DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, DC 20350-2000

IN REPLY REFER TO

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23 November 2004

From: Chairman, Naval Radiation Safety Committee
To: Distribution

Subj: NAVAL RADIATION SAFETY COMMITTEE (NRSC) BULLETIN 2004-03: NOTIFICATIONS AND REPORTS FOR REPORTABLE EVENTS

Ref: (a) OPNAVINST 6470.3 series
(b) Title 10, Code of Federal Regulations (CFR), Part 20 and Part 35
(c) NUREG-1556, Consolidated Guidance About Material Licenses, Volume 9, Program-Specific Guidance About Medical Use Licenses
(d) NAVENVIRHLTHCEN Information Notice 2002-01, 6470 Ser OEM/00665 of 22 May 02

Encl: (1) NRMP Reporting Requirements

1. This information notice is issued to remind Permittees of the Navy's reporting and notification procedures in accordance with the Naval Master Materials Licensing (MML) Program requirements as stipulated in reference (a). Specific requirements for reporting can also be found in references (b) and (c).

2. Reference (d) is hereby superceded.

3. Direct communication with the Nuclear Regulatory Commission (NRC) will be conducted only by the Chairman of the Naval Radiation Safety Committee (NRSC) or the designated representative on policy matters and reportable events, or by the Technical Support Centers (TSC) for administrative and technical matters. The Executive Secretary (N455) is the designated NRSC representative. The Navy Environmental Health Center (NAVENVIRHLTHCEN) is the TSC for medical and research Naval Radioactive Material Permit (NRMP) programs.

4. All reportable events should be reported to the NAVENVIRHLTHCEN Radiation Health Team Leader at DSN: 377-0766/0767/0768 or (757) 953-0766/0767/0768. For after hours or on weekends, the Radiation Health Team Leader can be contacted by cell phone at (757) 651-2814, or via the Command Duty Officer

(CDO) at NAVENVIRHLTHCEN at (757) 621-1967. For situations requiring immediate telephone notification and when the Radiation Health Team cannot be reached, Radiation Safety Officers are directed to contact either the Naval Radiation Safety Committee BUMED representative (M3F7) at the Bureau of Medicine and Surgery at DSN: 762-3447, Commercial (202) 762-3447, Cell (202) 445-0940 or the Executive Secretary of the Naval Radiation Safety Committee (OPNAV N455) at DSN 332-5365, Commercial (703) 602-5365. If any of the above individuals cannot be contacted for whatever reason, leave a message and continue to make every attempt to notify them as required.

5. The Radiation Safety Officers shall ensure that their Radiation Safety Committees (RSC) and NRMP radiation workers (i.e., radiation safety personnel, authorized users, nuclear medicine technicians, physicists, etc.) are briefed on this Bulletin, and reporting criteria and notification procedures as stipulated in their NRMP. Verification of this briefing will be made during subsequent NAVENVIRHLTHCEN inspections of NRMP programs.

6. Typical situations and requirements for notifications and/or reports are appended as Enclosure (1). Note that this list is not inclusive, and there may be other situations in which you may be required to make notifications and/or reports. In addition, if it is unclear as to whether or not to make a notification, contact NAVENVIRHLTHCEN to discuss the issue and determine if a formal notification is required.

7. Note that NAVENVIRHLTHCEN shall be notified as soon as practicable to allow adequate time for the NRSC to prepare and make official notification to the NRC. In addition, trigger level timelines for notification to NAVENVIRHLTHCEN are much shorter than for notification to the NRC. This is required for the Radiation Health Team at NAVENVIRHLTHCEN to properly evaluate each incident, to identify potential radiation safety risks to workers and members of the public, and to take appropriate actions to minimize the chance of future incidents throughout the NRMP Program.

8. 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.

9. For additional information, please contact the Radiation Health Team Leader, LCDR Brian D. Pomije at NAVENVIRHLTHCEN at DSN 377-0766 or (757) 953-0766, facsimile (757) 953-0685 or by e-mail at pomijeb@nehc.med.navy.mil.

L. L. FRAGOSO
By direction

Distribution:
All Medical and Medical Research NRMP holders

Copy to:
BUMED (M3F71)
NAVENVIRHLTHCEN, Portsmouth, VA

NRMP Reporting Requirements

(Notifications will be made to NAVENVIRHLTHCEN and NOT directly to the Nuclear Regulatory Commission (NRC))

Event (*NOT Limited to the Following*)	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Medical Event (1) (i) The total dose delivered differs from the prescribed dose by 20 percent or more;	Immediate to NEHC (1 day to NRC)	10 days to NEHC, at their request (15 days to NRC)	10 CFR 35.3045(a)(1)
(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more **[Note: Criteria (i) & (iii) above also apply to Linac-based external beam therapy]**	*To NRC: if any of the conditions in the column on the left are applicable, and a dose differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin* ***[Note: Linac-based Medical Events are not reportable to the NRC]***		
Medical Event (2) (i) An administration of a wrong radioactive drug containing byproduct material; (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration; (iii) An administration of a dose or dosage to the wrong individual or human research subject; (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or (v) A leaking sealed source	Immediate to NEHC (1 day to NRC)	10 days to NEHC, at their request (15 days to NRC)	10 CFR 35.3045(a)(2)
	To NRC: if any of the conditions in the column on the left are applicable, and a dose exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin		
Medical Event (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive	Immediate to NEHC (1 day to NRC)	10 days to NEHC (15 days to NRC)	10 CFR 35.3045(a)(3)
Medical Event (4) A permittee shall report any event resulting from intervention of a patient or human research subject in which the administration of	Immediate to NEHC (1 day to NRC)	10 days to NEHC (15 days to NRC)	10 CFR 35.3045(b)

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Event (*NOT Limited to the Following*)	Telephone Notification	Written Report	Regulatory Requirement
byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician			
Dose to embryo/fetus or nursing child (1) A permittee shall report any dose to an embryo/fetus that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user	Immediate to NEHC (1 day to NRC) *To NRC: only if the dose to an embryo/fetus is greater than 50 mSv (5 rem) dose equivalent*	10 days to NEHC, at their request (15 days to NRC)	10 CFR 35.3047(a)
Dose to embryo/fetus or nursing child (2) A permittee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual	Immediate to NEHC (1 day to NRC) *To NRC: only if the dose to a nursing child is greater than 50 mSv (5 rem) total effective dose equivalent; or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician*	10 days to NEHC, at their request (15 days to NRC)	10 CFR 35.3047(b)
Any stolen, lost, or missing radioactive material	Immediate to NEHC *To NRC immediately: only if the permitted material was in an aggregate quantity ≥ 1,000 times the quantity specified in Appendix C to part 20 under such circumstances that it appears to the permittee that an exposure could result to persons in unrestricted areas; or* *To NRC within 30 days: only if the permitted material was in a quantity >10 times the quantity specified in Appendix C to part 20 that is still missing at this time* *(30 day written report to NRC)*	20 days to NEHC, at their request	10 CFR 20.2201(a)(1)(i)

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Event (*NOT Limited to the Following*)	Telephone Notification	Written Report	Regulatory Requirement
Receiving and opening packages: if removable surface contamination exceeds the limits of 10 CFR 71.87(i); or external radiation levels exceed the limits of 10 CFR 71.47	Immediate to NEHC and NRC (*also notify final delivery carrier immediately*)	20 days to NEHC (30 days to NRC)	10 CFR 20.1906
Any event involving radioactive material possessed by the permittee, that may have caused an individual to receive a whole body dose greater than 0.05 Sv (5 rem)	Immediate to NEHC	20 days to NEHC, at their request	10 CFR 20.2202(a)(1)(i); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(i); 10 CFR 20.2203(a)(1)
	To NRC immediately: a whole body dose greater than 0.25 Sv (25 rem); or *To NRC within 24 hours: a whole body dose greater than 0.05 Sv (5 rem) received in 24 hours* *(30 day written report to NRC)*		
Any event involving radioactive material possessed by the permittee, that may have caused an individual to receive a lens dose equivalent greater than 0.15 Sv (15 rem)	Immediate to NEHC	20 days to NEHC, at their request	10 CFR 20.2202(a)(1)(ii); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(ii); 10 CFR 20.2203(a)(1)
	To NRC immediately: a lens dose equivalent greater than 0.75 Sv (75 rem); or *To NRC within 24 hours: a lens dose equivalent greater than 0.15 Sv (15 rem) received in 24 hours* *(30 day written report to NRC)*		
Any event involving radioactive material possessed by the permittee, that may have caused an individual to receive an extremity dose greater than 0.5 Sv (50 rem)	Immediate to NEHC	20 days to NEHC, at their request	10 CFR 20.2202(a)(1)(iii); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(1)(iii); 10 CFR 20.2203(a)(1)
	To NRC immediately: an extremity dose greater than 2.5 Sv (250 rem); or *To NRC within 24 hours: an extremity dose greater than 0.5 Sv (50 rem) received in 24 hours* *(30 day written report to NRC)*		
Any release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received any intake	Immediate to NEHC	20 days to NEHC, at their request	10 CFR 20.2202(a)(2); 10 CFR 20.2203(a) 10 CFR 20.2202(b)(2); 10 CFR 20.2203(a)(1)
	To NRC immediately: a release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake; or		

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Event (*NOT Limited to the Following*)	Telephone Notification	Written Report	Regulatory Requirement
	To NRC within 24 hours: a release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake *(30 day written report to NRC)*		
Doses in excess of any of the following: (i) The occupational dose limits for adults in 10 CFR 20.1201; or (ii) The occupational dose limits for a minor in 10 CFR 20.1207; or (iii) The limits for an embryo/fetus of a declared pregnant woman in 10 CFR 20.1208; or (iv) The limits for an individual member of the public in 10 CFR 20.1301; or (v) Any applicable limit in the permit; (vi) The ALARA constraints for air emissions established under 10 CFR 20.1101(d)	Immediate to NEHC (See 10 CFR 20.2202)	20 days to NEHC (30 days to NRC)	10 CFR 20.2203(a)(2)
	To NRC: in addition to the notifications required by 10 CFR 20.2202, each permittee shall submit a written report within 30 days after learning of any of the occurrences in the 1st column		
Levels of radiation or concentrations of radioactive material in: (i) A restricted area in excess of any applicable limit in the permit; or (ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the permit (whether or not involving exposure of any individual in excess of the limits in 10 CFR 20.1301)	Immediate to NEHC (See 10 CFR 20.2202)	20 days to NEHC (30 days to NRC)	10 CFR 20.2203(a)(3)
	To NRC: in addition to the notifications required by 10 CFR 20.2202, each permittee shall submit a written report within 30 days after learning of any of the occurrences in the 1st column		
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate to NEHC and NRC	20 days to NEHC (30 days to NRC)	10 CFR 30.50(a)

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Event (***NOT Limited to the Following***)	**Telephone Notification**	**Written Report**	**Regulatory Requirement**
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	Immediate to NEHC (24 hours to NRC)	20 days to NEHC (30 days to NRC)	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any permitted material or device, container, or equipment with permitted material	Immediate to NEHC (24 hours to NRC)	20 days to NEHC (30 days to NRC)	10 CFR 30.50(b)(4)
Defect in equipment that could create a substantial safety hazard	Next day to NEHC (2 days to NRC)	20 days to NEHC (30 days to NRC)	10 CFR 21.21(d)(3)(i)
Leaking source: leak testing reveals presence of 0.005 microcuries or more of removable contamination	Next day to NEHC (none to NRC)	3 days to NEHC (5 days to NRC)	10 CFR 35.3067
Planned special exposures	1 week to NEHC (none to NRC)	20 days to NEHC (30 days to NRC)	10 CFR 20.2204
Report to individuals of exceeding dose limits	1 week to NEHC (none to NRC)	20 days to NEHC (30 days to NRC)	10 CFR 20.2205
Report of individual monitoring	none	annually	10 CFR 20.2206