



DEPARTMENT OF THE NAVY

NAVY ENVIRONMENTAL HEALTH CENTER

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NORFOLK, VIRGINIA 23513-2617

6470

Ser 31/ 3703

JUN 02 1992

From: Commanding Officer, Navy Environmental Health Center

Subj: INFORMATION REGARDING THE NAVY RADIOACTIVE MATERIAL PERMIT PROGRAM

1. This notice discusses events involving the Radioactive Material Permit program at several Navy Medical Department activities. The events involved falsification of records and unauthorized use of radioactive material.

2. In one instance a Nuclear Medicine Technician did not actually perform a daily dose calibrator constancy check but only recorded the values from the previous day. A subsequent investigation revealed that, on occasion, results of other required radiation safety procedures, such as daily ambient dose rate surveys, may have been recorded without actually being performed. This incident showed a lack of understanding of the significance of the radiation safety program by personnel responsible for the daily operation of the program. Authorized Users and Radiation Safety Officers shall reinforce the significance of falsification of the radiation safety program records for all personnel working under their supervision. Title 10 Code of Federal Regulations Part 2 states that individuals as well as commands can be held accountable for violations of Nuclear Regulatory Commission regulations and may face criminal as well as monetary penalties.

3. Most Navy Medical Treatment Facilities that have a Navy Radioactive Material Permit (NRMP) are authorized to use radioactive material for medical use only. Medical use means the intentional internal or external administration of radioactive material or the radiation therefrom to human beings in the practice of medicine. Some Navy Medical Treatment Facilities and Medical Research Facilities are authorized to use radioactive material for medical research not involving human beings. At this time, no Navy Medical Facility is authorized to use radioactive material in/on human beings when not medically indicated. Use of radioactive material in normal human beings may only be accomplished with prior approval of the Command's Clinical Investigation Department, a Food and Drug Administration empowered Radioactive Drug Research Committee, and the Navy Radiation Safety Committee. At two Medical Treatment Facilities radioactive material was administered to human beings for purposes not medically indicated without prior approval.

a. One event involved the administration of technetium-99m MAA to a volunteer Nuclear Medicine Technician to determine if there was a breakdown in the size of the MAA particles. This was done as part of the Command's investigation of a misadministration.

b. The second event occurred when a Nuclear Medicine Technician, who had not conducted a ventilation study using a new aerosol system, performed the study on a volunteer hospital staff member to verify the procedure prior to its use on an emergent patient. These uses of radioactive material were not for medically indicated procedures and therefore were not authorized by the Command's Permit.

4. In both of the above cases an Authorized User approved the use of the radioactive material apparently without realizing that such usage was not



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authorized. Both of these incidents could have been avoided by the use of other procedures.

a. In the first case a comparison of the radiopharmaceutical usage logs with the activity and/or volume of each radiopharmaceutical would have shown that the wrong radiopharmaceutical had been injected into the patient.

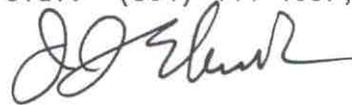
b. In the second case the Nuclear Medicine Technician could have discussed the procedure with technicians from other facilities who had used the equipment, requested to observe the procedure at another hospital in the area or initially performed the procedure on a non-emergent patient for whom the study was clinically indicated.

5. Authorized Users shall review their Permit and standard operating procedures to ensure that radioactive material is used only as authorized by the Permit. Authorized Users shall instruct all personnel working under their supervision on what usages of radioactive material are authorized under the Permit issued to the Command.

6. The Nuclear Regulatory Commission (NRC) had considered taking escalated enforcement action against the Navy as authorized in Title 10 Code of Federal Regulations Part 2 because of these events. Due to the prompt notification and prompt and comprehensive corrective actions by the Commands, and comprehensive investigations by the Navy Radiation Safety Committee, the NRC did not escalate enforcement. You shall notify this Command promptly whenever there is a problem involving your Navy Radioactive Material Permit. This notification shall be made even though the problem may not require a report to be submitted to the NRC. If there is a question as to the significance of a problem, clarification can be obtained by contacting this Command.

7. This Command shall be notified by letter or message when the training required by paragraphs two and five has been completed. This training shall be completed by 1 August 1992.

8. Point of contact is LCDR G. I. Snyder, MSC, USN, Head, Radiation Health Department (NEHC-31), DSN: 564-4657, Commercial: (804) 444-4657, Ext. 413.



J. J. EDWARDS

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