



DEPARTMENT OF THE NAVY

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

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Ser OMSJW/ 02952

20 NOV 1995

From: Commanding Officer, Navy Environmental Health Center

Subj: NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM
INFORMATION NOTICE 95-0910

Encl: (1) U. S. Nuclear Regulatory Commission Information
Notice 95-51: Recent incidents involving potential
loss of control of licensed material
(2) List of 1995 NAVENVIRHLTHCEN Information Notices
Pertaining to the NRMP Program

1. I am forwarding enclosure (1) for your information. Please review this information for applicability to your operations and distribute it to appropriate staff.

2. Enclosure (2) is a list of all previous NRMP Information Notices issued by Navy Environmental Health Center (NAVENVIRHLTHCEN) during calendar year 1995. Copies of letters listed in this enclosure are available from NAVENVIRHLTHCEN.

3. You may contact LCDR S. J. Wolff, MSC, USN for more information at DSN 864-5575 or (804)363-5575.

S. J. Wolff
S. J. WOLFF
By direction

DISTRIBUTION:

NATNAVMEDCEN Bethesda MD
(ATTN: CDR L. F. Parr, MSC, USN)

NAVMEDECEN Oakland CA
(ATTN: LCDR D. J. Shumaker, MSC, USN)

NAVMEDECEN Portsmouth VA
(ATTN: LCDR S. Kirtland, MSC, USN)
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(ATTN: LCDR D. J. Dunn, MSC, USN)

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NAVHOSP Camp Pendleton CA
(ATTN: LCDR C. J. Scialdone, MC, USN)
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NAVDRUGLAB Great Lakes IL
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NAVENVIRHLTHCEN DET Bethesda MD
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(ATTN: LT S. L. Gaiter, MSC, USN)
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(LT P. S. Son, MSC, USN)
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(LCDR M. M. D'Alesandro, MSC, USN)
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(ATTN: Mr. H. E. Morton)
NAVAEROMEDRSCHLAB Pensacola FL
(ATTN: LTJG S. C. Hecht, MSC, USN)
NAVMEDRSCHU TWO Jakarta ID
NAVMEDRSCHU THREE Cairo EG
NAVMEDRSCHINSTITUTE DET Lima PE
NAVENPVNTMEDU TWO Norfolk VA
(ATTN: CIHL)
NAVENPVNTMEDU FIVE San Diego CA
(ATTN: CIHL Mare Island)
(ATTN: CIHL San Diego)
NAVENPVNTMEDU SIX Pearl Harbor HI
(ATTN: CIHL)

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

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555-0001

October 27, 1995

NRC INFORMATION NOTICE 95-51: RECENT INCIDENTS INVOLVING POTENTIAL LOSS OF CONTROL OF LICENSED MATERIAL

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to alert addressees to two recent incidents involving potential loss of control of licensed material, resulting in internal contamination of individuals. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

Recently, NRC was informed of and responded to two incidents involving phosphorus-32 (P-32) internal contamination of individuals at biomedical research facilities. P-32 is widely used in research institutions, as are many other radionuclides. Although these incidents both involved P-32, the inherent security issues extend to all facilities using licensed material.

Case 1: On June 30, 1995, a licensee informed NRC that an incident involving internal contamination of a female researcher had been reported to the licensee's radiation safety office the previous evening. The researcher was in her fourth month of pregnancy at the time of the incident. Contamination was detected when the researcher's husband, who worked with her at the licensee's facility, performed a routine survey of their lab. The licensee identified the radionuclide as P-32. Accidental contamination appeared unlikely because the woman had stopped working with radioactive material in their lab about a month before, and because the radioisotope (P-32) identified in bioassay samples is not of the same type her lab used. Licensee security officials and the Federal Bureau of Investigation are investigating the possibility that the woman ingested food or liquids deliberately contaminated with the radioisotope. Initial calculations (now being refined by NRC, the licensee, and the researcher's own technical experts) estimated that the researcher ingested tens of megabecquerels (hundreds of microcuries) of P-32.

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Subsequent licensee surveys identified a few droplets of P-32 on the floor in front of a refrigerator in a lounge adjacent to labs the couple use and an internally contaminated water cooler in the same building. Urine bioassays of other workers identified approximately 25 additional individuals who have low-level internal P-32 contamination. In early July 1995, NRC sent an Augmented Inspection Team to investigate the circumstances surrounding the contamination incident. While the inspection and investigations are ongoing, NRC has obtained licensee agreement to improve the control of radioactive materials used in its biological and medical research programs.

Case 2: On October 16, 1995, a licensee informed NRC that an incident involving internal contamination of a researcher had occurred at its facility almost 2 months earlier. Licensee officials told NRC staff that they had not reported the incident earlier because their analyses suggest that the researcher's internal dose was below the 10 CFR Part 20 reporting criteria.

According to the licensee, the researcher discovered that he was contaminated during a routine survey of his work area. Also according to the licensee, it subsequently detected P-32 contamination on an item of clothing that the researcher had worn earlier that week, when he had last handled P-32 in the laboratory. The licensee performed urine bioassays, and informed the researcher that he may have ingested what was described as a drop of P-32 containing 21.4 megabecquerel (579 microcuries). The researcher has told licensee campus police that he believes the contamination was not accidental. NRC and campus police are investigating his allegation. Also, the researcher has requested that an independent consultant prepare a second dose estimate.

The licensee initially secured all radioactive materials in the lab after discovery of the contamination event. Since then, the licensee has permitted work with radioactive material to resume, after requiring more stringent inventory and accountability in the lab and tightening security. On October 17, 1995, NRC dispatched an Incident Investigation Team to the licensee's site to begin an immediate investigation of the incident. NRC also sent a letter to the licensee requiring that certain steps be taken, ensuring among other things that control of radioisotopes is adequate to provide reasonable assurance against another such incident. NRC's investigation is ongoing.

Discussion

The two recent P-32 internal contamination incidents raise a number of safety and regulatory issues. NRC is reviewing its regulations to determine if they need to be revised in light of these events. Among these issues are radioactive material security and accountability, survey procedures, preparation for bioassays, and reporting requirements. Each of these issues is addressed separately below.

- a. Security. In controlled or unrestricted areas, licensees are required by 10 CFR 20.1801 and 20.1802 to secure stored material, and to control and maintain, under constant surveillance, licensed material that is not in storage. Access to restricted areas is required to be controlled to prevent unauthorized access to licensed material. Licensees should review their programs to ensure that they have a radiation safety program in place that will prevent deliberate misuse of radioactive materials in all licensee areas.
- b. Accountability. 10 CFR Part 20 requires the reporting of theft or loss of materials above defined levels. In addition, the Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope," published for comment in October 1994, states that license applicants:

... should develop and maintain a strong inventory and accountability system. The institution should have the capability to continually track incoming shipments of licensed material and account for material usage, decay, transfer, and disposal. A licensee's inventory and control system should have the capability to ensure that licensed possession limits are not exceeded and that material is accounted for throughout the institution at any given time.

In light of these events, licensees should review their programs to determine whether they need to improve their radioactive material accountability systems, commensurate with the scope of their programs.

- c. Detecting licensed material. NRC emphasizes that conducting surveys with adequate, calibrated equipment is a crucial step in conducting safe operations. Many commercially available survey instruments, such as Geiger-Mueller detectors, are capable of detecting P-32, even after ingestion, in the activity range used in research facilities. In both of these cases, internal contamination was originally detected when the researchers conducted routine surveys of their laboratories and detected high background readings. Licensees should review their programs to ensure that they are conducting surveys with adequate, calibrated equipment.

- d. Bioassay preparation. All licensees are responsible for responding to incidents. Some licensees already have bioassay programs in place to comply with the requirement in 10 CFR 20.1502 to monitor workers whose intake is likely to exceed 10 percent of the occupational dose limits. Interpretation of bioassay data, when regulatory thresholds are approached, may be difficult. Important information on the proper conduct of a bioassay program is provided in Regulatory Guide 8.9, Rev. 1, July 1993, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program" and NUREG/CR-4884, "Interpretation of Bioassay Measurements." Licensees that need immediate medical consultation to respond to an ongoing internal contamination event can contact the Radiation Emergency Assistance Center/Training Site (REAC/TS), which is funded by the U.S. Department of Energy to provide consultation in such situations. The NRC Operations Center can connect callers with REAC/TS.

If internal contamination is detected, health physics consultants are commercially available to assist with bioassay and other response measures. However, licensees that plan to use consultants may want to identify and make arrangements for those resources now, rather than wait until an incident occurs. Licensees that need help in identifying health physics services should contact professional societies or organizations for references.

- e. Food and beverage storage. Generally, licensees have procedures prohibiting eating, drinking, and smoking in radiologically restricted areas. In light of these events, licensees should review their programs to determine how food, particularly lunches, snack foods, and beverages in unsealed containers, are permitted or stored in their facilities.
- f. Contact NRC if deliberate misuse of licensed material is suspected. NRC considers deliberate misuse of licensed material to be of significant regulatory interest, and expects to be contacted in such situations. Although the magnitude of the dose could be within NRC's regulatory limits, the possibility that such a dose was delivered intentionally, and possibly with malice, raises concerns about a licensee's, a contractor's, or any employee's deliberate misconduct, as addressed in 10 CFR 30.10, 40.10, 70.10, and 72.12. In addition, pursuant to 10 CFR 30.9(b), 40.9(b), 70.9(b), and 72.11(b), each licensee is required to "... notify the Commission of information identified ... as having for the regulated activity a significant implication for public health and safety" Notification shall be provided in such cases to the Regional Administrator within 2 working days.

The issues raised in these two cases should lead licensees to consider reexamining their own methods to prevent and, if necessary, respond to internal contamination incidents.

The information in this notice is preliminary, and the investigations and inspections in these two cases are ongoing. NRC may issue further guidance, as necessary, once results are known and conclusions drawn on these two cases.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact the technical contacts listed below or the appropriate regional office.



Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Scott Moore, NMSS
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Attachments:

1. List of Emergency Contacts
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

1995
NAVENVIRHLTHCEN INFORMATION NOTICES
NAVY RADIOACTIVE MATERIALS PERMIT PROGRAM

- 95-01: NAVENVIRHLTHCEN ltr 6470 Ser 312/00087 of 17 Jan 95
Brachytherapy misadministration and QMP
Distributed to medical treatment facilities only
- 95-02: NAVENVIRHLTHCEN ltr 6470 Ser 31/00613 of 23 Feb 95
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 6470 Ser 31/00655 of 26 Feb 95
Draft regulatory guides
Distributed to non-hospitals only
- 95-04: NAVENVIRHLTHCEN ltr 6470 Ser OMSJR/01104 of 25 Apr 95
Quality Management Program clarification
Section 206 posting requirement
New NRMP application form
Guidelines for preparation of NRMP application
Distributed to medical treatment facilities only
- 95-05: NAVENVIRHLTHCEN ltr 6470 Ser OMSJR/01191 of 28 Apr 95
Section 206 posting requirement
New NRMP application form
Distributed to Navy Drug Screening Labs only
- 95-06: NAVENVIRHLTHCEN ltr 6470 Ser OMSJR/01199 of 01 May 95
Section 206 posting requirements
New NRMP application form
Distributed to research facilities only
- 95-06: Should have been number 95-07
NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/02549 of 15 Sep 95
New NAVENVIRHLTHCEN telephone numbers
Distributed to all medical department NRMP holders
- 95-08: NAVENVIRHLTHCEN ltr 6470 Ser OMSJW/02643 of 02 Oct 95
New NRC Form 3 for posting
Distributed to all medical department NRMP holders

Enclosure (2)