NMSS Licensee Newsletter

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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LOUISIANA ENERGY SERVICES GAS CENTRIFUGE URANIUM ENRICHMENT FACILITY LICENSE ISSUED

On December 15, 2003, Louisiana Energy Services (LES) submitted a license application for a proposed gas centrifuge uranium enrichment plant to be located in Lea County, New Mexico. LES proposed to use gas centrifuge technology developed by Urenco in Europe. Urenco has been operating gas centrifuge enrichment facilities for over 30 years in the United Kingdom, the Netherlands, and Germany. The proposed plant would have a capacity of 3 million Separative Work Units and would produce enrichments up to 5 percent uranium-235.

On June 15, 2005, staff completed its safety and environmental reviews and issued its "Safety Evaluation Report for the National Enrichment Facility in Lea County, New Mexico," NUREG-1827, and the "Final Environmental Impact Statement for the Proposed National Enrichment Facility in Lea County, New Mexico," NUREG-1790. After completion of contested and mandatory hearings before the Atomic Safety and Licensing Board (ASLB), the license was issued on June 23, 2006. This licensing action was completed within the 30-month schedule set out by the Commission.

In response to a January 30, 2004, notice offering an opportunity to intervene in the proceeding, petitions were submitted by: (1) the New Mexico Environment Department; (2) the New Mexico Attorney General; and (3) Nuclear Information and Resource Service (NIRS) and Public Citizen (PC) (combined petition). The contentions that were admitted were in the areas of: (a) LES' proposed radiation protection program, (b) disposal cost estimates, (c) impacts on ground and surface water, (d) impact on water supplies, (e) depleted uranium storage and disposal, (f) decommissioning costs, (g) need for the facility, and (h) natural gas pipeline accidents. In August 2005, the New Mexico

agencies settled with LES and withdrew from the proceeding. Under the agreement, LES agreed to limits for storage of depleted uranium, and overfunding the decommissioning funding plan. The ASLB held evidentiary hearings on the contentions in February 2005, October 2005, and February 2006.

In addition to the contested hearing on the admitted contentions, uranium enrichment facility licensing actions also require a mandatory hearing in which the ASLB evaluates whether the U.S. Nuclear Regulatory Commission (NRC) staff's safety and environmental reviews are adequate. The evidentiary part of the mandatory hearing was held in March 2006.

On May 31, 2006, the ASLB issued its final decisions on the contested hearing in favor of LES and the NRC staff. On June 23, 2006, it issued its decision on the mandatory hearing, finding that the NRC staff had performed adequate environmental and safety reviews. Based on these decisions, on June 23, 2006, the staff issued a license to LES to construct and operate the gas centrifuge uranium enrichment facility. On June 12, 2006, NIRS/PC appealed the contested hearing decision to the Commission.

LES now plans to begin construction of its plant in August 2006 and begin operations in late 2008. Full-capacity operation is expected in 2013. At this time, LES has sold over 80 percent of its planned capacity for the first 10 years of operation.

(Contact: Timothy C. Johnson, Office of Fuel Cycle Safety and Safeguards, 301-415-7299, e-mail: tcj@nrc.gov)

CLARIFICATION OF WORK EXPERIENCE IN MEDICAL USE OF BYPRODUCT MATERIAL

Paragraph (c)(1) of 10 CFR 35.290, "Training for imaging and localization studies," requires physicians seeking approval as authorized users of unsealed byproduct material for imaging and localization studies to complete classroom and laboratory training and supervised work experience in specific topics and tasks. Similar training specifications are outlined in 10 CFR 35.190(c)(1) and 35.390(b)(1).

The NRC and its Advisory Committee on the Medical Uses of Isotopes believe that hands-on work experience forms a critical cornerstone of any complete radiation safety program. Thus, individuals seeking approval as authorized users for the medical use of byproduct material must demonstrate hands-on work experience where they perform the tasks listed in the regulations describing the supervised work experience requirements. Mere observation is insufficient to fulfill this requirement. For example, 10 CFR 35.290(c)(1)(ii)(F) requires individuals seeking approval as authorized users to demonstrate work experience involving "administering dosages of radioactive drugs to patients or human research subjects." In this case, applicants must personally administer the dosage to the patient. Similarly, under 10 CFR 35.290(c)(1)(ii)(G), applicants must physically elute the generator system, perform the measuring and testing of the eluate, and process the eluate with reagent kits to prepare radioactive drugs.

Licensees are encouraged to refer to 10 CFR Part 35 for additional detail on these training requirements.

(Contact: Cindy Flannery, Office of Nuclear Material Safety and Safeguards, 301-415-0223; e-mail: cmf@nrc.gov)

AVAILABILITY OF RADIOACTIVE SEED LOCALIZATION GUIDANCE

Recently, guidance was developed for a 10 CFR 35.1000 medical-use procedure called radioactive seed localization. The purpose of radioactive seed localization of non-palpable lesions (i.e., an area of suspicious tissue detected by mammography that needs further evaluation) is to localize suspicious tissues for excision with the use of radioactive seeds.

This technique uses radioactive seeds previously approved for brachytherapy. Typically, iodine-125 and palladium-103 seeds between 7.4 - 11.1 megabecquerel (200 – 300 μCi)/seed are implanted into a breast lesion using a standard 18-gauge needle. These seeds are normally implanted within mammography or ultrasound suites and removed within surgical suites between 2 and 5 days post implantation. The radioactive seed(s) are located with appropriate instrumentation (using a technique similar to sentinel lymph node biopsy and radioguided parathyroidectomy) and surgically removed with minimal injury to non-affected tissue. The seed(s) may be removed from the tissue specimen in surgery, or the tissue specimen containing the seed(s) can be sent to pathology for removal of the seed and analysis of the tissue. The seed or seeds are then disposed of in accordance with 10 CFR 35.92 or the equivalent Agreement State regulations.

The guidance is available at any one of the following websites:

- *NRC's medical user's Licensee Toolkit at http://www.nrc.gov/materials/miau/ med-use-toolkit. html;*
- *NRC's Office of State and Tribal Programs website at http://nrc-stp.ornl.gov/materials. html; and*
- *The Organization of Agreement States website at http://www.agreementstates.org/whatsnew.html.*

Licensees desiring to use radioactive seed localization must submit an amendment request for this 10 CFR 35.1000 medical use to the appropriate NRC regional office.

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

THE ENERGY POLICY ACT (EPAct), SECTION 656, "SECURE TRANSFER of NUCLEAR MATERIAL," and SECTION 652, "FINGERPRINTING and CRIMINAL HISTORY RECORD CHECKS"

On August 8, 2005, the President signed the EPAct of 2005 into law. In the legislation, two sections, 656 and 652, relate to fingerprinting and background checks.

During the Section 656 rulemaking, recently issued as a proposed rule, the Commission has determined that manifest requirements are already covered by existing Department of Transportation (DOT) and NRC regulations. In addition, it was determined that the most appropriate and comprehensive approach for establishing requirements for security background checks is part of the broader considerations of NRC's planned rulemaking to implement Section 652 of the EPAct. The individuals referred to under Section 656 are a subgroup (i.e., those transferring radioactive material pursuant to an export or import license) of the larger group of individuals at a licensed facility, that have unescorted access to radioactive material, who would ultimately be included under a Section 652 rulemaking. The goal of the Section 652 rulemaking is to develop requirements for access that are coherent, and use a graded approach for the wide range of licensees impacted by Section 652. Individuals affected in this section are those who might import or export radioactive material. Section 652 will also address the need for coordinated consideration of appropriate exceptions for domestic import/export transport.

Additionally, as noted in Section 656, the Commission is proposing to amend its regulations to except from the security background check requirements of Section 170I of the Atomic Energy Act (AEA), as amended, licensees who have not received NRC Orders restricting unescorted access to radioactive materials based on background checks for trustworthiness and reliability that include fingerprinting and criminal history record checks. As of May 2006, Orders issued regarding unescorted access to radioactive materials have only been based on background checks that do not include fingerprinting. However, it is anticipated that Orders restricting access based on fingerprinting and criminal history record checks will be prepared for certain licensees. Under this proposed rule, those licensees who did not receive Orders for both fingerprinting and background checks would be excepted from the security background check requirements of Section 170I of the AEA .

The current schedule for the rulemaking to implement Section 652 calls for issuance of a proposed rule in late 2007, and a final rule in late 2008. While the more comprehensive Section 652 rulemaking is being conducted, the combination of NRC's system of Orders to a broad range of licensees setting conditions for access to radioactive material, as well as the system of security regulations under the Department of Homeland Security and the DOT for transport personnel, provide adequate protection of the common defense and security, as they relate to persons accompanying and receiving material.

The rulemaking package for Section 656 was provided to the Commission on June 20, 2006, in SECY-06-0139. This draft version of the rule was placed on NRC's RuleForum website for information on July 6, 2006. On August 30, 2006, the proposed rule on Section 656 was issued in the Federal Register for public comment (71FR51534). The public comment period closes on September 29, 2006. It is anticipated that a final rule implementing Section 656 will be issued in late 2006. NRC staff is currently preparing the technical basis to support implementation of Section 652 of the EPAct. As noted above, it is anticipated that a proposed rule will be issued in late 2007, and a final rule is anticipated in late 2008.

(Contact: Frank Cardile, Office of Nuclear Material Safety and Safeguards, 301-415-6185, e-mail: fpc@nrc.gov)

ENSURING THE COMPLETENESS AND ACCURACY OF ATTESTATIONS FOR RECOGNIZING AUTHORIZED INDIVIDUALS

The regulations in 10 CFR Part 35 identify two main pathways for individuals seeking recognition as an authorized individual (i.e., authorized user, authorized medical physicist, radiation safety officer, or authorized nuclear pharmacist). The first pathway, the board certification pathway, is for individuals who have received certification from a board whose certification process is recognized by the NRC. The other, referred to as the alternate pathway, involves demonstration directly to the NRC of the completion by the individual of the training and experience requirements specified in the rule for the particular authorization being sought.

For an individual to gain status as an authorized individual under the board certification pathway, the combined efforts of the certification boards, training Program Directors, preceptors, and the proposed authorized individual are needed. NRC realizes and appreciates that the vast majority of certification boards, training Program Directors, preceptors, and proposed authorized individuals strive to ensure that proposed authorized individuals have completed the required training and supervised work experience that is necessary for continued protection of the public health and safety. Nevertheless, NRC staff wishes to remind all of these parties of their individual roles in assuring truthful complete and accurate representations.

A certificate issued to an individual by a certification board with a recognized certification process indicates that an applicant is qualified to be designated by NRC as an authorized individual. The certificate is relied upon by NRC in making a regulatory decision. It is a representation to NRC that the individual has completed training and supervised work experience that includes all of the hours, in all of the topics, specified by NRC regulations. Such statements must be complete and accurate in all material respects.

Certification boards recognized by the NRC should ensure that all candidates for certification fulfill NRC's certification pathway training and experience requirements. It is the role of the Program Directors of the various training programs (e.g., radiology, nuclear medicine, radiation oncology), to assure that information supplied to the certification boards about training and experience completed by applicants for certification is accurate. Similarly, NRC relies on the truthful and accurate attestations of the preceptors for individuals seeking authorization under the board certification and the alternate pathways.

If a certification board becomes aware of training programs that are not including all the topics, or specified training time, or actual supervised work experience that is necessary for the certification candidates to meet the necessary NRC certification pathway training and experience requirements, the certification board should deny certification to these individuals, until they complete the required training and experience. Furthermore, for training programs that are residency programs, the certification board should consult with the Residency Review Committee if the certification board becomes aware of any inadequacy of training in those programs.

Each training Program Director and preceptor who verifies the training and experience for a proposed authorized individual must, to the best of his or her professional ability and judgment, determine that the candidate has actually received the training and supervised work experience claimed. Program Directors and preceptors are encouraged to take reasonable measures to ensure that proposed authorized individuals have completed all of the required training and supervised work experience (e.g., contacting individuals providing the training and supervised work experience). Further, proposed authorized individuals must provide complete and accurate documentation of their own training and experience, and should cooperate in the attestation process so that the Program Director and preceptor will have a thorough understanding of the specific training and experience that the proposed authorized individual has received.

Cognizant persons (e.g., Certification Boards, Program Directors, preceptors) should notify NRC if they become aware of any proposed authorized individual who is misrepresenting his or her own training and supervised work experience, or of any other Program Director or preceptor who is making inaccurate attestations about the completion of training and supervised work experience. False attestations and misrepresentations may cause a violation of 10 CFR 30.9 or 30.10, and violate 18 U.S.C 2001.

(Contact: Cindy Flannery, Office of Nuclear Material Safety & Safeguards, 301-415-0223; e-mail: cmf@nrc.gov)

PROPOSED RULE: REGULATORY IMPROVEMENTS TO THE NUCLEAR MATERIALS MANAGEMENT AND SAFEGUARDS SYSTEM

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to licensee reporting requirements for source material and special nuclear material (SNM) to the Nuclear Materials Management and Safeguards System (NMMSS). The amendments are needed to improve the accuracy of material inventory information maintained in the NMMSS. The annual reporting requirements would be new requirements for licensees that possess 350 grams or less, of SNM. However, the proposed changes would reduce some reporting burden on licensees subject to current reporting requirements. The NRC expects to publish the proposed rule for comments, in early 2007.

The NMMSS is the national database used in the United States by NRC licensees, Agreement State licensees, and U.S. Department of Energy (DOE) contractors, to report the possession of certain SNM and source material. The NRC reporting requirements related to the NMMSS are primarily contained in 10 CFR Parts 40, 72, 74, 75, 76, and 150. Using licensee submittals, the NMMSS database serves two important functions: meeting international reporting obligations, and assisting in the oversight of licensee material control and accounting (MC&A) programs required by 10 CFR Parts 40, 72, 74, 75, and 150.

PROPOSED AMENDMENTS

The following sections summarize the significant proposed changes to the regulations in 10 CFR Parts 40, 72, 74, and 150.

Special Nuclear Material Status Reports

Current: licensees are required by 10 CFR 74.13(a) to report annual SNM inventories to the NMMSS, only if they are authorized to possess more than 350 grams of SNM.

Proposed: would require annual reporting by licensees that possess 1 gram or more of SNM. Submission of material balance reports for licensees possessing less than 350 grams, no later than March 31 of each year.

Special Nuclear Material Transaction Reports

Current: licensees are required by 10 CFR 74.15(a) to report to the NMMSS whenever they transfer or receive one gram or more of SNM.

Proposed: would also require reporting to the NMMSS whenever a licensee makes an on-site adjustment to the SNM inventory by 1 gram or more. (The inventory adjustments may be due to decay, normal operational losses or accidental losses.)

Source Material Transaction Reports

Current: 10 CFR 40.64(a) requires submission of a Nuclear Material Transaction Report whenever a licensee transfers, receives, imports, exports or adjusts the inventory of foreign obligated source material by one kilogram or more.

Proposed: would also require reporting when a licensee uses 1 kilogram or more of source material in enrichment services, downblend material initially enriched in the U-235 isotope to 10 percent or more, or mixed oxide fuel fabrication, regardless of obligation.

Source Material Status Reports

Current: 10 CFR 40.64(b) requires annual source material inventory reports of foreign obligated source material for licensees authorized to possess more than 1000 kilograms of source material.

Proposed: would require annual reporting for licensees that possess1 kilogram or more of foreign obligated source material.

Reconciliation of Submitted Inventories

Current: reconciliation of NMMSS values and licensee inventories is in the guidance documents, not in the regulations.

Proposed: would require licensees to reconcile any inventory discrepancies identified by the NRC in the NMMSS database within 30 days of submission of licensee inventory information.

Reduction in Reporting Requirements for Material Shipments

Current: licensees who export reportable quantities of SNM or source material file both the shipper's and receiver's information on two separate forms when exporting nuclear material.

Proposed: licensees would be required to file only the shipper's information form unless a significant shipper/receiver difference, or, a theft or diversion is identified. This proposed change in reporting requirement would reduce the licensees' reporting burdens when shipping nuclear materials without significantly impacting the quality of the information reported to the database.

Upon Commission approval, the proposed rule will be published in the Federal Register for public comments.

(Contact: Neelam Bhalla, Nuclear Material Safety and Safeguards, 301-415-6843, e-mail: nxb@nrc.gov)

MEETING SUMMARY AND AVAILABILITY OF MEETING MATERIAL FROM FUEL CYCLE INFORMATION EXCHANGE 2006 (FCIX 2006)

The Nuclear Regulatory Commission (NRC) hosted a seminar on August 30 and 31, 2006 to provide an opportunity for licensees, NRC staff, and other stakeholders to exchange information and discuss issues of interest pertaining to the regulation of NRC-regulated fuel cycle facilities.

The seminar was held in Rockville, Maryland, at the Universities of Maryland at Shady Grove Campus Auditorium and was open to the public. The meeting notice and agenda can be found on the NRC Public Meeting web site: http://www.nrc.gov/public-involve/public-meetings/index.cfm.

Ninety four persons attended the meeting. The agenda items and presenters are listed below:

August 30, 2006

Safety Culture Importance of Safety Culture and Lessons Learned from Various Events
Martin Virgilio, NRC

Industry Perspectives
Marvin Fertel, NEI

The Future of the Fuel Cycle Industry
Joseph Giitter, NRC

Global Nuclear Energy Partnership (GNEP): Closing the Fuel Cycle While Reducing Proliferation Risk
David Henderson, DOE

Status Report of Current NRC Fuel Cycle Related Initiatives: Security, Emergency Preparedness, Licensee Performance and Evaluation, Enforcement Policy Changes and ISG-02
Robert Pierson, NRC

Revisions to the Fuel Facility Inspection Program and Procedures: Planned Changes to Inspection Manual Chapter (IMC) 2600, IMC 610, and Safety Inspection Procedures
Dr. William Travers, NRC
Douglas Collins, NRC

Fuel Cycle Security Activities: What Lies Ahead for Fuel Cycle Facilities from a Security Point of View
Robert Caldwell, NRC

Inspection and Enforcement Comments from the Fuel Cycle Industry
Randy Shackelford, NFS

Stakeholder Evaluation of Fuel Cycle Regulation
Joseph Giitter, NRC

Risk-Informed Decision-Making Process and Risk Guidelines for NMSS
Dr. Dennis Damon

Global Perspective of the Radiation Health Impact from the Fuel Cycle
Dr. Judith Johnsrud, Sierra Club

GNEP is a REALLY Bad Idea
Kevin Kamps, Nuclear Information and Resource Service (NIRS)

Impact of Increased Nuclear Energy in Domestic Energy Generation
Dr. David Manuta,
Manuta Chemical Consulting Inc.

August 31, 2006

ISA Summary Reviews, Lessons Learned and Best Practices: Lessons Learned by the NRC and What "Best Practices" Were Demonstrated From Review of ISA Summaries
James Smith, NRC

License Renewal Procedures New Draft ISG Under Development by the NRC to Address License Renewal Procedures Related to the New Subpart H
Steven Schilthelm, BWXT
Nick Baker, NRC

Databases and IROFS Tracking Systems: Discussion on AREVA's Experience In Using Computer Systems for IROFS Tracking
Robert Link, AREVA NP

Status of 10 CFR 70.72 Rulemaking Update on NRC Rulemaking and Guidance Development Efforts Related to 10 CFR 70.72(c)(2)
Melanie Galloway, NRC

International Guidance Documents: Summary of Recent NEA Guidance Documents and a Discussion of How the IAEA Prepares Safety Guides, Requirement Documents, and Standards and the Relevance of These Documents to NRC Licensees
Robert Pierson, NRC Yawar Faraz, NRC

Boundaries of IROFS: How LES and Other Licensees Have Developed Procedures Specific for Developing IROFS Boundary Packages
Stan Day, LES

Overview and Experience Under the NRC's New Hearing Process by Fuel Cycle Applicants and Licensees

Overview of the NRC's New Hearing Processes Based Upon Experience With Duke, Cogema, Stone & Webster's Mixed-Oxide Fuel Fabrication Facility and USEC Inc.'s American Centrifuge Plant

Overview of the Hearing Process in the Context of the Recent Issuance of a Combined License to Construct and Operate Louisiana Energy Services' National Enrichment Facility

Donald Silverman
Morgan, Lewis & Bockius
James Curtiss, Winston & Strawn

Electronic copies of the presentations used at the seminar can be obtained by contacting the staff member listed below.

(Contact: James Smith, Project Manager, Fuel Cycle Safety and Safeguards, Special Projects Branch Technical Support Section, 301-415-6459, Fax: 301-415-5370, e-mail: jas4@nrc.gov)

HIGH-LEVEL WASTE REPOSITORY SAFETY KNOWLEDGE MANAGEMENT PROGRAM

The Division of High Level Waste Repository Safety (HLWRS) in the Office of Nuclear Material Safety and Safeguards (NMSS) is developing and implementing a Knowledge Management strategy for capturing and organizing key information to support staff preparations for reviewing a potential license for the Yucca Mountain high-level waste repository. The HLWRS prelicensing review activities in the last two decades have resulted in a large knowledge base of technical and process information on Yucca Mountain. This includes a variety of documents related to NRC review processes (e.g., the Yucca Mountain Review Plan), and interactions with DOE (e.g., Key Technical Issues (KTI) agreements and DOE responses). In addition, the HLWRS program employs a number of subject matter experts (SMEs) with extensive institutional knowledge of the HLW program at the NRC and at the Center for Nuclear Waste Regulatory Analysis (CNWRA) who may retire or change jobs. As the projected license application submission date draws closer, it is important for a timely review to capture, recover, and disseminate efficiently to current and new staff members key relevant knowledge on issues, approaches, methods and models developed over the years.

A phased, progressive approach is being used for the HLWRS Knowledge Management (KM) and Knowledge Transfer (KT) strategies. A suite of issue tracking databases are being compiled that are based upon a foundation of existing publicly available HLW KTI documents. These preliminary databases will be converted to XML databases to provide broader accessibility and functionality for the HLWRS and CNWRA staff. Web-based classification tools are being developed based on in-depth knowledge of key scientific and engineering issues at Yucca Mountain. For example, a taxonomy that will be developed would be used as a dictionary to index documents and allow precision searches in different knowledge bases. The goal is to improve staff productivity and assist the staff in conducting a timely review of the potential license application within the time frame specified in the Nuclear Waste Policy Act.

Parallel to the above effort, the HLWRS continues its extensive technical reviewer qualification training program and anticipates supplementing the program with a virtual community of practice (CoP) in the NRC Knowledge Center (KC). A technical reviewer CoP was created in the KC, in which libraries of reviewer qualification session assignments, study guides and reading materials are organized and maintained. Training sessions were conducted to familiarize the division staff with the new knowledge management platform and environment in the KC. Other virtual communities, e.g., a knowledge transfer working group CoP, are being formulated and populated with knowledge bases.

Moreover, the staff plans to use the KC's online collaboration and project management features for both the prelicensing and licensing phases of the Yucca Mountain Project. The goal is to use the KC as an HLWRS knowledge store and a vehicle for efficient knowledge acquisition and dissemination.

The third aspect of the HLWRS KM and KT strategy and effort is to capture, recover and disseminate the knowledge of subject matter experts. New staff is teamed up with SMEs to ensure the transfer of knowledge as well as the eventual retention and succession of project responsibilities. Knowledge transfer seminars are prepared and presented by these SMEs. The seminar supporting materials are added to HLWRS knowledge bases and will be incorporated into the KC to become a searchable, multimedia library of lessons learned. Additionally, consultant arrangements can be made with retired SMEs, emphasizing knowledge transfer and recovery, such activities would include interviews with the SME in a format of questions and answers. The important knowledge that can be obtained from this process would be used in a lessons learned library in the KC.

The HLWRS KM and KT efforts are being coordinated with agency-wide efforts. As the HLWRS continues to implement its knowledge management and transfer strategy, teamwork and contributions from all the staff are the essential ingredients. A successful Knowledge management strategy contributing to the mission of the agency and individual division programs requires concerted and coordinated efforts and integration into the staff's routine business practices.

(Contact: Andrew C. Campbell, Ph.D., Division of High-Level Waste Repository Safety, 301-415-6897, Fax: 301-415-5399, e-mail: acc@nrc.gov)

WHAT'S NEW IN THE MEDICAL USES LICENSEE TOOLKIT

The Medical Uses Licensee Toolkit (http://www.nrc.gov/materials/miau/med-use-toolkit.html) has been updated to include new links or new information under the following two headings:

"Regulations and Medical Policy Statement"
(1) Correcting Amendment, Medical Use of Byproduct Material—Recognition of Specialty Boards; Correction, (71 FR 1926). This corrected 10 CFR Part 35 by inserting a reference that was inadvertently omitted in the final regulations amending the Commission's training and experience requirements in 10 CFR Part 35 published in the Federal Register March 30, 2005 (70 FR 16336). The correction was related to authorized medical physicists, authorized nuclear pharmacists, or authorized users who could be recognized as Radiation Safety Officers and was discussed in the last NMSS Newsletter.

(2) Final Rule, 10 CFR Parts 1, 13, 20, 30, 32, 35, 40, 55, 70, 73, 110, and 140, (71 FR 15005) which corrected several miscellaneous errors in the Code of Federal Regulations (CFR), update the address for Region III, and remove all references to Subpart J in Parts 32 and 35.

(3) The Proposed NARM RULE published in the Federal Register (71 FR 42952) which incorporates the new definition of byproduct material into NRC's regulations.

"Other Guidance"
(1) NRC recognized new medical specialty boards in the "Specialty Boards Certification Recognized by NRC" web page linked under this heading.

(2) Revised licensing guidance for 10 CFR 35.1000 sealed sources and devices to reflect that Proxima Therapeutics was purchased by Cytyc Corporation and the name of the product manufacturer has changed to Cytyc Surgical Products. The guidance also clarifies that the Cytyc Surgical Products' Gliasite Spectrum System is not covered by the guidance. Applicants who intend to use the new Gliasite Spectrum System need to contact the appropriate NRC Regional office for assistance.

(3) Revised licensing guidance for 10 CFR 35.1000 sealed sources and devices to reflect that the Novoste Intervascular brachytherapy products were bought by Best Vascular, Inc., and the product name has changed accordingly.

(4) Revised licensing guidance for 10 CFR 35.1000 sealed sources and devices to add a new 35.1000 medical use - "Iodine125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions."

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

GENERIC COMMUNICATIONS ISSUED (June 1, 2006 - August 31, 2006)

The following are 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 - http://www.nrc.gov/reading-rm/doc-collections/ gen-comm/. 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 Angela R. McIntosh, (301) 415-5030, or by e-mail: arm@nrc.gov.

Bulletins (BLs)

None.

Generic Letters (Gls)

None.

Information Notices (INs)

IN 2006-11, "Applicability of Patient Intervention in Determining Medical Events for Gamma Stereotactic Radiosurgery and Other Therapy Procedures," was issued on June 12, 2006. This IN was issued to all medical licensees.

(Technical contact: Ronald E. Zelac, PhD, NMSS, 301-415-7635; e-mail: rez@nrc.gov)

IN 2006-12, "Exercising Due Diligence When Transferring Radioactive Materials," was issued on July 6, 2006. This IN was issued to all material licensees.

(Technical contact: Joseph DeCicco, PhD, NMSS, 301-415-7833; e-mail: jxd1@nrc.gov)

IN 2006-13, "Ground-water Contamination Due to Undetected Leakage of Radioactive Water" was issued on July 10, 2006. This IN was issued to all holders of operating licenses for nuclear power and research and test reactors including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor, and those authorized by Title 10 of the Code of Federal Regulations Part 72 licenses to store spent fuel in water-filled structures.

(Technical contacts: Timothy Frye, NRR, 301-415-9676, e-mail: tjf@nrc.gov; Marvin Mendonca, NRR, 301-415-2191, e-mail: mmm@nrc.gov; John White, Region 1, 610-337-5114; e-mail: jrw1@nrc.gov; or James Shepherd, NMSS, 301-415-6712, e-mail: jcs2@nrc.gov)

IN 2006-16, "Implementing Search Requirements for Personnel, Packages and Material at NRC-Licensed Facilities" was issued July 28, 2006. This IN was issued to all power reactors, category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants. Note that the information notice contains physical security information and is, therefore, being withheld from public disclosure in accordance with 10 CFR 2.390.

(Technical contact: F. Paul Peduzzi, NSIR, 301-415-5734, e-mail: fxp1@nrc.gov)

Regulatory Issue Summaries (RIS')

RIS 2006-11, "Requesting Quality Assurance Program Approval Renewals Online by Electronic Information Exchange" was issued July 20, 2006. This RIS was issued to all 10 CFR Part 71 quality assurance program and certificate holders.

(Technical contacts: Frank Gee, NMSS, 301-415-7414; e-mail: fsg@nrc.gov; and John Skoczlas, OIS, 301-415-7186, e-mail: jas1@nrc.gov)

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

SIGNIFICANT EVENTS (May 1, 2006 - August 30, 2006)

Event #1: Brachytherapy Overdose Event

Date and Place: May 9, 2006, Bozeman, Montana

Nature and Probable Causes: The licensee reported a medical event involving dose to an unintended site. The incident was identified during the post-implant CT scan of a prostate implant patient. A total of 88 iodine-125 seeds, with a total activity of 1.12 gigabecquerel (30.3 millicuries), was implanted. However, three seeds were recovered after the procedure. The CT scan confirmed that most of the seeds were located in an area surrounding the urethra instead of in the prostate. The licensee has estimated that the radiation dose to the unintended site was

14,500 centigray (rad). The patient's physician was informed. The patient was informed and advised of the possible side effects. The licensee will continue to investigate the incident. NRC Region IV dispatched an inspector to the licensee's facility to review the incident.

Event #2: Brachytherapy Overdose Event

Date and Place: July 10, 2006, Akron, Ohio

Nature and Probable Causes: The licensee reported that a patient prescribed to receive a prostate seed implant procedure received seeds with 27 percent higher activity than intended. The licensee stated that the default seed strength of the computer planning system is specified in air kerma units. However, the activity of the seeds was entered in units of millicurie. When the seeds for this patient were ordered, the activity was not changed to millicurie. The patient was prescribed to receive 111 iodine-125 seeds, each with an activity of 14.58 megabecquerel (0.394 millicurie). The patient was implanted with seeds that had an activity of approximately 18.5 megabecquerel (0.5 millicurie) each. The physician, patient, and the State of Ohio were notified of the incident on July 13, 2006. The State Agency inspected the licensee's facility on July 18, 2006.

Event #3: Brachytherapy Underdose Event

Date and Place: June 5, 2006, Oklahoma City, Oklahoma

Nature and Probable Causes: The licensee reported an administration that was 68 percent less than prescribed during one of a series of brachytherapy doses to a patient. The patient received 116 centigray (rad) instead of the prescribed 360 centigray (rad). This was the first use of the new High Dose Remote (HDR) modality mammosite treatment equipment. An iridium -192 source (Varian) with an activity of 222 gigabecquerel (6 curies) was used. The quality control (QC) on the instrument was performed before the patient treatment. The treatment plan was sent from the dosimetry computer to the HDR control computer. The computer, or personnel, chose the plan used from the QC. The computer interpreted the plan to mean that a particular amount of dose had already been given. Inspection of computer records revealed that the exposure had been stopped during treatment. The licensee informed the patient of the dose discrepancy. Corrective actions taken by the licensee included performing the QC activity in a way that can't be confused with the therapy. The State of Oklahoma is sending an inspector to the site.

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

SIGNIFICANT ENFORCEMENT ACTIONS

The U.S. Nuclear Regulatory Commission's (NRC's) enforcement program can be accessed via 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.

Hospitals

Hospital Andres Grillasca, Inc. (EA-06-125)

On July 21, 2006, a Notice of Violation was issued for a Severity Level III violation, involving the failure to implement written procedures to provide high confidence that each patient treatment is in accordance with the treatment plan and written directive, and that both manual and computer-generated dose calculations are verified. As a result of the failure to verify that an High Dose Rate (HDR) treatment was administered in accordance with the written directive, a dose was calculated and delivered to a depth of one centimeter rather than the prescribed two centimeter depth, resulting in an underdose of 57 percent.

Southside Community Hospital (EA-06-097)

On July 12, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to perform surveys, or secure from unauthorized removal, or limit access to six vials, at least two of which contained radioactive material in the form of iodine-131, sodium iodide. The vials were subsequently disposed of as non-radioactive waste on December 1, 2005.

IUPUI/Indiana University Medical Center (EA-06-095)

On July 10, 2006, a Notice of Violation was issued for a Severity Level III violation involving the licensee's failure to develop, implement,

and maintain written procedures to provide high confidence that each administration of NRC-licensed material is in accordance with the written directive of an authorized user physician, as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive."

Community Hospitals of Indiana, Inc. (EA-06-101)

On July 10, 2006, a Notice of Violation was issued for a Severity Level III problem involving the failure to develop written procedures to provide high confidence that each administration was in accordance with a written directive. Specifically, the licensee's written procedure for high dose rate (HDR) brachytherapy did not describe that the HDR metal interface connector was to be attached during treatment simulation to determine appropriate location of the sources within the patient. In addition, the licensee did not notify the NRC Operations Center by the next calendar day after discovery of the medical event.

Radiography

Southwest X-Ray Corporation (EA-06-014)

On May 25, 2006, a Notice of Violation was issued for a Severity Level III violation involving a radiographer's assistant's failure to wear a direct reading dosimeter and personnel dosimeter, on the trunk of his body during radiographic operations.

Portable Gauges

ECS Mid-Atlantic, LLC (EA-05-177)

On May 22, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal, or limit access to, a portable gauge containing licensed material, while the gauge was in an unrestricted area and not in storage; nor did the licensee control and maintain constant surveillance of this licensed material. While the gauge was unattended, it was run over by a front end loader and destroyed. (General Contact: Sally Merchant, Office of Enforcement, 301-415-2747, e-mail: slm2@nrc.gov)

Eastern Shoshone & Northern Arapaho Tribes (EA-06-040)

On July 14, 2006, a Notice of Violation was issued for a Severity Level III problem involving failure to conduct operations so that the total effective dose equivalent to individual members of the public would not exceed 0.001 sievert (Sv) (0.1 rem) in a year. Specifically a member of the public, working in close proximity to the portable gauge storage area, received a calculated dose in excess of 0.001 Sv during calendar years 2000 and 2001. In addition, from March 2000 through May 2006, the licensee failed to make, or cause to be made, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public as required. The NRC is exercising enforcement discretion and is refraining from issuing a civil penalty because the licensee has transferred all NRC-licensed material to an authorized recipient, and requested termination of its NRC license.

SELECTED *FEDERAL REGISTER* NOTICES (June 1, 2006 – August 31, 2006)

10 CFR Part 73 [RIN 3150-AH94] "Relief From Fingerprinting and Criminal History Records Check for Designated Categories of Individuals." 71 FR 33989, June 13, 2006.

(Contact: Jared K. Heck, Office of the General Counsel, 301-415-1623, e-mail: jkh3@nrc.gov, or Marjorie U. Rothschild, Office of the General Counsel, 301-415-1633, e-mail: mur@nrc.gov)

10 CFR Parts 20 and 32 [RIN 3150-AH48] "National Source Tracking of Sealed Sources ; Proposed rule." 71 FR 34024 June 13, 2006.

(Contact: Merri Horn, Office of Nuclear Material Safety and Safeguards, 301-415-8126, e-mail: mlh1@nrc.gov)

"State of Rhode Island Relinquishment of Sealed Source and Device Evaluation and Approval Authority and Assumption by the Nuclear Regulatory Commission." 71 FR 38189, July 5, 2006.

(Contact: Jennifer C. Tobin, Office of State and Tribal Programs, 301-415-2328, e-mail: jct1@nrc.gov)

10 CFR Part 72 [RIN 3150-AH93] " List of Approved Spent Fuel Storage Casks: NUHOMS[supreg]HD Addition; Withdrawal of Direct Final Rule." 71 FR 39520, July 13, 2006.

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

10 CFR Part 110 [RIN 3150-AH88] "Implementation of the Nuclear Export and Import Provisions of the Energy Policy Act of 2005; Correction." 71 FR 40003, July 14, 2006.

(Contact: Michael T. Lesar, Office of Administration, 301-415-7163 or Toll-Free: 1-800-368-5642, e-mail: MTL@nrc.gov)

10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171[RIN 3150-AH84] "Requirements for Expanded Definition of Byproduct Material; Proposed rule." 71 FR 42951, July 28, 2006.

(Contact: Lydia Chang, Office of Nuclear Material Safety and Safeguards, 301-415-6319, e-mail: lwc1@nrc.gov)

10 CFR Part 36 [Docket No. PRM-36-01] "American National Standards Institute N43.10 Committee; Denial of Petition for Rulemaking." 71 FR 47751, August 18, 2006.

(Contact: Thomas Young, Office of Nuclear Material Safety and Safeguards, 301-415-5795, e-mail: tfy@nrc.gov)

10 CFR Part 73 [RIN 3150-AH90] "Secure Transfer of Nuclear Materials, Proposed rule." 71 FR 51534, August 30, 2006.

(Contact: Frank Cardile, Office of Nuclear Material Safety and Safeguards, 301-415-6185, e-mail: fpc@nrc.gov)

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

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