NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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NMSS Licensee Newsletter (June 2002)

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PUBLICATION OF 10 CFR PART 35, "MEDICAL USE OF BYPRODUCT MATERIAL"

On April 24, 2002, the U.S. Nuclear Regulatory Commission (NRC) published, in the *Federal Register*, the revised final rule of 10 CFR Part 35, "Medical Use of Byproduct Material." This final rule, designed to be both risk-informed and more performance-based, focuses the regulations on the medical procedures that pose higher risks to workers, patients, and the public, from a radiation-safety perspective. The regulations also eliminate some of the previous detailed requirements for those who perform lower-risk diagnostic medical procedures, such as bone or thyroid scans. This regulation becomes effective 6 months after the publication date in the *Federal Register* (i.e., by October 24, 2002). The Agreement States will have 3 years to implement the final rule after the publication date in the *Federal Register*.

Highlights of the revised rule are:

(1) Patient notification/reportable events—

Under the revised regulations, the term "medical event," referring to the administration of radioactive materials in a manner that differs substantially from the physician's direction, replaces the previous term "misadministration." The regulations continue to require that, when a medical event occurs, the licensee must notify NRC, the referring physician, and the affected patient, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Previously, the licensee was required to provide a written description of the medical event regardless of whether it was requested. Under the revision, the patient must be informed that such a description can be obtained from the licensee. Also, under the revision, if the physician is not the licensee, the licensee must provide a copy of the medical event record to the referring physician.

(2) Radiation Safety Committee—

Under the revised regulations, the Radiation Safety Committee is responsible for broad oversight of the uses of certain radioactive materials. However, the current specific responsibilities of the Radiation Safety Committee have been transferred from the Committee to licensee management. A Committee is still required for certain medical licensees performing two or more higher-risk activities, such as those used in the treatment of cancer. The regulations specify radiation safety goals or objectives for the Committee, but allow licensee management flexibility in implementing those goals.

(3) Physician's written directions—

Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the revised regulations require that licensees have written procedures for those activities involving higher risk. Licensees must develop and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician's written instructions.

(4) Training and experience—

Some of the training requirements for individuals performing diagnostic procedures using radioactive materials in unsealed form have been reduced, consistent with the lower risk associated with these procedures. However, the revised regulations retain the current training requirements for individuals using sealed sources of radioactive material for therapeutic administrations because of the higher risk associated with using these types of material. The training and experience requirements contained in Subpart J of the current regulation are also being retained for a 2-year transition period from the effective date of the revised rule. For Agreement States, this 2-year transition period begins on the effective date of the revised rule and runs concurrently with the 3-year timeframe for adopting a compatible medical rule.

The revised rule also addresses a petition for rulemaking filed by the University of Cincinnati. The petition requested a 5-millisievert (mSv) (500-millirem) radiation dose limit for certain individuals (whom the physicians have determined are necessary for the patients' physical or emotional support) visiting patients who are required to be confined to the hospital while receiving radiation treatment. The response to the petition, incorporated into the rule, allows physicians the discretion to permit visitors to receive up to 5 mSv (500 millirem) from exposure to a hospitalized patient. The current limit of 1 mSv (100 millirems) per year for visitors is the same as for members of the public under other circumstances. The Agency believes the emotional benefits to the patients and the visitors outweigh any small increases in radiation risk to the visitors, and, accordingly, physicians should be provided the flexibility to make decisions regarding patients' visitors. In addition, the revised rule adds a requirement for reporting unintended medical radiation exposure of an embryo, fetus, or nursing child.

Revised Part 35 can be viewed at:
http://ruleforum.llnl.gov/cgi-bin/library?source=&library=final_lib&file=**

(Contact: Roger W. Broseus, 301-415-7608; e-mail: rwb@nrc.gov)

STATUS OF GAS CENTRIFUGE ENRICHMENT ACTIVITIES

Background

Enrichment of uranium in the United States has been performed since the 1950s at three gaseous diffusion plants in Oak Ridge, Tennessee; Piketon, Ohio; and Paducah, Kentucky. Currently, only the Paducah plant, operated by U.S. Enrichment Corporation (USEC), is still enriching uranium in the U.S. Gaseous diffusion technology has been effectively used over the last 50 years, but is energy-intensive and more expensive than the gas centrifuge enrichment currently being used by Urenco in the United Kingdom, Germany, and The Netherlands. Over the last 15 years, uranium enrichment has become a very competitive industry. Until 1998, the Federal government operated the enrichment plants in the U.S. under the auspices of the U.S. Department of Energy (DOE), and its predecessors, and USEC, as a Federal corporation. In 1998, the Federal government privatized USEC through an Initial Public Offering process.

In the 1980s, DOE developed a gas centrifuge program, including construction of a test cascade at the Piketon enrichment plant. However, in 1986, DOE decided to drop gas centrifuge in favor of the Advanced Vapor Laser Isotope Separation (AVLIS) process. Research on the AVLIS process continued until 2000, when USEC, which had acquired the rights to the process in its privatization, decided to terminate the program because it did not believe a full-scale plant would provide an adequate rate of return on its investment. Instead, USEC began to reconsider gas centrifuge technology as a more practical advanced enrichment technology to replace the gaseous diffusion process.

In the early 1990s, Urenco teamed up with several U.S. utilities to form the Louisiana Energy Services (LES) partnership. LES submitted a license application for a 1.5 million Separative Work Unit (SWU) plant to be sited in Homer, Louisiana. As a result of an extended licensing hearing process, in 1998, LES decided to terminate the licensing action.

The LES Program

In December 2001, LES informed the U.S. Nuclear Regulatory Commission (NRC) that it intended to submit, in 2002, a license application for a gas centrifuge plant, using the technology it had developed in Europe.

LES considers that there was a market need for low-cost, reliable enrichment capacity within the U.S. Based on LES experience in using gas centrifuge enrichment in Europe, it wants to license and construct at least a 3-million SWU plant and begin production in 2007. The plant would consist of six 500,000-SWU cascades.

The LES partnership is made up of limited and general partners currently consisting of Urenco, Exelon, Duke Power, Louisiana Power and Light, and Fluor Daniel. The partnership intends to use sixth-generation Urenco gas centrifuge technology that is currently operating in Europe. Presently, Urenco has a capacity of about 5 million SWU (about 15 percent of the world enrichment market) and provides enrichment services in Western Europe, the U.S., and Asia.

LES plans to submit, to NRC, a license application and an environmental report in 2002. LES projects license approval in the second or third quarter of Calendar Year (CY) 2004, with construction beginning in third or fourth quarter CY 2004. The first 500,000-SWU cascade is planned to be on-line by the end of CY 2006. Full capacity is projected to be in 2010 or 2011, depending on market demand. LES has not yet selected a site for its enrichment facility, but indicated it would be co-located with an existing nuclear facility.

The USEC Program

In January 2002, USEC informed NRC, that it would submit a license application for a lead cascade plant in late 2002. The lead cascade will be based on DOE Advanced Gas Centrifuge technology. In the 1980s, more than 1300 gas centrifuges were installed and 700 operated with uranium hexafluoride at the Gas Centrifuge Enrichment Plant in Piketon, Ohio. About 100 machines operated for 9 months. The USEC objective is to replicate the existing technology and reduce costs using advances in carbon fiber and other material and manufacturing technologies. It is not to develop a new technology.

The USEC program would be performed in three phases: (1) a demonstration program under DOE auspices and regulatory control; (2) the lead cascade phase; and a (3) commercial deployment phase. The demonstration phase is intended to obtain detailed test data for the gas centrifuge machines. The lead cascade program is intended to provide reliability information on the machines and auxiliary systems as it would be used in commercial operations. The plant would recycle tails and product with no production withdrawals except for sampling. Up to 240 gas centrifuge machines would be used in the lead cascade and have a possession limit of 250 kg (500 lbs) uranium hexafluoride at an enrichment level consistent with the current gaseous diffusion plants. The commercial plant would have a capacity of 3.5 million SWU per year, with up to 10 percent enrichment. USEC plans to submit a license application for the commercial-scale license in 2004. At this time, USEC has not decided on sites for the two facilities. A siting decision would be made as part of preparing the license application.

(Contact: Timothy Johnson, 301-415-7299; e-mail: tcj@nrc.gov)

DOSIMETRY PROCESSING LABORATORIES—REVISION OF ANSI STANDARD FOR PROFICIENCY TESTING

The U.S. Nuclear Regulatory Commission (NRC) and the National Institute of Standards and Technology, through an Interagency Agreement, provide an accreditation program for processors of personnel dosimeters. That accreditation program is known as the National Voluntary Laboratory Accreditation Program (NVLAP) for Ionizing Radiation Dosimetry. NRC's regulations (10 CFR 20.1501) require that personnel dosimeters that need to be processed to determine dose must be processed and evaluated by a dosimetry processor that holds current personnel dosimetry accreditation from NVLAP.

The standard used by NVLAP for testing and accrediting personnel dosimetry processors has been revised. The revised standard, ANSI/HPS N13.11-2001, "Personnel Dosimetry Performance—Criteria for Testing," has been adopted by NVLAP in the accreditation process. The phase-in period will begin July 1, 2002, and conclude June 30, 2004. During the phase-in period, dosimetry-processing laboratories will be tested against the revised standard when their normal accreditation dates come due. Any laboratory that fails the proficiency test because of changes made in the revised standard will not have its accreditation suspended, but will be given the opportunity to retest and pass those failed categories before June 30, 2004, to maintain accredited status. However, any failure of proficiency testing during this phase-in period not attributable to changes in the test standard could affect the laboratory's accreditation status, as is the current practice.

A copy of the revised standard, ANSI/HPS N13.11-2001, is available for a fee from the Health Physics Society at the following internet address: http://www.hps.org. For further information on the implementation of the revised standard, contact Carroll S. Brickenkamp, National Institute of Standards and Technology, Department of Commerce, NVLAP, Building 820, Room 286, Gaithersburg, MD 20899, telephone 301- 975-4291, e-mail: cbrickenkamp@nist.gov.

(Contact: Betty Ann Torres, 301-415-0191; e-mail: bat@nrc.gov)

USE OF NUREG-1556, "CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES," BY LICENSEES, APPLICANTS AND AGREEMENT STATE REGULATORS

Note: This is a reprint of an article from the December 2001-January 2002 issue.

The United States Nuclear Regulatory Commission (NRC) has produced a series of technical reports (NUREG-1556 series, "Consolidated Guidance about Materials Licenses") providing program-specific guidance. The series contains 20 volumes intended to facilitate the processes of license application, NRC review of applications, renewal of licenses, and NRC inspection of licensees. This series of NUREGs also provides a comprehensive source of reference information about materials regulations for those involved in various aspects of licensed materials use. The NUREGs are reviewed and, if necessary, revised every 3 years.

All 20 NUREGs, with the exception of Volume 9, "Program-Specific Guidance About Medical Use Licenses," have been published in final form. Volume 9 will be issued for a 60-day public comment period and finalized after comments have been considered. Development of the NUREG-1556 series supports NRC's performance goals of maintaining safety, improving public confidence, and increasing efficiency, effectiveness, and realism, as well as reducing unnecessary regulatory burden.

NRC strongly encourages current licensees, applicants for licenses, and Agreement State regulators to use the NUREG-1556 guidance documents in preparing new and renewal applications. We believe that use of these documents will make the NRC staff's review of these applications and inspections more effective and efficient. It is particularly important that licensees and applicants use these documents, because they

supersede much of the guidance previously used for licensing. NRC's report, "Phase II—Byproduct Materials Review," August 2001, specifically recommended that NRC take a pro-active posture by encouraging licensees to use the NUREG-1556 documents as a means of improving the process for materials licensing. Future license renewal letters will strongly request that licensees use the NUREG-1556 documents in preparing applications.

The NUREGs are available electronically by visiting NRC's Home Page (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/). For your convenience, a list of these NUREGs follows:

Vol. No.	Volume Title	Final Published
1, Rev. 1	"Program-Specific Guidance about Portable Gauge Licenses"	11/01
2	"Program-Specific Guidance about Radiography Licenses"	08/98
3	"Applications for Sealed Source and Device Evaluation and Registration"	07/98
4	"Program-Specific Guidance about Fixed Gauge Licenses"	10/98
5	"Program-Specific Guidance about Self-Shielded Irradiators"	10/98
6	"Program-Specific Guidance about 10 CFR Part 36 Irradiators"	01/99
7	"Program-Specific Guidance about Academic, Research and Development, and Other Licenses of Limited Scope"	12/99
8	"Program-Specific Guidance about Exempt Distribution Licenses"	09/98
9	"Program-Specific Guidance about Medical Use Licenses"	Draft
10	"Program-Specific Guidance about Master Material Licenses"	12/00
11	"Program-Specific Guidance about Licenses of Broad Scope"	04/99
12	"Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution"	12/00
13	"Program-Specific Guidance about Commercial Radiopharmacy Licenses"	09/99
14	"Program-Specific Guidance about Well Logging, Tracer, and Field Flood Study Licenses"	06/00
15	"Guidance about Changes of Control and about Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses"	11/00
16	"Program-Specific Guidance about Licenses Authorizing Distribution to General Licensees"	12/00
17	"Program-Specific Guidance about Licenses for Special Nuclear Material of Less Than Critical Mass"	11/00
18	"Program-Specific Guidance about Service Provider Licenses"	11/00
19	"Guidance for Agreement State Licensees Proposing to Work in NRC Jurisdiction (Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters) and Guidance for NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)"	12/00
20	"Guidance about Administrative Licensing Procedures"	12/00

(Contact: Carrie Brown, 301-415-8092; e-mail: cxb@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The U.S. Nuclear Regulatory Commission's (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." Cases are listed under "Enforcement Documents," which can be accessed at *http://www.nrc.gov/reading-rm/doc-collections/enforcement/*. Additionally, 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, telephones: 301-415-4737, or 1-800-397-4209.

Medical

Providence Hospital (EA 01-157)

On March 22, 2002, a Notice of Violation was issued for a Severity Level III problem based on multiple failures involving the licensee's quality management program for the strontium-90 eye applicator program, which had resulted in 14 misadministrations.

González Martínez Oncologic Hospital
EA-02-001 and EA-02-002

On March 12, 2002, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $7500 was issued for a Severity Level III problem involving multiple violations associated with the failure to secure (loss of) licensed material [a radioactive implant containing approximately 3.6 gigabecquerels (97 millicuries) of cesium-137], for approximately 19 hours. A Notice of Violation was also issued for a Severity Level III violation, for failure to notify NRC of the missing material within the required time limit.

Other

Department of the Army (EA 02-017)

On March 28, 2002, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, licensed material [approximately 1.3 gigabecquerels (34 millicuries) of cobalt-60] and the failure to control and maintain constant surveillance of this licensed material.

Individual Actions

Gerald Williams (IA 01-049)

On December 3, 2001, a Notice of Violation was issued for a Severity Level III violation involving an individual's activities while employed at Centennial Engineering & Research, Inc. The individual deliberately caused his employer to be in violation of NRC requirements when he failed to: (1) submit an amendment request to reflect the designation of a new radiation safety officer; and (2) confine possession of byproduct material to the location authorized by the license.

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

SIGNIFICANT EVENTS

The U.S. Nuclear Regulatory Commission (NRC) is providing summaries of these events to inform licensees of conditions they may encounter and of actions that may be taken to deal with them.

Event 1: Gamma Stereotactic Radiosurgery (Gamma Knife) Medical Event at Saint Luke's Medical Center, Milwaukee, Wisconsin

Date and Place: July 10, 2001; Saint Luke's Medical Center; Milwaukee, Wisconsin.

Nature and Probable Consequences: The licensee reported a medical event involving a patient who received a Cobalt-60 gamma knife treatment to the wrong treatment site. Two patients were prepared for treatment, but the wrong treatment plan was used for the first patient. Approximately 3.5 treatment fractions (of a total of eight fractions) were administered to the wrong site before it was discovered that the wrong treatment plan was being used. The patient received approximately 1280 centigray (rad) to the 50% isodose line, over a short period of time, to a small area of the brain. The patient subsequently received the correct treatment.

The attending physician and the patient were notified on July 11, 2001. The root cause of this event was the failure to verify that the treatment plan used was for the patient being treated. NRC contracted a medical consultant to review this event. The consultant concluded that the dose to the 50% isodose line may be at the threshold of late central nervous system injury and the dose of approximately 2500 cGy (rad) to the 100% isodose line may produce symptoms. The consultant also concluded that long-term follow-up was indicated and that the patient is eligible for the U.S. Department of Energy, Office of Epidemiology and Health Surveillance, Long-term Medical Study Program.

Actions Taken to Prevent Recurrence

Licensee: Corrective actions include a more prominent display of the patient's name on the treatment forms, triple verification of each treatment coordinate, and physician sign-off that the treatment plan matches the patient being treated.

NRC: NRC conducted a special inspection on July 12 through July 27, 2001, with continuing review through November 9, 2001. NRC identified two Severity Level IV violations for failure to verify that the treatment parameters implemented were for the patient being treated. The inspectors also determined that this medical event constituted an isolated failure to properly implement the Quality Management Program written procedures.

(Contact: Roberto Torres, NMSS, 301-415-8112; e-mail: rjt@nrc.gov)

GENERIC COMMUNICATIONS ISSUED (February 1, 2002 - April 30, 2002)

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/reading-rm/doc-collections/gen-comm/*.

Please note that this address is case-sensitive and must be entered exactly as shown.

Information Notice (IN)

IN 1999-28, Supplement 1, "Recall of Star Brand Fire Protection Sprinkler Heads," was issued on March 22, 2002. This notice was issued to all holders of licenses for nuclear power, research and test reactors, and fuel cycle facilities, to notify them that the Consumers Product Safety Commission is seeking to expand the original recall of the Star brand fire protection sprinkler heads. This supplement provides information that came to light after the issuance of the original IN.

(Contacts: Paul Lain, NRR, 301-415-2346, e-mail: pwl@nrc.gov;
Peter Lee, NMSS, 301-415-8111, e-mail: psl1@nrc.gov)

Regulatory Issue Summary (RIS)

RIS 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays," was issued on April 16, 2002. This summary was issued to all medical licensees to inform them of a personnel radiation monitoring compliance issue identified during recent inspections of medical licensees. In addition, this RIS provides specific guidance for determining doses to individuals who receive exposures from medical x-ray radiation, while wearing protective apparel (i.e., protective apron, or protective apron and thyroid shield).

(Contact: Joseph E. DeCicco, NMSS, 301-415-7833, e-mail: jdx1@nrc.gov)

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

SELECTED *FEDERAL REGISTER* NOTICES (March 1, 2002 - March 31, 2002)

NOTE: U.S. Nuclear Regulatory Commission (NRC) contacts may be reached by mail at the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. *Federal Register* Notices may be found at *http://www.access.gpo.gov/su_docs/aces/aces140.html*.

FINAL RULES

"List of Approved Spent Fuel Storage Casks: NAC-MPC Revision," 67 FR 11566, March 15, 2002. (Contact: Roger W. Broseus, NMSS, 301-415-7608; e-mail: rwb@nrc.gov)

"List of Approved Spent Fuel Storage Casks: HI-STORM 100 Revision," 67 FR 14627, March 27, 2002. (Contact: Jayne M. McCausland, NMSS, 301-415-6219; e-mail: jmm2@nrc.gov)

"Correction: Revision of Fee Schedules; Fee Recovery for FY 2002," 67 FR 14818, March 27, 2002.

PROPOSED RULES

"List of Approved Spent Fuel Storage Casks: NAC-MPC Revision," 67 FR 11629, March 15, 2002. (Contact: Roger W. Broseus, NMSS, 301-415-7608; e-mail: rwb@nrc.gov)

"List of Approved Spent Fuel Storage Casks: HI-STORM 100 Revision," 67 FR 14662, March 27, 2002. (Contact: Jayne M. McCausland, NMSS, 301-415-6219; e-mail: jmm2@nrc.gov)

OTHER NOTICES

The States of Nevada and Minnesota; Denial of Petition for Rulemaking, 67 FR 10853, March 11, 2002. (Contacts: Mark Haisfield, NMSS, 301-415-6196; e-mail: mfh@nrc.gov; Timothy McCartin, NMSS, 301-415-7285; e-mail: tjm3@nrc.gov)

" 'Yucca Mountain Review Plan, NUREG-1804, Revision 2;' Draft Report for Comment," 67 FR 15257, March, 29, 2002. (Contact: Jeffrey A. Ciocco, NMSS, 301-415-6391; e-mail: jac3@nrc.gov)

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

Comments, and suggestions you may have for information not currently included, that might be helpful to licensees, should be sent to:
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