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

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From: Commanding Officer, Navy Environmental Health Center
To: Distribution List

Subj: INFORMATION REGARDING THE NAVY RADIOACTIVE MATERIAL PERMIT (NRMP) PROGRAM

Encl: (1) NRC Information Notice No. 91-71: Training and Supervision of Individuals Supervised by an Authorized User

1. Enclosure (1) is forwarded for review by your Radiation Safety Officer, Radiation Safety Committee, and Authorized Users.

2. Enclosure (1) addresses the regulatory requirements of 10 CFR Part 35, Section 35.25, for supervision of individuals who use radioactive material under the supervision of an authorized user. This includes technologists, physician assistants, residents, and other medical personnel who are permitted to use radioactive material under the supervision of an authorized user. Examples are provided of recent cases where inadequate instruction and/or supervision were major factors leading to misadministration or license violations.

3. You should review the regulations of 10 CFR Part 35.25 and the guidance of enclosure (1) to ensure that your command directives and procedures adequately address staff instruction and supervision to preclude events similar to the ones described in enclosure (1) from occurring.

4. Point of contact on this subject is Mr. P. D. Tveten, Radiation Health Department (NEHC-312), AUTOVON: 564-4657 or Commercial: (804) 444-4657, Ext 227.

G. I. Snyder

G. I. SNYDER
By direction

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

November 12, 1991

NRC INFORMATION NOTICE 91-71: TRAINING AND SUPERVISION OF INDIVIDUALS SUPERVISED BY AN AUTHORIZED USER

Addressees

All U.S. Nuclear Regulatory Commission (NRC) medical licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to remind licensees of the importance of providing adequate instruction and supervision to individuals working under the supervision of an authorized user. Supervised individuals who infrequently use radioactive materials, such as part-time or cross-trained technologists, and technologists whose services are used under contract of a temporary employment service are of particular concern. It is expected that licensees will review this information for applicability to their own procedures, distribute this notice to those responsible for radiation safety, all authorized users, and facility management, and consider actions, as appropriate, to preclude situations similar to the ones described in this notice from occurring at their facilities. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action or written response is required.

Description of Circumstances

Reports received by NRC of recent events that led to misadministrations or violations indicate that some licensees are not providing individuals working under the supervision of authorized users with adequate instruction or supervision. In the six recent cases described below, lack of adequate instruction and/or supervision were major contributing factors that led to: (1) a significant diagnostic misadministration by a cross-trained technologist; (2) the alteration of patient nuclear medicine films and significant violations of NRC requirements by a contract temporary technologist; (3) unauthorized transfer of radioactive material to a patient and nearby facility; (4) a significant therapy misadministration during a brachytherapy implant and unnecessary extremity exposure to a nurse's hands; (5) a diagnostic misadministration of iodine-131; and (6) failure of the licensee to have a trained operator present present during patient treatment on a High Dose Rate (HDR) Afterloader on two occasions.

Case 1: An X-ray technologist, cross-trained to perform emergency nuclear medicine scans on an on-call basis, erroneously prepared and administered approximately 175 millicuries of a technetium-99m labeled radiopharmaceutical

instead of the prescribed dosage of 8 millicuries. This misadministration resulted in the patient receiving excess dose for an estimated whole body dose of 3 rad and an estimated bladder dose of 36 rad.

NRC inspection of events surrounding the misadministration revealed that the X-ray technologist had not been adequately trained by the licensee. Specifically, the technologist was not familiar with the correct procedures for generator elution or the preparation of the radiopharmaceutical, nor was the individual familiar with any of the procedures established by the Radiation Safety Officer (RSO) or authorized users, or applicable NRC regulations governing the facility's operations. Further review of this case also revealed that the licensee, through the RSO, was not exercising effective oversight of the medical use program.

Case 2: A nuclear medicine technologist, on temporary assignment from a contracted medical personnel service, apparently presented fraudulent nuclear medicine films for physician interpretation. An investigation performed by the licensee revealed that the films presented for interpretation were films from patients previously imaged at the hospital. The licensee's conclusion was based upon two observations: 1) the names of previously imaged patients appeared to be partially erased on the films and covered up by the names of patients scheduled to be imaged by the contract technologist; and 2) some of the films the licensee had reviewed had computer generated patient names that were different from the names of the scheduled patients. The prescribed dosages or radiopharmaceuticals actually administered to those patients cannot be determined due to poor recordkeeping. The licensee had not familiarized the contract technologist with the instructions of the supervising authorized users, procedures established by the RSO, and NRC regulations and license requirements. Also, the licensee did not provide adequate supervision of the contract employee's activities to ensure that proper radiopharmaceuticals were ordered, received, administered, and disposed of. The licensee relied heavily on the individual's credentials, including professional certifications by technologist registries and a favorable employment history.

Case 3: A physician requested an X-ray technologist, cross-trained to perform emergency nuclear medicine scans on an on-call basis, to perform a patient lung scan. The technologist incorrectly prepared the technetium-99m labeled radiopharmaceutical and infiltrated the patient dosage. As a result of these mistakes and the patient's medical condition, the primary care physician decided to consult with a nearby facility to see if that facility could perform the procedure. The X-ray technologist transferred a vial of technetium-99m to the patient's spouse for transport to the nearby hospital since that facility did not have a sufficient amount of technetium-99m but did have the radiopharmaceutical kit available. Upon arrival at the nearby hospital, radiation surveys indicated that contamination was present on both the patient, the patient's spouse, and the lead shield. A survey of the patient's automobile did not detect radiation levels above background.

After notification by both hospitals, the NRC performed an inspection of the licensee responsible for the unauthorized transfer of radioactive material. The inspection revealed a number of violations associated with this incident, including the failure to record the results of radiation and contamination

surveys, and to prepare shipping papers. The licensee had failed to adequately instruct the cross-trained technologist to perform nuclear medicine procedures. In addition, if the technologist had been adequately supervised during the training period, it might have become apparent that the technologist was not capable of performing these procedures independently.

Case 4: A catheter containing iridium-192 seeds encased in ribbon was inserted through a patient's nasal cavity. According to a representative of the nursing staff, the catheter appeared to be in place at the time of implant. Subsequently, during the 11 p.m. to 7 a.m. shift, a second nurse noted that the implanted catheter was located outside of the patient's nose at approximately 12 midnight and 2 a.m. Not recognizing that the radioactive seeds were located within the dislodged portion of the catheter, she handled it with her bare hands and taped it to the patient's face. This resulted in a misadministration with a significant dose contribution to the patient's face, and unnecessary radiation exposure to the nurse's hands. At approximately 5 a.m., another nurse removed the ribbon from the patient's face and placed it in a lead container in the patient's room. The RSO and radiation oncologist were notified, the catheter was reimplanted and the treatment continued as prescribed. NRC inspection revealed that the individual nurse assigned to care for the brachytherapy implant patient on the midnight shift had not been adequately trained in radiation safety precautions associated with implant patient care.

Case 5: A 37 year old female patient, 2 days post partum, was administered 5.0 millicuries iodine-131 instead of the intended dosage of 50 microcuries iodine-131. The patient was diagnosed to have a mediastinal mass and was referred for a thyroid scan to rule out a possible substernal goiter. In this medical facility, this procedure normally involves a dosage of 50 microcuries iodine-131. The Physician's Assistant (PA), who is permitted by the licensee to write orders for procedures at the request of a physician, gave the order for the scan to the floor nurse for processing. The floor nurse placed the order with the Nuclear Medicine department. The nuclear medicine technologist contacted the PA to arrange a time for the scan. During this conversation, the appropriateness of the study ordered was questioned by the technologist based on the patient information supplied by the PA. The PA agreed to change the order from a thyroid scan, which required a dosage of 50 microcuries of iodine-131, to a whole body scan requiring the administration of 5.0 millicuries of iodine-131. At no time during this decision making process was the authorized user consulted. The licensee had not established quality assurance procedures regarding the ordering and administering of radiopharmaceuticals, nor had instruction to the technologist been provided to prohibit the changing of the referring physician's orders without authorized user approval. This is clearly a violation of 10 CFR 35.25(a)(1) in that the licensee failed to provide the supervised individual with adequate instruction to prohibit changing or disregarding the prescribed procedure without the permission of an authorized user or the referring physician.

Case 6: NRC conducted an announced inspection of a High Dose Rate (HDR) Afterloading Brachytherapy program to review the circumstances surrounding two reported therapy misadministrations. The license application contained operating procedures, reviewed and approved by the radiation safety committee, that required a trained operator to be present during any use of the HDR unit.

During the inspection, licensee representatives informed NRC inspectors that only their physicists are considered to be trained operators. However, on two occasions a nurse and a dosimetrist were left to control the treatment console during patient treatment when the trained operator was not physically present. The licensee did not provide adequate supervision to ensure that the unit was not operated by untrained individuals in the absence of the trained operators.

Discussion

The regulatory requirements for supervision of individuals who use byproduct material under the supervision of an authorized user are described in 10 CFR Part 35, Section 35.25, "Supervision." This section provides as follows:

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

Additional requirements for the instruction of workers are described in 10 CFR 19.12, "Instructions to workers." Personnel training programs must be described as part of each licensee's radiation safety program submitted as supporting documentation when applying for an NRC license.

The terms "instruction" and "supervision" are not defined in 10 CFR Part 35; however, the Statements of Consideration (SOC) for revised Part 35 (effective April 1, 1987) discusses these terms in the context of responding to comments on the proposed rule. The following discussion is based on the SOC. With respect to the term "instruction," NRC recognizes that instruction may be in the form of lectures, audiovisual packages, printed handouts, laboratory exercises, preceptorials, or apprenticeships. The format of the instruction is not important, but it must be presented in a manner that is appropriate for each individual's use of or exposure to byproduct material. An opportunity for questions and answers should be an integral part of each instruction module. The NRC recognizes that the authorized user physician identified on the license is responsible for providing quality medical care and the practice of medicine is regulated differently in each state. Therefore, a prescriptive definition of supervision that describes tasks that may be delegated, time requirements

for the availability of the supervising authorized user, and training requirements may not be appropriate for all licensees. The purpose of adequate supervision is to ensure that technologists and supervised physicians do not use byproduct material in a manner that is contrary to the requirements of the license or the regulations, or that is otherwise hazardous to public health and safety. Adequate supervision must encompass a system of checks and balances whereby the authorized user is responsible for: (1) creating and implementing procedures and protocols for the administration of byproduct material; (2) instructing the workers or individuals under the supervision of the user to ensure comprehension and compliance; (3) monitoring their performance to detect deficiencies and to develop corrective measures, and to provide feedback to these individuals.

Licensees should review the aforementioned regulations on the instruction and supervision of their staff to ensure that all procedures and requirements are adequately addressed and implemented, and that sufficient safeguards are in effect to preclude events similar to the ones described in this notice from occurring at their own facilities.

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

John E. Greeves

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Janet R. Schlueter, NMSS
(301) 492-0633

Roy Caniano, RIII
(312) 790-5721

Attachments:
1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-66	(1) Erroneous Data in "Nuclear Safety Guide, TID-7016, Revision 2," (NUREG/CR-0095, ORNL/ NUREG/CSD-6 (1978)) and (2) Thermal Scattering Data Limitation in the Cross-Section Sets Provided with the KENO and SCALE Codes	10/18/91	All fuel cycle licensees, critical mass licensees, interim spent fuel storage licensees, and all holders of operating licenses or construction permits for test, research, and nuclear power reactors.
91-65	Emergency Access to Low-Level Radioactive Waste Disposal Facilities	10/16/91	All NRC licensees.
91-60	False Alarms of Alarm Ratemeters Because of Radiofrequency Interference	09/24/91	All Nuclear Regulatory Commission (NRC licensees authorized to use sealed sources for industrial radiography
91-49	Enforcement of Safety Requirements for Radiographers	08/15/91	All Nuclear Regulatory Commission (NRC) licensees authorized to use sealed sources for industrial radiography.
91-44	Improper Control of Chemicals in Nuclear Fuel Fabrication	07/07/91	All nuclear fuel facilities.
91-39	Compliance with 10 CFR Part 21, "Reporting of Defects and Noncompliance"	06/17/91	All Nuclear Regulatory Commission (NRC) material licensees.
91-35	Labeling Requirements for Transporting Multi-Hazard Radioactive Materials	06/07/91	All U.S. Nuclear Regulatory Commission (NRC) licensees.
91-30	Inadequate Calibration of Thermoluminescent Dosimeters Utilized to Monitor Extremity Dose at Uranium Processing and Fabrication Facilities	04/23/91	All fuel cycle licensees routinely handling unshielded uranium materials.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
91-70	Improper Installation of Instrumentation Modules	11/4/91	All holders of OLs or CPs for nuclear power reactors.
91-69	Errors in Main Steam Line Break Analyses for Determining Containment Parameters	11/1/91	All holders of OLs or CPs for pressurized-water reactors.
91-68	Careful Planning Significantly Reduces the Potential Adverse Impacts of Loss of Offsite Power Events During Shutdown	10/28/91	All holders of OLs or CPs for nuclear power reactors.
90-51, Supp. 1	Failures of Voltage-Dropping Resistors in the Power Supply Circuitry of Electric Governor Systems	10/24/91	All holders of OLs or CPs for nuclear power reactors.
91-67	Problems With the Reliable Detection of Intergranular Attack (IGA) of Steam Generator Tubing	10/21/91	All holders of OLs or CPs for pressurized-water reactors.
91-66	(1) Erroneous Data in "Nuclear Safety Guide, TID-7016, Revision 2," (NUREG/CR-0095, ORNL/NUREG/CSD-6 (1978)) and (2) Thermal Scattering Data Limitation in the Cross-Section Sets Provided with the KENO and SCALE Codes	10/18/91	All fuel cycle licensees, critical mass licensees, interim spent fuel storage licensees, and all holders of operating licenses or construction permits for test, research, and nuclear power reactors.
91-65	Emergency Access to Low-Level Radioactive Waste Disposal Facilities	10/16/91	All NRC licensees.

OL = Operating License
CP = Construction Permit