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NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NUREG/BR-0117
No. 98-2
June - July '98

BIOASSAY REQUIREMENTS FOR MEDICAL PERSONNEL WHO ADMINISTER RADIOIODINE TO PATIENTS

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to significant thyroid burdens. To monitor this possible intake, the U.S. Nuclear Regulatory Commission (NRC) requires, in 10 CFR 35.315(a)(8), that "For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 35.75 of this chapter, a licensee shall...Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage...." Section 35.75, "Release of individuals containing radiopharmaceuticals or permanent implants" specifies the requirements that must be met to release patients from the hospital. The purpose of this article is to alert licensees and their radiation safety personnel to the fact that, although some of their occupational workers may not be required to be included in a bioassay program under 10 CFR Part 35, they may still be required to be monitored for intakes under 10 CFR Part 20.

Historically, bioassay for medical personnel has been required only in cases of administration to hospitalized patients because these are the patients receiving substantial dosages of radiopharmaceuticals. This in turn meant that the medical personnel who prepared and administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. This greater risk for intakes led to the requirement for bioassay for these medical personnel. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials, and preparation and administration of these dosages posed a relatively smaller risk to the medical personnel involved.

The situation regarding confinement of patients has changed with the recent revision of 10 CFR 35.75. The most significant change was that 10 CFR 35.75 now bases the release of patients administered radioactive materials on the doses that may be received by members of the public from the released patients. These new dose-based release criteria may, in some cases, involve the administration of relatively large dosages of radioactive materials without requiring patient confinement. Because the bioassay requirement for medical personnel in §35.315(a)(8) is applicable only in the case of administration to hospitalized patients, it is now possible, under the new patient release criteria, for medical personnel to prepare and administer substantial doses of radiopharmaceuticals without coming under this §35.315(a)(8) bioassay requirement.

Licensees should note, however, that although medical personnel administering radiopharmaceuticals may not fall within the scope of the bioassay requirements specified in 10 CFR 35.315(a), they are still subject to the requirements of 10 CFR 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose." This section of the regulations requires licensees to monitor all occupationally exposed personnel who may receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) (Annual Limit on Intake) in Table 1, Columns 1 and 2, of Appendix B to 10 CFR Part 20.

NMSS Licensee Newsletter
(June 1998 – July 1998)

Comments, and suggestions you may have for information that is not currently being included, that might be helpful to licensees, should be sent to:
E. Kraus
NMSS Licensee Newsletter Editor
Office of Nuclear Material Safety and Safeguards
Two White Flint North, Mail Stop 8–A–23
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555–0001

Medical personnel who prepare or administer radiopharmaceuticals are occupationally exposed personnel, and therefore are subject to 10 CFR 20.1502 of the regulations. Licensees are required to review the potential exposures of their employees for the upcoming year, and to monitor them for intakes if there is a likelihood that this intake, during the year, may exceed 10 percent of the limit. Monitoring, in the context of intakes, means inclusion of these personnel in a bioassay program designed to monitor and quantify their intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay, depending on the isotope or combination of isotopes handled during the monitoring period. It should be noted that, although 10 CFR 35.315(a) specified only thyroid burden monitoring for those handling iodine-131, Part 20 is more general, and applies to intakes of any licensed material. It therefore has much broader applicability than 10 CFR 35.315(a). For medical licensees primarily using radioiodine, thyroid monitoring may continue to be the preferable form of bioassay.

Although 10 CFR 35.315(a) no longer requires bioassay for some medical personnel who previously would have been monitored (under the old bioassay requirements in Part 35), the requirements in Part 20 to monitor for intakes apply to all occupationally exposed personnel. Licensees are expected to assess potential exposures from all sources of radiation for their employees for the upcoming monitoring year and include them in a suitable monitoring program if their doses or intakes may exceed 10 percent of the applicable limits. This assessment of potential exposures may be based on past exposure histories, details of upcoming work schedules, or the professional judgment of the radiation safety personnel.

(Contact: Sami Sherbini, NMSS, 301–415–7902, e-mail: sxs2@nrc.gov)

PROPER STORAGE OF HIGH-ENERGY BETA- AND NEUTRON-PRODUCING SOURCES

Licensees need to properly shield all radiation sources. Although gamma and x-ray sources require high-atomic-number materials like lead, tungsten, steel, or depleted uranium to provide adequate shielding, high-energy beta and neutron sources require low atomic-weight materials such as plastics, paraffin, water, or boronated water to provide adequate shielding. Strontium eye applicators, americium/beryllium sources in moisture density gauges, and plutonium/beryllium sources in ne ron

generators are examples of either high-energy-beta or neutron-producing sources. In many cases these sources should be stored in their shipping containers because the shipping containers have low-atomic-weight shielding materials.

U.S. Nuclear Regulatory Commission inspectors recently observed higher than expected radiation levels at the outside of two wooden boxes, each containing a strontium-90/yttrium-90 eye applicator. One licensee had improperly stored the eye applicator in a tungsten/stainless steel inner sleeve within another aluminum sleeve and a lead pig. The second licensee's wooden storage box was lead-lined. The higher-than-expected radiation levels were caused by bremstrahlung produced when the high-energy betas interacted with the tungsten/steel sleeve and the lead, respectively. Similar problems were addressed in 1984, in Information Notice 84–43: "Storage and Handling of Ophthalmic Beta Radiation Applicators." At that time, licensees were removing the loose pieces of aluminum that the manufacturer put in the boxes to shield the source and prevent excessive bremstrahlung.

In an unrelated case, the U.S. Department of Energy reported an employee receiving an unexpected radiological exposure to neutrons from an improperly stored americium-beryllium source. The source had been stored in a lead-shielding container. The source had been properly stored in its shipping container for years before being moved to the lead-shielding container. The shipping container contained low-atomic-weight material and effectively absorbed the neutrons.

(Contact: Dr. Donna–Beth Howe, NMSS, 301–415–7848, e-mail: dbh@nrc.gov)

PATIENTS RECEIVED LESS THAN PRESCRIBED DOSAGE WHEN ONE OF TWO I–131 CAPSULES WAS NOT ADMINISTERED

A medical misadministration occurred at the Edward Hospital in Naperville, Illinois, when a patient was given less than the prescribed dose. A patient was to have been given 5.6 GBq (150 mCi) of I–131 sodium iodide in two capsules on May 21, 1998. However, on June 6, 1998, it was discovered that the patient was only administered one capsule. The second capsule was found still in the shipping container.

Another misadministration occurred at the Rhode Island Hospital in Providence on June 3, 1998. A patient was administered only 260 MBq (7 mCi) of a prescribed 370–MBq (10–mCi) dose of I–131, because only one 260–MBq (7–mCi) capsule of a two-capsule dose was administered. The other capsule (110 MBq) (3 mCi) was found during an inventory survey of the hot lab on June 17, 1998.

There is a concern that nuclear medicine technologists are erroneously assuming that the prescribed I–131 dose is contained in only one capsule, when it may instead have been placed in multiple capsules. Based on review of 10 misadministrations, the U.S. Nuclear Regulatory Commission suggests that licensees that administer I–131 capsules review their protocol and training, and take action appropriately.

(Contact: Eric Compton, NMSS, 301–415–5799, e-mail : ebc@nrc.gov)

CLOSING OF WALNUT CREEK (CA) FIELD OFFICE

The U.S. Nuclear Regulatory Commission (NRC) Region IV Walnut Creek Field Office, California (WCFO) will be closed after September 30, 1998. All activities performed by the WCFO will be transferred to the main Region IV office in Arlington, Texas. When calling the office before its closure, please note that there is a new area code. The general number for the WCFO is 925–975–0200. Since the WCFO is currently transferring functions to the Arlington office, effective immediately, all licensing and other correspondence should be directed to the Arlington office. The mailing address for the Arlington office is:

USNRC, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011–8064.

Event notifications and other general communications with Agreement State officials should be directed to the Region IV Arlington, Texas, office. The general telephone number for the Arlington office is 817–860–8100. Emergency calls should be directed to the Headquarters Operations Center at 301–816–5100.

(Contact: Mark Shaffer, RIV, 817–860–8287, e-mail: mrs@nrc.gov)

SELECTED *FEDERAL REGISTER* NOTICES

(April 1, 1998 – May 31, 1998)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

FINAL RULES

"Access Authorization Fee Schedule for Licensee Personnel," 63 FR 25156, May 7, 1998. Contact: Beth Bradshaw, 301–415–6540, e-mail mbb1@nrc.gov.

PROPOSED RULES

"Revision of Fee Schedules; 100% Fee Recovery, FY 1998," 63 FR 16046, April 1, 1998. Contact: Glenda Jackson, Office of the Chief Financial Officer, 301–415–6057.

"Revision of Fee Schedules; 100% Fee Recovery, FY 1998 (Correction)," 63 FR 17130, April 8, 1998. Contact: Glenda Jackson, Office of the Chief Financial Officer, 301–415–6057.

OTHER NOTICES

Issuance and Availability of Draft NUREG–1617, "Standard Review Plan for Transportation Packages for Spent Nuclear Fuel," 63 FR 16594, April 3, 1998.

"State of Oregon Relinquishment of Sealed Source and Device Evaluation and Approval Authority and Reassumption by the Commission," 63 FR 17903, April 10, 1998. Contact: James H. Myers, 301–415–2328, e-mail, jhm@nrc.gov.

Availability of Draft NUREG–1556, Vol. 6, "Consolidated Guidance About Irradiator Licensees," 63 FR 20224, April 23, 1998. Contact: Mrs. Sally L. Merchant, 301–415–7874; e-mail, slm2@nrc.gov.

Department of Energy, "Technical Assistance and Funding for Safe Routine Transportation and Emergency Response Training," 63 FR 23753, April 30, 1998. Contact: Ms. Corinne Macaluso, U.S. Department of Energy, 202–586–2837.

"Revision of NRC Enforcement Policy," 63 FR 26630, May 13, 1998. Contact: James Lieberman, 301–415–2741; e-mail: jxl@nrc.gov.

U.S. Environmental Protection Agency, "Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations," 63 FR 27354, May 18, 1998. Contacts: Betsy Forinash, Scott Monroe, or Sharon White, EPA, 202 564–9310.

(General Contact: Paul Goldberg, NMSS, 301–415–7842, e-mail: pfg@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (August 1, 1997 – April 30, 1998)

Note that these are only summaries of U.S. Nuclear Regulatory Commission (NRC) generic communications. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the NRC library of generic communications is — www.nrc.gov/nrc/fedworld/nrc-gc/index.html. Please note that this address is case-sensitive and must be entered exactly as shown.

Bulletins (BLs)

BL 97–02, "Puncture Testing of Shipping Packages under 10 CFR Part 71," was issued on September 23, 1997, to all holders of NRC Certificates of Compliance for shipping packages. The bulletin informed addressees of physical tests that were not performed in accordance with Part 71 requirements and requested all certificate holders to review the assessment of their certified package designs and determine if the tests were performed in accordance with Part 71. Contact: David Tiktinsky, NMSS, 301–415–8523, e-mail: dht@nrc.gov.

Information Notices (INs)

IN 97–61, "U.S. Department of Health and Human Services (HHS) Letter to Medical Device Manufacturers on the Year 2000 Problem," was issued on August 6, 1997, to all medical licensees, veterinarians, and manufacturers/distributors of medical devices. It informs addressees of a letter issued by the HHS Food and Drug Administration about the Year–2000 computer problem. Contact: Patricia K. Holahan, NMSS, 301–415–8125, e-mail:pkh@nrc.gov.

IN 97–64, "Potential Problems Associated with Loss of Electrical Power in Certain Teletherapy Units," was issued on August 13, 1997, to all medical teletherapy licensees. It informs addressees of potential problems with the Theratron 1000 teletherapy unit manufactured by Theratronics International, Limited. Contact: Nader Mamish, NMSS, 301–415–6316, e-mail: nlm@nrc.gov.

IN 97–65, "Failures of High-Dose-Rate (HDR) Remote Afterloading Device Source Guide Tubes, Catheters, and Applicators," was issued on August 15, 1997, to all HDR remote afterloader licensees. It alerts addressees to reports of failures in equipment used with HDR devices supplied by three major U.S. vendors. Contact: Robert L.

Ayres, NMSS, 301–415–5746, e-mail: rxa1@nrc.gov.

IN 97–72, "Potential for Failure of the Omega Series Sprinkler Heads," was issued on September 22, 1997, to all power reactors and fuel cycle facilities. The notice alerts addressees to a potential problem with Omega Series sprinkler heads manufactured by Central Sprinkler Company of Lansdale, PA. Contacts: E.A. Connell, NRR, 301–415–2838, e-mail: eac@nrc.gov; P.W. Lain, NMSS, 301–415–6317, e-mail: pwl@nrc.gov.

IN 97–75, "Enforcement Sanctions Issued as a Result of Deliberate Violations of NRC Requirements," was issued on September 24, 1997, to all NRC licensees. The notice informs addressees of a company president who was sentenced to 3 years probation and fined $3000 for falsifying equipment calibration records. Contacts: Nader Mamish, NMSS, 301–415–6316, e-mail: nlm@nrc.gov; John McGrath, RI, 610–337–5069, e-mail: jrm@nrc.gov.

IN 97–86, "Additional Controls for Transport of the Amersham Model No. 660 Series Radiographic Exposures Devices" was issued on December 12, 1997, to all registered users of the packages and all industrial radiography licensees. The notice alerts addressees to recent failures during hypothetical accident tests and discusses additional controls for transport that have been added to Certificate of Compliance No. 9033. Contacts: Ross Chappell, NMSS, 301–415–8510, e-mail: crc1@nrc.gov; David Tiktinsky, NMSS, 301–415–8523, e-mail: dht@nrc.gov.

IN 97–87, "Second Retrofit to Industrial Nuclear Company IR–100 Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility," was issued on December 12, 1997, to all industrial radiography licensees. The notice informs addressees of a retrofit to the lock of the IR–100 radiography camera. Contacts: David Wesley, California Dept. of Health Services, 916–445–1884; Michele Burgess, NMSS, 301–415–5868, e-mail: mlb5@nrc.gov.

IN 97–89, "Distribution of Sources and Devices Without Authorization," was issued on December 29, 1997, to all sealed source and device manufacturers and distributors. The notice alerts addressees to the recent breakdown, of a vendor's regulatory program, that resulted in unauthorized distribution of sources and devices to specific licensees and general licensees. Contact: Douglas Broaddus, NMSS 301–415–5847, e-mail: dab@nrc.gov.

IN 97–91, "Recent Failures of Control Cables Used on Amersham Model 660 Posilock Radiography Systems," was issued on December 31, 1997, to all industrial radiography licensees. This notice alerts addressees to several recent incidents where the control cable broke at the male end, and emergency procedures were implemented to recover the disconnected source assembly. Contact: Larry W. Camper, NMSS, e-mail: lwc@nrc.gov.

IN 98–01, "Theft of Portable Gauges," was issued on January 15, 1998, to all portable gauge licensees. This notice alerts addressees to several recent incidents where portable gauges were stolen from vehicles and storage sheds. Contact: Anthony S. Kirkwood, NMSS, 301–415–6140, e-mail: ask@nrc.gov.

IN 98–04, "1997 Enforcement Sanctions for Deliberate Violations of NRC Employee Protection Requirements," was issued on February 9, 1998, to all NRC licensees. It reminds licensees of the sanctions that could result from deliberately violating NRC requirements in the area of employee protection. Contact: Michael Stein, OE, 301–415–1688, e-mail: mhs@nrc.gov.

IN 98–06, "Unauthorized Use of License to Obtain Radioactive Materials, and Its Implications Under the Expanded Title 18 of the U.S. Code," was issued on February 19, 1998, to all NRC licensees. It alerts them to an incident involving unauthorized use of a broad-scope medical license to obtain radioactive materials, and the subsequent criminal investigation. Contact: John Davidson, NMSS, 301–415–8130, e-mail: jjd@nrc.gov.

IN 98–08, "Information Likely to be Requested if an Emergency Is Declared," was issued on March 2, 1998, to all nonreactor licensees required to have an NRC-approved emergency plan. It informs them of the information expected by NRC when an Alert or Site Area Emergency is declared. Contacts: Yen–Ju Chen, NMSS, 301–415–5615, e-mail: yjc@nrc.gov; Kevin Ramsey, NMSS, 301–415–7887, e-mail: kmr@nrc.gov.

IN 98–09, "Collapse of an Iscocam II, Dual-Headed Nuclear Medicine Gamma Camera,"was issued on March 5, 1998, to all medical licensees. It alerts them to an incident involving a gamma camera manufactured by Park Medical Systems of Quebec, Canada. Contact:

Steven Baggett, NMSS, 301–415–7273, e-mail: slb@nrc.gov.

IN 98–10, "Probable Misadministrations Occurring During Intravascular Brachytherapy with the Novoste Beta-Cath System," was issued on March 9, 1998, to all medical licensees. It alerts them to two reported incidents involving the failure of the sources to return to the device storage safe at the conclusion of the treatments. Contact: Robert Ayres, NMSS, 301–415–5746, e-mail: rxa1@nrc.gov.

IN 98–12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers," was issued on April 3, 1998, to all nuclear pacemaker licensees. It reminds them of their responsibilities regarding the reporting and follow-up requirements for nuclear-powered pacemakers. Contact: Torre Taylor, NMSS, 301–415–7900, e-mail: tmt@nrc.gov.

IN 98–16, "Inadequate Operational Checks of Alarm Ratemeters," was issued on April 30, 1998, to all industrial radiography licensees. It alerts them to an incident where two radiographers approached an exposed source but neither alarm ratemeter alarmed because inadequate operational checks failed to detect weak batteries. Contacts: Robert Gattone, RIII, 630–829–9823, e-mail: rgg@nrc.gov; J. Bruce Carrico, NMSS, 301–415–7826, e-mail: jbc@nrc.gov.

(General Contact: Kevin Ramsey, NMSS, 301–415–7887, e-mail: kmr@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

Detailed information regarding these enforcement actions can be accessed via the U.S. Nuclear Regulatory Commission (NRC) homepage [http://www.nrc.gov/]. Access "Program Offices," then "Office of Enforcement," then "Enforcement Actions Issued." Cases are listed alphabetically. To view the complete enforcement action, click on the highlighted text following each case description.

Measuring Gauges

Ground Engineering and Testing Service, Inc., Louisville, Kentucky, EA 98–021. A $5500 civil penalty was assessed for willful failure to file for reciprocity before conducting work in NRC jurisdiction.

The Stroh Brewery Company, Lehigh, Pennsylvania, EA 97-486. A $4400 civil penalty was assessed for improper disposal of two generally licensed gauges, which were transferred to a scrap recycler.

Radiography

CTI, Alaska, Inc., Anchorage, Alaska, EA 97–539. A $5500 civil penalty was assessed for violations that involved: 1) approaching a radiography exposure device before the source was moved to its shielded position; and 2) failing to use an operable survey instrument to perform a radiation survey of the device.

Other Materials Licensees

Koch Engineering Company, Inc., Newark, Delaware, EA 98–061. A $4400 civil penalty was assessed for failure to ensure, by examination or test, that each closure device of a package containing cesium-137 sources was properly installed, secured, and free of defects before transportation. The package arrived empty and the sources were later recovered at a Federal Express facility.

Mallinckrodt Inc., Maryland Heights, Missouri, EAs 97–342 and 97–355. A $55,000 civil penalty was assessed for violations involving: (1) a shallow-dose equivalent exposure to an occupational worker in excess of 500 mSv (50 rems) caused by failure to survey; and (2) Molybdenum-99/Tecnetium-99m generators that arrived at their destinations with contact radiation levels that exceeded 2mSv (200 millirem).

United States Enrichment Corporation, Paducah, Kentucky, EA 97–431. A $55,000 civil penalty was assessed for five examples of failure to maintain control of classified matter.

United States Enrichment Corporation, Portsmouth, Ohio, EA 98–012. A $55,000 civil penalty was assessed for 16 violations involving major deficiencies in the nuclear criticality safety and self-assessment programs at the facility.

Westinghouse Electric Corporation, Columbia, South Carolina, EA 97–442. A $13,750 civil penalty was assessed for eight violations involving criticality safety controls.

(Contact: Joseph DelMedico, OE, 301–415–2739, e-mail: rjd@nrc.gov)

Federal Recycling Program

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