

NMSS Quarterly Newsletter



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**Office of Nuclear
Material Safety
and Safeguards**

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INTEGRATED SAFETY ANALYSIS REVIEWS -- MOVING TOWARDS a MORE RISK-INFORMED APPROACH to FUEL CYCLE LICENSING

The new Subpart H of 10 Code of Federal Regulations (CFR) Part 70 identifies risk-informed performance requirements and requires applicants and existing licensees to conduct an integrated safety analysis (ISA) and submit an ISA Summary, as well as other information. In general terms, the requirements in 10 CFR Part 70 specify the information that an applicant must supply in its safety program description. Currently, ISAs are more qualitative in nature as opposed to a quantitative approach used in probabilistic risk assessments prepared for nuclear power reactors. The decision to use this qualitative approach was based, in part, on the fact that each of the six fuel cycle and nuclear materials facilities affected has unique processes, equipment, and safety features. Much of the current information and data used in the accident scenarios is based to a large degree on

the licensees’ expert judgment and in-depth knowledge of their processes. The ISA approach has offered unique challenges to both development and review of these ISAs in an objective and transparent manner.

Standard Review Plans and Interim Staff Guidance (ISG) documents have been developed by the NRC to offer a consistent approach for reviewing the methods, assumptions and data used in the ISAs. The primary document, NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility,” complements 10 CFR Part 70 by identifying the specific information to be submitted by an applicant and evaluated by the staff. As issues have been raised and addressed, the NRC has developed draft ISGs to further guide and document its approach to these issues. NRC has provided the first eight ISGs to industry in the summer and fall of 2004. To date, NRC has received comments on the first six draft ISGs forwarded. Public comment and NRC review of these documents are under way. NRC will incorporate appropriate comments into the final ISGs or subsequent revisions.

Important issues remain regarding moving ISAs toward a more risk-informed approach -- namely, the treatment of dependent failures, human reliability, the treatment of uncertainty, and the aggregation or assembly of the scenarios into overall facility or system measures of risk. As more issues come to light, the NRC will continue to revise or augment the ISGs to provide clarification and support consistency in the reviews of the ISA summaries. As experience is gained and consensus developed on the ISGs, NUREG-1520 will be modified to be more risk-informed, and therefore, more effective and efficient. It is assumed that now that these initial models have been developed, and the data requirements are better defined, a greater amount of objective data will become available in the future. For example,

operational and maintenance data from these systems can be fed back into the models to replace or validate initial assumptions. Additionally, the availability of this data will allow the uncertainties associated with the systems to be better quantified. In this way, the ISA process will achieve its true objective: becoming a living document that accurately reflects the facility processes and hazards and ensures that those hazards are appropriately managed and controlled.

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MISCONNECT TEST ADDED to MAINTENANCE of RADIOGRAPHY CAMERAS

In response to a recent incident involving a Florida industrial radiography licensee, AEA Technology QSA (formerly Amersham) issued a service bulletin, "Sentinel Service Bulletin September 2004," to instruct its customers to add performance of a "Misconnect Test" to the quarterly inspection and maintenance procedure for the AEA exposure devices. The misconnect test is designed to detect long-term wear of the entire locking system.

The test is needed because, even when the wear is within specifications for the components individually, a misconnect can occur when slightly worn components are used together. The Service Bulletin describes the steps of how to conduct the test and specifies the conditions when the equipment must be removed from operation. It must be noted that misconnect tests must be performed on each combination of all the devices and all the control assemblies that are used to detect the combined effects of wear. The tests should only be performed by personnel who are formally trained, authorized, and familiar with the quarterly maintenance procedures.

AEA Technology started distributing the Service Bulletin in December 2004, with each of its source changer shipments and intends to continue such distributions for about 6 months. The next editions of the operating manuals will also include the misconnect test. For further information the contact at AEA Technology is Ms. Lori Podolak, telephone (781) 272-2000, ext. 241, e-mail: Lori.Podolak@aeat-qa.com.

This article was developed jointly by Walter Cofer, Bureau of Radiation Control, Florida Dept. of Health and John Jankovich, Office of Nuclear Material Safety and Safeguards, NRC.

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TRACKING of RADIOACTIVE SOURCES

The events of September 11, 2001, heightened the nation's concerns regarding the use of radioactive materials for a malevolent act. In June 2002, the Secretary of Energy and the Chairman of the Nuclear Regulatory Commission (NRC) met to address these concerns and discuss the nation's ability to adequately protect inventories of nuclear materials that could be used in a radiological dispersal device (RDD). An attack involving an RDD has been of particular concern because of the widespread use of radioactive materials in the United States and abroad by industry, hospitals, and academic institutions. In May 2003, the report written by the U.S. Department of Energy (DOE)/NRC Working Group (WG) convened to study these concerns was accepted by the DOE Secretary and the NRC Chairman. The WG generated a list of radionuclides and thresholds for which the tracking of sources was recommended. A similar study undertaken by the International Atomic Energy Agency (IAEA) created a list of radionuclides and thresholds similar to the DOE/NRC list. The U.S. Government subsequently committed to using the IAEA list to support international cooperation on source tracking.

NRC has started work on a new national system to track radioactive sources of greatest concern as designated on the IAEA list. However, since current regulations do not require reporting source inventories, NRC and the Agreement States (AS') only know the quantities a given licensee has been authorized to use, not what a licensee has at a given moment. Thus, the first step, as directed by the Commission, was the creation of an interim inventory -- a "snapshot" of the existing sources. The interim inventory is necessary to provide NRC and the AS' with greater detail on the source population, to plan the development of the source tracking system.

From October 2003 to September 2004, NRC and the AS' contacted over 2600 licensees authorized to possess quantities of radionuclides which in aggregate, could exceed the thresholds on the IAEA list discussed above. This first round of the

inventory asked for details of the sources, and additional data such as the number of physical locations of sources under the license, near-term disposition plans, and import/export aspects were subsequently requested. Approximately 99.8 percent of the licensees contacted provided responses. Each year, until a national source tracking system is established, NRC and the AS' will again contact all licensees authorized to possess quantities of radionuclides which could exceed the IAEA thresholds and ask for the details of sources exceeding the thresholds.

The second round of the interim inventory began in December 2004. Approximately 25 percent of the licensee population will be contacted each calendar quarter until a national source tracking system is established. Although participation in the data collection is voluntary, licensees are encouraged to provide the information when requested. Licensees will be provided the information currently in the database and requested to update it. Licensees may update the information either by on-line entry or by mail. The overall goal is to create a working tracking system by the end of 2006.

(Contacts: William Ward, Office of Nuclear Material Safety and Safeguards, 301-415-7038; e-mail: wrw1@nrc.gov or Merri Horn, Office of Nuclear Material Safety and Safeguards, 301-415-8126; e-mail: mlh1@nrc.gov)

SIGNIFICANT MEDICAL EVENTS

Event 1: Dose to Fetus

Date and Place: April 20, 2004; Department of Veterans Affairs, North Little Rock, Arkansas

The licensee reported an event involving a dose to a fetus at the Veterans Affairs Medical Center in Birmingham, Alabama. The patient signed a form stating that she was not pregnant and a blood sample was obtained for a serum pregnancy test. However, when the licensee retrieved the pregnancy test result, the result from a test performed two months previously was erroneously retrieved; that test result was negative for pregnancy. The patient was then orally administered 0.222 megabecquerel (6 microcuries) of Iodine-131 sodium iodide on April 20, 2004. On April 21, 2004, the patient was intravenously administered 0.444 gigabecquerel (12 millicuries) of Technetium-99m pertechnetate. After both dosages were administered, the licensee discovered that the patient was pregnant. An ultrasound test was used to determine gestation was at 9 to 11 weeks. The dose to the fetal thyroid was

estimated to be 6.6 centisieverts (rem) if the thyroid was functioning, or 0.5 to 1 centisieverts (rem) if the thyroid was not functioning. The most likely dose to the fetus and fetal thyroid was estimated at less than 1 centiseivert (rem), based on a fetal age of 10 weeks. The root cause was the failure to follow procedures and/or inadequate procedures.

Actions Taken to Prevent Recurrence

Corrective actions include retraining nuclear medicine staff and requiring authorization by the radiation safety officer before administering any therapeutic dose to female patients of childbearing age. In addition, procedures will be modified to require a staff nuclear medicine physician to acknowledge pregnancy test results and give approval in writing.

Event 2: Dose to Wrong Patient

Date and Place: May 10, 2004; University Hospital, Cincinnati Ohio

The licensee reported that a patient was administered 74 megabecquerel (2 millicuries) of Iodine-131(I-131) instead of the prescribed dose of 7.4 megabecquerel (200 microcuries) of Iodine-123(I-123). The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was scheduled to receive the I-131 dose. The mistake occurred because the technologist did not follow procedures regarding proper patient identification. An investigation by the Ohio Department of Health occurred on May 11-12, 2004. The licensee's corrective actions were deemed adequate.

Actions Taken to Prevent Recurrence

Corrective actions included modification of the Quality Management Program to delete visual recognition of patients as a means of patient identification, and replacing this with verification via photo identification. Another action included re-emphasis of the need to thoroughly check patient identification using two approved methods.

Event 3: Overdose of Radioiodine

Date and Place: August 10, 2004; Northeast Alabama Regional Medical Center, Birmingham, Alabama

The licensee reported that a patient received 111 megabecquerel (3 millicuries) of Iodine-131 (I-131) for the assessment of metastatic thyroid disease instead of the prescribed dose of 0.93

megabecquerel (25 microcuries). The imaging technologist misunderstood the referring physician's order and the authorized user did not approve the dose. The referring physician and patient were notified of the event. As a result of the dose, the patient could eventually become hypothyroid.

Actions Taken to Prevent Recurrence

Corrective measures included re-instructing personnel and ensuring that the authorized user approves all procedures.

(Contact: Angela R. McIntosh, NMSS, 301-415-5030; e-mail: arm@nrc.gov)

NRC's Medical Advisory Committee Meeting for Fall 2004

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a public meeting on October 13-14, 2004, at the Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland. The morning session on October 13 was closed to the public so that NRC staff could provide the ACMUI with its required annual ethics briefing, and also discuss other issues not appropriately discussed in an open, public forum. During the open, public forum, the agenda items discussed included such diverse topics as, "Radiation Safety Aspects of Iodine-125 Therapeutic Seeds Used as Markers in Breast Cancer Tumors"; "Update to Medical Event Criteria Definition"; "Draft Final 10 CFR Part 35 Training & Experience: Status of Rulemaking; Proposed Changes to the Abnormal Occurrence Criteria"; and "Radioimmunotherapy and Microsphere Therapy."

The agenda items generated much useful discussion among the ACMUI, the NRC staff, and members of the public in attendance. In addition to the fruitful discussions between the ACMUI and the NRC staff, the ACMUI Chair expressed his appreciation, on behalf of the members, regarding the improved relations between the committee and NRC staff, and thanked NRC management for its efforts in cultivating a relationship that continues to evolve.

A summary of the October 13-14, 2004 meeting can be viewed at <http://www.nrc.gov/what-we-do/regulatory/advisory/acmui.html>

(Contact: Angela R. McIntosh, 301-415-5030; e-mail: arm@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The NRC's enforcement program can be accessed via the U. S. Nuclear Regulatory Commission's (NRC's) homepage [<http://www.nrc.gov/>] under "What We Do." Documents related to cases can be accessed at [<http://www.nrc.gov/>], "Electronic Reading Room," "Documents in ADAMS." ADAMS is the Agency wide Document Access and Management System. Help in using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

Gauges

Dominion Geotechnical Services, Inc. (EA-04-165)

On October 14, 2004, a Notice of Violation was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of licensed material. Specifically, 333 megabecquerel (MBq) (9 millicuries) of cesium-137, and 1628 MBq (44 millicuries) of americium-241, contained in a moisture density gauge that was in an unrestricted area that was not in storage.

Irradiator

Baxter Healthcare Corporation (EA-04-118)

On October 25, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$44,000 was issued for two willful Severity Level II violations (assessed \$28,800 for three occurrences of failure to adhere to emergency procedures and \$9,600 for failure to perform an adequate survey), and a willful Severity Level III violation (\$6,000 for failure to provide an individual radiation monitoring device) related to an event involving personnel entering an irradiator when the source was stuck in an unshielded position.

Medical

University of Virginia (EA-04-149)

On October 5, 2004, a Notice of Violation was issued for a Severity Level III problem involving the failure to secure licensed material (iridium-192 seeds contained in a nylon ribbon) and the failure to perform an adequate survey of the patient and the patient's room.

William Beaumont Hospital (EA-04-129)

On September 14, 2004, a Notice of Violation was issued for a Severity Level III violation involving the administration of a dosage of liquid iodine-131 to a patient for a thyroid uptake study that was approximately 90 times larger than the 370 kilobecquerels (10 microcurie) dosage prescribed by the authorized user physician.

Other

Integrated Production Services (IPS), Inc. (EA-04-124)

On October 12, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,000 was issued for a Severity Level III violation involving the use of byproduct material in offshore waters without either: (1) following the reciprocity provisions of 10 CFR Part 150.20, which would have granted IPS an NRC general license to conduct activities permitted by its State of Louisiana license; or (2) obtaining a specific NRC license authorizing it to conduct licensed activities in offshore waters.

Soil Consultants, Inc. (EA-04-103)

On October 6, 2004, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$9,600 was issued for a Severity Level II violation for discrimination against an employee for engaging in certain protected activities (reporting safety concerns to his employer or to the NRC).

(General Contact: Sally Merchant, Office of Enforcement, 301-415-2747; e-mail: slm2@nrc.gov)

SELECTED FEDERAL REGISTER NOTICES (September 1, 2004 - November 30, 2004)

“Medical Use of Byproduct Material Minor Amendments: Extending Expiration Date for Subpart J,” 69 FR 55736, September 16, 2004.

(Contact: Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, 301-415-6233; e-mail: ant@nrc.gov)

“Export and Import of Nuclear Equipment and Radioactive Materials: Security Policies,” 69 FR 55785, September 16, 2004.

(Contact: Suzanne Schuyler-Hayes, Office of International Programs, 301-415-2333; e-mail: ssh@nrc.gov)

“Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments; Correction,” 69 FR 58038, September 29, 2004.

(Contact: Mary Adams, Office of Nuclear Material Safety and Safeguards, 301-415-7249; e-mail: mta@nrc.gov)

“Criminal History Check: Assessment of Application Fee,” 69 FR 58820, October 1, 2004.

(Contact: Patricia A. Smith, Security Branch, Office of Administration, 301-415-7739; e-mail: pas5@nrc.gov)

“List of Approved Fuel Storage Casks: NAC-MPC Revision, Confirmation of Effective Date,” 69 FR 61592, October 26, 2004.

(Contact: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, 301-415-6219, e-mail: jmm2@nrc.gov)

“Adjustment of Civil Penalties for Inflation,” 69 FR 62393, October 26, 2004.

(Contact: Shelly D. Cole, Office of the General Counsel, 301-415-2549; e-mail: sdc1@nrc.gov)

“Revision of the NRC Enforcement Policy,” 69 FR 62485, 26 October, 2004.

(Contact: Michael T. Lesar, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59; e-mail comments to: nrcrep@nrc.gov)

Draft Appendix C (DG-1138) to Regulatory Guide 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” Workshop. 69 FR 64115, 3 November, 2004.

(Contact: Mr. A. Singh, Office of Research, 301-415-0250; e-mail: axs3@nrc.gov)

Availability of draft proposed rule language, 10 CFR Parts 2, 30, 40, 50, 52, 63, 70, 72, 73, 76, and 150, “Protection of Safeguards Information,” 69 FR 67070, 16 November, 2004

(Contacts: Marjorie Rothschild, Division of Rulemaking and Fuel Cycle, 301-415-1633; e-mail: mur@nrc.gov or Bernard Stapleton, Office of Nuclear Security and Incident Response, 301-415-2432; e-mail: bws2@nrc.gov)

(General Contact: Michael K. Williamson, Office of Nuclear Material Safety and Safeguards, 301-415-6234; e-mail: mkw1@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (September 16, 2004 - December 8, 2004)

The following are summaries of U.S. Nuclear Regulatory Commission (NRC) generic communications issued to NMSS licensees. 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 - <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html>. Please note that this address is case-sensitive and must be entered exactly as shown. If you have any questions or comments about generic communications in general, please contact Ivelisse M. Cabrera, NMSS, at (301) 415-8152, or by e-mail: imc1@nrc.gov.

Bulletins (BLs)

No bulletins have been issued to date.

Information Notices (INs)

IN 2004-12, “Spent Fuel Rod Accountability,” was issued on June 25, 2004. This IN was sent to all holders of operating licenses for nuclear power reactors, research and test reactors, decommissioned sites storing spent fuel in a pool, and wet spent fuel storage sites. This notice informed addressees of issues at two reactor facilities regarding the effectiveness of the material control and accounting program.

(Technical Contacts: Todd Jackson, Region I, 610-337-5308; e-mail: tjj@nrc.gov or Martha Williams, NSIR, 301-415-7878; e-mail: msw2@nrc.gov)

IN 2004-13, “Registration, Use, and Quality Assurance Requirements for NRC-Certified Transportation Packages,” was issued on June 30, 2004. This IN was sent to all materials and decommissioning reactor licensees to clarify responsibilities regarding the packaging and transportation of licensed material, as delineated in 10 CFR Part 71. Specifically, this IN was issued to remind licensees of 10 CFR 71.12 requirements to notify NRC before the first use of NRC-approved transport packages (user registration), and to ensure licensees have copies of the current Certificates of Compliance, or other approval, and comply with all

their conditions prior to each transport; and, if necessary, to properly transfer licensed material prior to transport, or delivery to a carrier for transport.

(Technical Contacts: Cynthia Barr, NMSS, 301-415-4015; e-mail: csb2@nrc.gov or Tomas Herrera, NMSS, 301-415-7138; e-mail: txh1@nrc.gov)

IN 2004-18, “Recent Safety-Related Event at Panoramic Wet-Source-Storage Irradiator,” was issued on October 26, 2004. This IN was sent to all licensees authorized to possess and use sealed sources in panoramic wet-source-storage irradiators, and irradiator vendors to inform them of a recent safety-related incident at a panoramic wet-source-storage irradiator.

(Technical Contacts: Kathy Modes, Region I, 610-337-5251; e-mail: kad@nrc.gov or Betsy Ullrich, Region I, 610-337-5040; e-mail: exu@nrc.gov or Tom Decker, Region I - Atlanta Office, 404-562-4721; e-mail: trd@nrc.gov.)

Regulatory Issue Summaries (RIS’)

RIS 2004-17, “Revised Decay-in-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material,” was issued on November 23, 2004. This RIS was sent to all licensees regulated under 10 CFR Parts 30, 32, 33, and 50 to inform them of changes to the policy for authorizing decay-in-storage requirements for radioactive waste containing byproduct material with half-lives of less than 120 days.

(Technical Contacts: Angela R. McIntosh, NMSS, 301-415-5030; e-mail: arm@nrc.gov or Pamela J. Henderson, Region I, 610-337-6952; e-mail: pjh1@nrc.gov.)

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Please direct any comments/suggestions for material in this, and future newsletters to:
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