UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

Report No.: 45-23645-01NA/93-24

Licensee: Department of the Navy

Docket No.: 030-29462 License No.: 45-23645-01NA

Inspection Conducted: October 28-29 and December 3, 1993

Inspector: _____ 1/6/94
Jerry D. Ennis, Health Physicist Date Signed
Nuclear Materials Inspection Section

Approved by: _____ 1/6/94
Charles M. Hosey, Chief Date Signed
Nuclear Materials Inspection Section
Nuclear Materials Safety and Safeguards Branch
Division of Radiation Safety and Safeguards

SUMMARY

This special, announced inspection was performed to review the circumstances and events surrounding a phosphorus-32 contamination event at the Naval Medical Research Institute's Rockville Annex (NMRI Annex), Rockville, Maryland and to evaluate the licensee's decontamination actions.

Results:

A violation was identified concerning the use of licensed byproduct material by an individual who had not been approved for such use by the NMRI Radiation Safety Committee (paragraph 3).

REPORT DETAILS

1. PERSONS CONTACTED

Licensee Personnel

Dr. J.C. Agular, Researcher, Naval Medical Research Institute Annex (NMRI-Annex), Rockville, MD
Dr. D. Doolan, Researcher, NMRI-Annex
Dr. S. French, Researcher, NMRI-Annex
CDR R. Hedstrom, Laboratory Supervisor, NMRI-Annex
*CDR T. M. Hickey, NMRI, Bethesda, MD
LCDR G. A. Higgins, Radiation Safety Officer (RSO), National Naval Medical Center (NNMC), Bethesda, MD.
CAPT S. L. Hoffman, Director, Malaria Program, NMRI-Annex
***LT B. K. Holland, RSO, NMRI
CDR R. L. LaFontaine, Head, Physics and Radiation Safety Division, NNMC
**CAPT J. Malinoski, Executive Secretary, Navy Radiation Safety Committee
CAPT K. G. Mendenhall, Bureau of Medicine and Surgery
***CAPT R. G. Walter, Commanding Officer, NMRI

* Attended exit interview on October 29, 1993.
** Participated in telephonic exit interview on December 3, 1993
*** Participated in October 29, 1993 and December 3, 1993, exit interviews.

2. CIRCUMSTANCES SURROUNDING THE CONTAMINATION EVENT (83822)

a. This special, announced inspection was conducted on October 28-29, 1993, and December 3, 1993, to ascertain the circumstances surrounding a phosphorus-32 (P-32) contamination event which occurred on October 7, 1993, at the NMRI-Annex, 12300 Washington Street, Rockville, MD. The NMRI-Annex possesses and uses radioactive material under Navy Radioactive Materials Permit (NRMP) 19-64223-41NP, which authorizes, in addition to other material, possession of up to 200 millicuries (mCi) of P-32 in any chemical or physical form for the purposes of laboratory research. Condition 11 of the Permit authorizes use of radioactive material at the NMRI-Annex.

b. Through discussions with license representatives and researchers and review of licensee records and procedures the inspector determined the following:

On October 5, 1993, the NMRI-Annex received their standing order of 250 microcuries (μCi) of "alpha P-32" and 250 μCi of"gamma P-32." The two containers were placed in storage in an unlocked refrigerator in Room 220 of the NMRI-Annex building.

On the morning of October 6, 1993, Researcher "A" approached the Room 220 laboratory supervisor and asked to use P-32 in an effort to identify a problem he was having in a DNA-synthesis experiment. The supervisor told "A" that he could not use P-32 in the

requested manner because "A" had not been trained in NMRI's procedures for the use of radioactive material. The supervisor did, however, instruct researcher "B", who had received radiation safety training at NMRI, to prepare the P-32 for "A's" use. Researcher "B" obtained the alpha P-32 container from the unlocked storage area and pipetted a total of 60 µCi of P-32 into six collection tubes (10 µCi of P-32 per tube) containing DNA material. These collection tubes were then turned over to "A" for his use. This was the only use of P-32 by "A" that the supervisor authorized.

Toward the end of the work day, "A" realized that, in addition to the 60 µCi of alpha P-32 material that had been pipetted for him that morning, he needed a DNA marker or standard. The individual who assisted him that morning appeared busy, so "A" went to the unlocked refrigerator in the laboratory, removed the gamma P-32 container, and extracted (pipetted) 150 µCi of material from the container. He returned the stock container and the 150 µCi of material to storage and did no further work with the gamma P-32 that day.

"A" returned to work on October 7, 1993, and approximately mid-morning began calibrating a centrifuge spin column. This involved centrifuging a small column containing a gel-filtration matrix (Sephadex) for three four-minute periods. Following completion of the calibration procedure, he placed the P-32-bearing material into the spin column and took it to the centrifuge, which was located next door to the laboratory in Room 218A (Cold Room). At the end of the centrifuging operation, approximately 135 µCi of the original 150 µCi of P-32 remained affixed to the gel (which was now a partially dehydrated resin) in the spin column and approximately 15 µCi was retrieved from the collection tube at the bottom of the spin column. "A" took "a couple of steps" from the radioactive material work station to the radioactive waste (radwaste) container and deposited the spin column and pipette tip in radwaste and returned the specimen containing approximately 15 µCi of P-32 to storage. "A" then surveyed his upper body and hands and surveyed the work area. No contamination was identified. "A" then left the laboratory for a meeting in the NMRI Annex Library (Room 208).

Researcher "A" had been at NMRI for approximately six months. When he arrived, it was not anticipated that his work would require the use of any radioactive material, so he did not receive training in NMRI's radiation safety or radioactive materials handling procedures. He had considerable experience working with radioactive materials, including P-32, at other locations. (The inspector reviewed a letter dated October 19, 1993, which verified that "A" had worked at a non-Navy, Agreement State facility, from January 1, 1989 to December 31, 1992, as a Post Doctoral Fellow. "A" was identified as a "Principle User" at the facility and was authorized to use more than one millicurie of sulphur-32,

hydrogen-3, and P-32. The licensee had requested and obtained this letter following the contamination event.)

In the afternoon of October 7, 1993, the laboratory supervisor returned to the laboratory, saw evidence that work was or had been performed at the radioactive workstation, which was adjacent to one of the laboratory's doors, and decided to survey the area. He found no contamination on the workbench. As the supervisor turned to walk to the nearby radwaste area, he dropped the survey probe (an end-window GM probe) by his side He immediately noticed an increase in the audio signal from the survey instrument. He then determined that there was contamination in several places on the floor between the workbench, the radwaste container, and the workbenches across the aisle from the radioactive workstation. The supervisor called the office of the NMRI RSO to report the event and, along with other laboratory personnel, began cleaning the area around the radioactive workstation. In the course of cleaning the area, it was discovered that the contamination was much more widespread than first believed.

Researcher "A" had no explanation for how or exactly when the contamination occurred. "A" acknowledged being told not to obtain P-32 from the storage container and admitted having done so anyway.

c. After discussions with the NMRI RSO, the senior officer at the annex decided to close the building and place personnel on administrative leave until the extent of the contamination could be determined and necessary decontamination efforts were complete.

Upon arrival of additional radiation safety support from NMRI and NNMC, screening stations were established at each of the building's two exits and personnel were surveyed before being allowed to depart. Several pairs of shoes were found to be contaminated and were retained on the premises. One person was identified as possibly having some face contamination and was decontaminated. Surveys of the possibly contaminated person showed 15 counts per minute (cpm) above background. The licensee's estimates of the dose to the skin for this individual was 2.8×10^{-6} Rads.

Licensee radiation safety personnel re-entered the building in protective clothing, performing surveys as they went. The surveys ultimately identified contamination throughout the building. No contamination was found outside the building or in the cars of persons who had been outside the building earlier on October 7, 1993, including Researcher "A's" car. The licensee did not find contamination in the building on any surfaces other than the floor.

The licensee had removed contamination where possible. Contamination that could not be removed had been fixed in place and was being allowed to decay. Concrete floors had been painted, tile floors covered with multiple coats of sealant, and carpet covered with carpet runners over plastic sheet material.

The NRSC notified NRC Region II of the contamination event on October 8, 1993.

3. INSPECTION RESULTS

The inspector performed removable contamination surveys in areas with concrete or tile floors. No removable contamination was detected.

In discussions with the licensee's RSO, the inspector determined that the specific "spin-column chromatography" research protocol which "A" was using at the time of the P-32 spill had not been approved by the NMRI Radiation Safety Committee.

On October 29, 1993, the inspector observed researcher "A" perform a reenactment of his actions of October 7, 1993 related to the calibration of and handling of a spin column. The reenactment demonstrated that the partially dehydrated gel slipped from the spin column very easily if the tube was held parallel or nearly parallel to the floor. The gel particles which fell to the floor were not easily observable. "A" stated that the tube could have been held in such a position as he leaned over to lift the lid to the radwaste container, but that he was unaware of the gel sliding from the tube, but he did not know when or how the P-32-material was spilled.

Observation of the radioactive work station in Room 220 showed it to be adjacent to one of the laboratory's three doors and on the primary walkway through the laboratory. The location of the workstation relative to the walkway appeared to facilitate the spread of contamination from the radioactive spill throughout the building.

Condition 18 to NRC License No. 45-23645-01NA requires, in part, that the licensee adhere to the provisions of the license application (the application) dated August 14, 1986.

Item 10.d of the application states, in part, that the NRSC may issue permits of broadscope to Navy commands authorizing the command's NRSC certain internal prerogatives, such as designating users of licensed material, consistent with the provisions of 10 CFR 33.13.

Use of byproduct material by a person who had not been authorized to use byproduct material by the NMRI Radiation Safety Committee under the authority delegated to NMRI by the Navy Radiation Safety Committee is an apparent violation of Condition 18 of NRC License No. 45-23645-01NA.

4. LICENSEE-CONDUCTED INSPECTION

The Naval Environmental Health Command (NEHC) conducted an inspection following the contamination event. The NEHC inspection identified the following three violations of NRMP permit conditions:

a. One investigator at the NMRI Rockville Annex was specifically directed by the authorized user for the laboratory not to pipet radioactive material but only to use prelabeled DNA. The investigator disregarded the direction and pipetted radioactive material.

b. One investigator at the NMRI Rockville Annex was allowed to use radioactive material [60 μCi of P-32] prior to receiving training on the safe use of this material.

c. One investigator at the NMRI Rockville Annex used a protocol to label and extract DNA. That protocol had not been previously used at the Rockville Annex and had not been approved by the Radiation Safety Committee.

5. EXIT INTERVIEW

An exit interview was held on October 29, 1993, with the persons indicated in paragraph one. The Commanding Officer, NMRI, was informed of the scope and results of the inspection. The licensee was also advised that the inspection results would be evaluated by NRC management and the results of that evaluation would be communicated to the licensee at a later date.

On December 3, 1993, a telephonic exit interview was held with the persons indicated in paragraph one. The licensee was informed that the use of radioactive material at the NMRI Annex by a person not authorized to use radioactive material by the NMRI Radiation Safety Committee under the authority delegated to it by the NRSC was a violation of License Condition 18 to NRC License No. 45-23645-01NA. The licensee provided the inspector with the following corrective actions which had been taken as a result of the contamination event:

a. A formal letter of reprimand has been issued to "A" and a copy of the letter has been provided to his employer for inclusion in his record. The letter also prohibits "A" from using any radioactive material for the remainder of his stay at NMRI.

b. General Radiation Safety Training will be conducted for all NMRI Annex personnel and this training will be completed by December 25, 1993.

c. A mandatory Radiation Safety training class will be conducted in January 199[illegible] for all NMRI personnel. The training class will address the following topics:

(1) Procedures for spills involving radioactive materials.

(2) Requirements for the use of radioactive materials.

(3) General precautions for working in and around spaces containing radioactive materials.

(4) Clearly define what is and is not an authorized use of radioactive materials.

d. The laboratory supervisor involved is no longer an authorized user of radioactive material at NMRI as a result of event.

e. Lock boxes are being obtained for the storage of radioactive material. Keys will be held by the senior officer at the Annex and one authorized user.

f. Any future approved protocols that utilize the Sephadex resin spin column will include warnings that the top of the column be recapped after use and prior to discarding and that the column be kept in an upright position when using or transporting.

g. A discussion of the NMRI event was included in Navy Radioactive Material Permit Program Information Notice 93-11, dated November 22, 1993, which was transmitted to all holders of medical or research radioactive material permits.