUs), Authorized Medical Physicists (AMPs) and Authorized Nuclear Pharmacists (ANPs). The final rule also revises the requirements for demonstrating the adequacy of training and experience for the educational pathway (i.e., alternate pathway) other than the certification pathway, for achieving authorized status. Per the NRC, the rule provides a more flexible and performance-based approach to specifying requirements for training and experience, using a graded approach to ensure that training in radiation protection is consistent with the need for adequate understanding and skills.

2. The NRC also recognizes individuals with "experience" as either an RSO, AU, AMP or ANP, and that when previously listed on an NRC or Agreement State license, or on a permit issued under a Master Materials License (MML) prior to 29 April 2005, need not comply with certain training requirements in Articles and/or Subparts as specified in 10 CFR 35.57.

3. The following summary of "significant amendments" to Part 35 of reference (a) have recently been published by the NRC in reference (b):

a. The requirement in 10 CFR 35.390(b)(1)(ii)(F) for experience with the elution of generators, testing, processing, and preparation of labeled radioactive drugs, is removed from 10 CFR 35.390.

b. The requirements for experience with oral and parenteral administrations of byproduct material for which a written directive (WD) is required, currently in 10 CFR 35.390(b)(1)(ii)(G), are removed from the requirements for recognition of specialty board certification processes. However, the regulations continue to require this experience for individuals to qualify as AUs for

uses of byproduct material for which a written directive is required under 10 CFR 35.300, for both the certification pathway and the alternate pathway.

c. A new 10 CFR 35.396, entitled "Training for the parenteral administration of unsealed byproduct material requiring a written directive", is included in the final rule. This allows individuals who do not meet other requirements in 10 CFR 35.390(b)(1), to serve as AUs for parenteral administration of byproduct material for which a WD is required, if they meet the requirements in 10 CFR 35.396.

d. Requirements for individuals to serve as RSOs were amended (10 CFR 35.50) to include medical physicists who meet the requirements specified therein.

e. A requirement is added for AUs in 10 CFR 35.190, 35.290, and 35.390, and for ANPs in 10 CFR 35.55, that training in basic radionuclide handling techniques must include a minimum number of hours of classroom and laboratory training, for individuals to be approved as AUs and ANPs under the alternate pathway. Specifically, the final rule requires 8, 80, and 200 hours of classroom and laboratory training for 10 CFR 35.190, 35.290, 35.55 and 35.390, respectively, under the alternate pathway.

f. "Attest" and "attestation" are used in place of "certify" and "certification", in requirements for the preceptor statements.

g. 10 CFR 35.10 provides for implementation of the requirements in 10 CFR 35.14(a) to provide the NRC with a copy of written attestation, signed by a preceptor, on or before October 25, 2005. [*Note that for U. S. Navy NRMP permittees, a copy shall be forwarded to the Navy Environmental Health Center in lieu of the NRC.*] Also, before October 25, 2005, a licensee shall satisfy the training requirements for an AU, AMP, ANP, or an RSO, by complying with either: (a) the training requirements in Subpart J, or (b) the appropriate training requirements in Subpart B or Subparts D through H.

4. The above and other changes to the rule are discussed in more detail in the Federal Register. Note also that licensing guidance for medical uses of byproduct material, NUREG-1556, Vol. 9, has been revised to conform to the revisions in the final rule.

5. The names of board certifications which have been recognized by the NRC or by an Agreement State as having met the certification process, will be posted on the NRC's Website at: http://www.nrc.gov/materials/miau/miau-reg-initiatives/spec-board-cert.html.

6. Subpart J of 10 CFR Part 35 will officially be deleted from the regulations on 25 October, 2005. Starting on that date, all approvals of individuals shall be based on compliance with the new regulations as specified in Subpart B or Subparts D through H.

Subj: NAVAL RADIOACTIVE MATERIALS PERMIT (NRMP) INFORMATION NOTICE 2005-02: MEDICAL USE OF BYPRODUCT MATERIAL – RECOGNITION OF SPECIALTY BOARDS; FINAL RULE

7. Additional guidance for medical use licensees has been made available by the NRC entitled "*Medical Uses Licensee Toolkit*", which can be accessed on the NRC's Website at: http://www.nrc.gov/materials/miau/med-use-toolkit.html.

8. Permittees shall document their Radiation Safety Committee's (RSC's) review of this Information Notice. No formal reply is required.

9. This letter shall be maintained on file with your NRMP and shall be considered as an integral part of your NRMP. This and other Bulletins and Information Notices can be found at http://www-nehc.med.navy.mil/occmed/nrmp.htm.

10. For additional information, please contact LCDR Brian D. Pomije, MSC, USN, Radiation Health Team Leader at DSN 377-0766, (757) 953-0766 or fax (757) 953-0685, or by E-mail at pomijeb@nehc.med.navy.mil.

B. D. POMIJE
By direction

Distribution:
All Medical NRMP Permittees
NSHS, Portsmouth, VA (Attn: Clinical Nuclear Medicine School)

Copy to:
OPNAV (N455)
BUMED (M342)