

North Carolina
Department of Environment and Natural Resources
Division of Radiation Protection



Michael F. Easley, Governor
William G. Ross, Secretary
Richard M. Fry, Director

DRP INFORMATION NOTICE 01-01

TO: Nuclear Pharmacy Licensees
FROM: J. Marion Eaddy III, Health Physicist 
DATE: Tuesday 23 January 2001
IN RE: Monitoring dose to the extremities

The agency is furnishing a copy of NRC Information Notice IN-2000-10 to all nuclear pharmacy licensees for review and consideration. This information notice is being furnished for informational purposes only, and thus, no response from the licensee is required.

Agency inspections of licensees have shown that the greatest potential for extremity exposure is in the nuclear pharmacy profession. The enclosed NRC information notice lists potential causes for high or over-exposures to the extremities, as well as provides some important reminders of the ALARA principle and its applicability in day-to-day operations.

Please review the enclosed notice carefully and compare your current ALARA program points to those referenced in the document. Should you require program changes to implement any "new" provisions, please send an amendment request to the agency so that your license and procedures currently on file can be updated. Amendment forms are available on our website (www.drp.enr.state.nc.us).

enclosure: NRC Information Notice IN-2000-10

1645 Mail Service Center Raleigh, North Carolina 27699-1645
Phone: (919) 571-4141 FAX: (919) 571-4148 Internet: www.drp.enr.state.nc.us

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

July 18, 2000

NRC INFORMATION NOTICE 2000-10: RECENT EVENTS RESULTING IN EXTREMITY
EXPOSURES EXCEEDING REGULATORY LIMITS

Addressees:

All material licensees who prepare or use unsealed radioactive materials, radiopharmaceuticals, or sealed sources for medical use or for research and development.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to alert addressees to recent events that resulted in personnel receiving occupational extremity doses in excess of the 0.5-sievert (50-rem) shallow dose equivalent limit specified in 10 CFR 20.1201(a)(2)(ii). 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 IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

Recently, NRC was notified by, and responded to, two licensees' facilities where personnel received radiation exposures to their extremities in excess of the 0.5-sievert (50-rem) limit. Although both events occurred at commercial radiopharmaceutical facilities, the issues pertain to all material licensees that may prepare or use unsealed radioactive materials, radiopharmaceuticals, or sealed sources for medical use, or for research and development.

Case 1:

The licensee - a radiopharmaceutical manufacturing facility - notified NRC of an event involving an employee directly handling an unshielded molybdenum-99/technetium-99m generator column. The column contained 700 gigabecquerels (19 curies) of molybdenum-99 (Mo-99) and 300 gigabecquerels (8 curies) of technetium-99m (Tc-99m). Event reenactments determined that the individual may have held the column using his thumb and index finger of his left hand for as long as 50 seconds while attempting to correct alignment problems with the inlet and outlet needles. The individual wore a ring badge on the right hand to measure extremity dose, and this monitor read 0.057 sieverts (5.7 rems). Calculations indicated that the dose to the individual's thumb and index finger of the left hand may be as much as 25-gray (2500-rad) shallow dose equivalent.

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The licensee's investigation into the event identified two additional exposure situations involving 13 other individuals in other areas of the facility.

One situation involved the hand-labeling of product vials that contained approximately 740 megabecquerels (20 millicuries) of indium-111, an accelerator-produced radioactive material. Ten individuals, over the period between 1995 and 1999, inclusive, held the product vials in their left hands, with the index fingers on the tops of the vials and their thumbs on the bottoms, in close proximity to the radioactive material, and applied the labels with their right hands. The individuals all wore their extremity monitors on their right hands. Licensee calculations determined that the individuals involved in this practice received between 0.5- and 6-sievert (50- and 600-rem) shallow dose equivalent during calendar years 1995 through 1999. Several individuals received exposures in excess of 0.5 sievert (50 rems) in multiple years.

The other situation involved three additional individuals who worked in one of the licensee's product testing laboratory. While performing their duties in this laboratory, the individuals removed aliquots of radioactive material for testing from product vials, using unshielded syringes, and in some instances, while holding the unshielded vials in their hands. These individuals received between 0.7- and 1.0-sievert (70- and 100-rem) shallow dose equivalent to their hands and fingers during calendar years 1997 and 1999. Again, some of the individuals received exposures in excess of 0.5 sievert (50 rems) in more than 1 year.

The licensee believed that the exposures recorded by the extremity monitors were the "doses of record," and did not recognize the significant difference between the recorded dose and the actual dose to the fingertips when handling unshielded vials and syringes of radioactive material. This contributed to the licensee not being fully aware of the extent of inadequate radiation handling practices. The extremity monitor results for the individuals involved in these last two situations did not provide any indications that they were receiving doses in excess of NRC regulatory limits.

Case 2:

A licensee -a commercial radiopharmacy- reported that the fingers of a radiopharmacist may have received an exposure in excess of the NRC limit. As reported by the licensee's dosimetry processor, the worker's extremity monitoring received approximately 0.082 sieverts (8.2 rems), 0.265 sieverts (26.5 rems), 0.131 sieverts (13.1 rems), and 0.12 sieverts (12.0 rems), during the months of February, March, April, and May, respectively. There had been significant delays in processing extremity dosimeters and assessment of the results.

The pharmacist did not have prior radiopharmacy experience, and the licensee provided the pharmacist with training in radiopharmacy operations and procedures, as well as with on-the-job training. The pharmacist performed routine radiopharmacy tasks, including elution of Mo-99/Tc-99m generators and formulation of unit doses of Tc-99m, as ordered by local hospitals.

To deal with the difficult time constraints and production pressures, in part, the pharmacist used a lighter syringe shield (without a flange needed to maximize shielding the radiation emanating from the vial septum) or no shielding. In addition, the pharmacist directly handled dosages without shielding during dose calibrations, and on many occasions conducted repeat dose calibrations while attempting to dispense requested activity.

Discussion:

Some of the contributing causes of these exposure events can be summarized as follows:

- Direct handling of unshielded material, or inadequate use of shielding and remote handling devices;
- Lack of direct supervisory review of work habits and techniques used to minimize exposure;
- Operational pressures to meet production outputs and deadlines;
- Inadequate attention to As Low As Reasonably Achievable (ALARA) programs;
- Extremity monitoring not being representative of actual dose;
- Delays in the receipt of dosimetry results; and,
- Absence of a questioning attitude toward extremity exposure, or a lack of awareness of exposure levels in close proximity of radiation sources.

All licensees that work with and handle unsealed radioactive materials, radiopharmaceuticals, and unsealed sources, are reminded of the importance of:

- Training and supervising new employees, to ensure that they understand the hazard associated with their work;
- Examining the operational procedures and activities for handling materials, and assuring that they are well understood by the individuals using them;
- Using appropriate shielding, and understanding the gravity of directly touching or handling unshielded syringes, vials, or other sources;
- Not allowing work pressures and workloads to interfere with appropriate radiation safety practices and the radiation safety program;
- Extremity monitoring and its proper placement, such that extremity monitor dose results are representative of the highest exposure expected to any extremity; and,
- ALARA programs reflecting appropriate and timely actions to reduce extremity doses as well as the total effective dose equivalent (TEDE);
- Selecting an appropriate monitoring interval and processing turnaround time to ensure that ALARA objectives and regulatory limits are met.

This information notice requires no specific action nor written response. If you have any questions about the information in this IN, please contact the technical contacts listed below or the appropriate regional office.

/RA/

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

Technical contacts: Jamnes L. Cameron, RIII
630-829-9833
E-mail: jlc@nrc.gov

Dr. Mohamed M. Shanbaky, RI
610-337-5209
E-mail: mms1@nrc.gov

Attachments:

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