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December 7, 2005

Docket No. 03029462
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Chief of Naval Operations
Environmental Readiness Division (N45)
ATTN: CAPT Lino Fragoso, Ph.D.
Radiological Controls and Health Branch
2000 Navy Pentagon (NCI Suite 2000)
Washington, D.C. 20350-2000

SUBJECT: DEPARTMENT OF THE NAVY, REQUEST FOR REVIEW OF NAVAL
RADIATION SAFETY COMMITTEE STANDARD OPERATIONS PROCEDURES
MANUAL, CONTROL NO. 137766

Dear Captain Fragoso:

This is in reference to your letter dated September 22, 2005 forwarding a copy of the Navy's Master Materials License Standard Operating Procedures for review. Below are our comments concerning this document.

NUREG-1556, Volume 10, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Master Materials Licenses, contains guidance for Federal organizations possessing a Master Materials License (MML) and the criteria to be used in reviewing MML applications and amendments. Applicable NRC policy or guidance was used in the review of each Chapter and Appendix of the SOP. Following are the SOP Chapter and Appendix titles with the NRC guidance used in this review in parenthesis:

- Chapter 1 - Organization and Responsibilities (NUREG-1556, Volume 10 and NUREG-1556, Volume 11, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses of Broad Scope)
- Chapter 2 - Naval Radioactive Materials Permit, Appendix A: NRMP Format, Appendix B, NRC State Codes for NRMPs, Appendix C, Use Codes for NRMPs, and Appendix G, NRMP Application for Medical Department Activities (NUREG-1556, Volume 20, Consolidated Guidance About Materials Licenses, Guidance About Administrative Licensing Procedures and NUREG-1556, Volume 11)
- Chapter 3 - Inspections (NRC Manual Chapter 2800, Materials Inspection Program and the NRC Enforcement Policy)
- Chapter 4 - Inspector/NRMP Reviewer Training, Qualification and Evaluation and Appendix F, Inspector/NRMP Reviewer General Training Requirements (NRC Manual Chapter 1246, Formal Qualification Programs in the Nuclear Material Safety and Safeguard Program Area)
- Chapter 5 - Communication With the NRC and Appendix D, NRMP Reporting Requirements (NUREG 1556, Volume 10)
- Chapter 6 - Required Meetings of the NRSC (NUREG-1556, Volumes 10 and 11)
- Chapter 7 - Emergency Procedures (NUREG-1556, Volumes 10 and 11)

- Chapter 8 - Allegations and Appendix E, Allegation Background Information Sheet (NRC Management Directive 8.8, Management of Allegations)
- Chapter 9 - Waste Management and Reduction (NUREG-1556, Volumes 10 and 11).

Page 4 of the SOP contains a list of references. The following references should be added since they are applicable to the Navy's program.

- NUREG-1556, Volume 1, Revision 1, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Portable Gauges
- NUREG-1556, Volume 2, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Industrial Radiography Licenses
- NUREG-1556, Volume 3, Revision 1, Consolidated Guidance About Materials Licenses, Applications for Sealed Source and Device Evaluation and Registration
- NUREG-1556, Volume 4, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Fixed Gauge Licenses
- NUREG-1556, Volume 5, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Self-Shielded Irradiators
- NUREG-1556, Volume 7, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope
- NUREG-1556, Volume 8, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Exempt Distribution Licenses
- NUREG-1556, Volume 9, Revision 1, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Medical Use Licenses
- NUREG-1556, Volume 10, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Master Materials Licenses
- NUREG-1556, Volume 11, Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Licenses of Broad Scope
- NUREG-1556, Volume 16, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Licenses Authorizing Distribution to General Licenses
- NUREG-1556, Volume 17, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses
- NUREG-1556, Volume 18, Consolidated Guidance About Materials Licenses, Program Specific Guidance About Service Provider Licenses
- NUREG-1556, Volume 20, Consolidated Guidance About Materials Licenses, Guidance About Administrative Licensing Procedures
- NUREG-1516, Management of Radioactive Material Safety Programs at Medical Facilities
- NUREG-1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)
- NUREG-1757, Volume 1, Revision 1, Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licensees
- NUREG-1757, Volume 2, Consolidated NMSS Decommissioning Guidance, Characterization, Survey, and Determination of Radiological Criteria
- NUREG-1757, Volume 3, Consolidated NMSS Decommissioning Guidance, Financial Assurance, Record keeping, and Timeliness
- Manual Chapter 2602, Decommissioning Procedures for Fuel Cycle and Materials Licensees
- NRC Manual Chapter 2800, Materials Inspection Program

- NRC Manual Chapter 2810, Master Materials License Inspection Program
- NRC Manual Chapter 1246, Formal Qualification Programs in the Nuclear Material Safety and Safeguard Program Area
- NRC Management Directive 8.8, Management of Allegations

Chapter 1 - Organization and Responsibilities references OPNAVINST 6770.3, 10 December 1985, Navy Radiation Safety Committee (NRSC), which was part of the original license application. This document delineates the responsibilities of the NRSC members and Technical Support Center (TSC) staff.

This Chapter should contain a clear commitment that the Navy will follow NRC requirements and criteria and should contain a discussion of how the Navy will ensure that the Navy program is updated as NRC guidance changes and that staff will be trained in current NRC guidance adopted by the Navy.

There should also be a discussion of how the NRSC is involved in decision making with regard to licensing and enforcement issues. Reference should be made to the Letter of Understanding (LOU) concerning notifications to the NRC.

MMLs must have an effective inventory and accountability system, with procedures for properly transferring, controlling, and accounting for material throughout the licensee's organization. The inventory and control system should also ensure that possession limits are not exceeded. The Navy should describe its material control and accountability program. (NUREG-1156, Volume 1, Section 8.10.3 contains useful information on this topic).

Chapter 2 - Naval Radioactive Materials Permit

Appendix A -NRMP Format

Appendix B - NRC State Codes For NRMPs

Appendix C - Use Codes For NRMPs

Appendix G - NRMP Application for Medical Department Activities Form

This Chapter contains licensing timeliness goals which are double those of the NRC and indicates that the Navy tracks the timeliness of licensing actions only when the process is in the control of the reviewer. While the reviewer is waiting for information from the permittee the "clock" is stopped. Since the NRC timeliness goals are "customer service" goals contained in our operating plan rather than a regulatory requirement, the Navy may select goals appropriate to their operation. The cover letter transmitting the SOPs explains the timeliness disparity as follows, "The NRSC has a very robust review process for permits and request we exceed NRC recommended review times due to the amount of research and the additional regulations unique to the Navy and Marine Corps permits." To assure that this point is clear, this rationale should be incorporated into the SOP or repeated in the cover letter transmitting the final SOP.

Section 204.2 contains the statement that, "NRC standard review plans will be used where applicable." This statement should be clarified to say that NRC guidance and policy, such as the applicable Reg Guides and NUREGs, SS&D Registry, NRC technical

positions, etc., will be used. Also, the Navy should commit to using standard license conditions. Permit license conditions should be comparable to NRC license conditions.

This Section should contain a discussion of exemptions. Exemptions to NRC regulations may only be granted by the NRC. Submittals to the NRC for exemptions should provide sufficient information for the license reviewer to determine that the proposed exemption is authorized by law, will not endanger life, property or the common defense and security, and is otherwise in the public interest.

Section 204.3 states that, "At the conclusion of each month, the Executive Secretary will forward a summary of all inspections and permit actions for that month to the NRC." This summary should be submitted quarterly and should also delineate those inspections which resulted in a Notice of Violation and licensing actions that deal with site release or permit termination. This could be provided at the quarterly Radiation Safety Committee meeting.

Section 204.5 discusses renewals and requires the command to initiate a renewal. This Section should contain a discussion of the Navy's license tracking system and of its controls to ensure that permits are not allowed to expire and that permittees are kept current with regulations and guidance.

Section 204.9 discusses decommissioning and requires a DP to be submitted for each NRMP termination. A DP is not required in all cases. This section should be expanded to reference current NRC guidance, the Timeliness Rule, and 10 CFR 30.51 which require the permittees to keep records of the receipt, transfer, and disposal of byproduct materials. These records must be forwarded and maintained by the MML until termination of the MML.

Chapter 3 - Inspections

Appendix C - Use Codes For NRMPs

Section 301, Introduction, states that, "Inspections will be in accordance with the NRC inspection manual..." This Chapter should reference Manual Chapter 2800, Materials Inspection Program, and Manual Chapter 2602, Decommissioning Oversight and Inspection Program For Fuel Cycle Facilities and Materials Licensees. The Navy should ensure that its inspections are consistent with guidance contained in these Manual Chapters and with the program specific Inspection Procedures.

The Navy commits to performing unannounced inspections except where prior notice has to be given due to the security of the facility, to allow proper administrative process to give the inspector access to the facility. This is also clarified in the cover letter to include the statement that no more than 3 days notice is given. This is in keeping with NRC policy for sites where considerable travel is required and in practice where NRC has to gain access to secure facilities. The cover letter verbiage should be included in the SOP or in the cover letter transmitting the final SOP.

Section 302.1 talks about scheduling such that inspections may be scheduled within a window around their inspection date of 25 percent. This is consistent with NRC policy

except that inspections of priority 5 licenses may vary around their due date +/- 1 year not 25%.

Page 16, last paragraph states that, "...the inspector documents the inspection results in accordance with guidance in this and other chapters and inspection procedures." This should be clarified to identify the inspection procedures that are used. The Navy should either commit to using NRC inspection procedures or state that internal inspection procedures and checklists have been developed and are comparable to or consistent with those in NRC Manual Chapter 2800.

Section 305.4 states that, "In most cases, the NRSC does not propose escalated enforcement actions where the permittee promptly identifies and comprehensively corrects violations". This Section should be expanded to incorporate the guidance for enforcement discretion contained in Section VII of the NRC Enforcement Policy; should describe the process by which the NRSC arrives at and documents the decision to exercise discretion; and should contain a statement that the NRC will be notified when a violation that meets the criteria for escalated enforcement is identified.

This Chapter should incorporate Supplements IV, V, VI, and VII of the NRC Enforcement Policy since they apply to the Navy MML and its permittees. This may be done by referencing these Supplements.

Chapter 4 - Inspector/NRMP Reviewer Training, Qualification and Evaluation Appendix F - Inspector/NRMP Reviewer General Training Requirements

NUREG 1556, Volume 10, Section 1.2 contains the statement, "...NRC must be able to assure itself that the MML licensee's inspectors and permit reviewers are able to meet the same training requirements (Inspection Manual Chapter 1246) ...as its NRC counterparts."

Appendix F - Inspector/NRMP Reviewer General Training requires the following NRC Courses; Inspection Procedures Course (G108), Licensing Practices and Procedures Course (G109), Transportation of Radioactive Materials Course (H308 or equivalent commercially available course) and the Root Cause/Incident Investigation Workshop (G205) or equivalent.

It goes on to state that other courses "shall be considered" as applicable to the TSC's mission, such as the Safety Aspects of Industrial Radiography Course (H-305), Diagnostic and Therapeutic Nuclear Medicine Course (H-304) and Teletherapy and Brachytherapy Course (H-313).

This Chapter should be brought into parallel with NRC Manual Chapter 1246 requiring the additional Core Training: for permit reviewers: Health Physics Technology Course (H-201) and for inspectors: Health Physics Technology Course (H-201), Fundamentals of Inspection (G-101) or Inspection Procedures Course (G-108), and Inspecting for Performance Course - Materials Version (G-304).

Technology-specific training should be required for reviewers and inspectors that will be involved in that type of permit/inspection activity. The following courses should be

required for inspectors/reviewers involved in decommissioning activities: Multi-Agency radiation Survey and Site Investigation Manual (MARSSIM) Course (H-121) and Environmental Monitoring for Radioactivity Course (H-111).

Section 402.3 (3) allows for, "An explanation of proposed exceptions or alternatives to the TSC's core requirements based on the prior knowledge and experience of the candidate." Exceptions are allowed by Manual Chapter 1246 but approval must be granted by upper management. This Chapter should include a discussion of the Navy's upper management review of such exceptions.

Chapter 5 - Communication With The NRC

Appendix D - NRMP Reporting Requirements

This Chapter requires communication with the NRC only by the NRSC Chairman or designated representatives on policy matters or the TSCs for administrative or technical matters and requires the Executive Secretary to be apprised of these communications.

This Chapter should be clarified to state that official communication dealing with MML matters should only be undertaken by authorized individuals but not to preclude any other communication with the NRC.

Chapter 6 - Required Meetings Of The NRSC

Section 601 requires a quorum of one-half of the NRSC voting membership. NUREG-1556, Volume 10, Section 3.10.8 calls for two-thirds of the voting membership to include the Chairman and the Radiation Control Program Director. The reference to Region II in this Section may be deleted.

Chapter 7 - Emergency Procedures

There are no comments on this Chapter.

Chapter 8 - Allegations

Appendix E - Allegation Background Information Sheet

Additional aspects of the NRC Allegation Program should be incorporated into this Chapter:

NRC Form 3 is the mechanism for informing licensee staff of their rights to contact the NRC with safety concerns and the method by which contact information is disseminated. Additionally, training is required to be provided to licensee staff on their rights and NRC staff on their responsibilities. The Navy should discuss their method of communicating contact information to permittee staff (the Navy's Form 3 equivalent) and commit to provide training to permittee staff on their rights; and initial and annual training to MML staff and TSC staff on receiving and handling allegations.

This Section should also contain a discussion of how allegations concerning TSC staff or permittee employee wrongdoing are handled. Where is this type of allegation referred? What are the Navy equivalents of the NRC's Office of Investigations, which

investigates possible wrongdoing by licensee staff; and Office of the Inspector General, which investigates possible wrongdoing by the NRC staff?

This Section should be expanded to say that follow up by TSC staff will address not only the particular allegation, but the overall area of concern, including the potential for generic implications and wrongdoing.

In discussing the protection of an alleged's identity, the Navy should include a policy that TSC inspectors will not advise a permittee that an inspection is based on an allegation.

Chapter 9 - Waste Management and Reduction

This Chapter should be expanded to include all references to waste management contained in 10 CFR Part 20, for example 10 CFR 20.2001, 2002, 2003, 2004, 2005, 2006, 2007, and 2108.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Please submit your Standard Operating Procedures Manual within 30 days of the date of this letter specifically requesting an amendment to your master Materials License to replace the existing Manual. Please reply to my attention at the Region I Office and refer to Mail Control No. 137766. If you have any technical questions regarding this deficiency letter, please call me at (864) 427-1032.

Sincerely,

Original signed by John D. Kinneman

Orysia Masnyk Bailey
Health Physicist
Materials Security and Industrial Branch
Division of Nuclear Materials Safety

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