U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

NUREG/BR-0117
No. 06-04
December 2006

Office of Nuclear Material Safety and Safeguards
Office of Federal and State Materials and Environmental Management Programs

LICENSEE NEWSLETTER

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REORGANIZATION OF THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS AND CREATION OF THE OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

The U.S. Nuclear Regulatory Commission's (NRC's) two newest offices have begun operation. They are a refocused Office of Nuclear Material Safety and Safeguards (NMSS) and the newly created Office of Federal and State Materials and Environmental Management Programs (FSME).

The refocused NMSS will concentrate on the nuclear fuel cycle, from uranium conversion and enrichment to fuel manufacturing and high-level waste storage, transportation, and disposal. The leadership of the Office will continue to be Jack Strosnider, Director. Other senior managers include E. William Brach, Director of the Division of Spent Fuel Storage and Transportation; Robert Pierson, Director of the Division of Fuel Cycle Safety and Safeguards; Lawrence Kokajko, Director of the Division of High-Level Waste and Repository Safety; and Mark Flynn, Director of the Program Planning, Budgeting, and Program Analysis staff.

FSME is comprised of the former Office of State and Tribal Programs, two technical divisions from the former NMSS, and a small program support staff. FSME is headed by Charles Miller as Director, with George Pangburn as Deputy Director. Other senior managers include Janet Schlueter, Director of the Division of Materials Safety and State Agreements; Dennis Rathbun, Director of the Division of Intergovernmental Liaison and Rulemaking; Larry Camper, Director of the Division of Waste Management and Environmental Protection; and Joseph Holonich, Director of the Program Planning, Budgeting and Program Analysis staff.

The reorganization was approved by the Commission in June to help the NRC meet new challenges in the materials, waste, and environmental areas. These challenges include increases in the number of Agreement States, as well as the expected applications for new nuclear power plants, spent-fuel reprocessing plants, and the high-level waste repository at Yucca Mountain. The NRC's Agreement State program has grown to 34 States, with three more States negotiating for Agreement State status. Agreement State status allows a State to regulate the industrial, academic, and medical uses of radioactive materials within its jurisdiction.

Martin Virgilio, Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs, said the reorganization will help NRC meet these demands while maintaining its ability to protect public health and safety and the environment. You can read more about the reorganization at http://www.nrc.gov/reading-rm/doc-collections/news/2006/06-122.html. The reorganization became effective October 1.

(Contact: Michael Williamson, Office of Federal and State Materials and Environmental Management Programs, 301-415-6234; e-mail: mkw1@nrc.gov)

SHAW AREVA MOX SERVICES, FORMERLY DUKE COGEMA STONE & WEBSTER, MIXED OXIDE FUEL FABRICATION FACILITY LICENSE APPLICATION AND INTEGRATED SAFETY ANALYSIS SUMMARY SUBMITTED

On September 27, 2006, Duke Cogema Stone & Webster (DCS) submitted a License Application and Integrated Safety Analysis (ISA) summary for a proposed Mixed Oxide Fuel Fabrication Facility (MFFF) to be built near Aiken, South Carolina. Under the U.S. Department of Energy's (DOE) Surplus Plutonium Disposition Program, DOE plans to use Shaw AREVA MOX Services (formerly DCS) as a contractor to convert approximately 34 metric tons of surplus weapons-grade plutonium into mixed oxide fuel to be used in commercial nuclear power plants.

On November 07, 2006, the U.S. Nuclear Regulatory Commission (NRC) sent a letter, to Shaw AREVA MOX Services, requesting that certain information submitted as proprietary in the ISA summary be included in the License Application. In response to this letter, Shaw AREVA MOX Services sent a revised License Application for NRC staff to review, incorporating the information requested on November 17, 2006.

At the time of this writing, the resubmitted License Application and existing ISA summary are undergoing a 45-day acceptance review. If the License Application and ISA summary are deemed acceptable, they will undergo a technical review. Before the beginning of a technical review of the License Application and ISA summary, there will be a public meeting, near the site, to discuss the staff's plan for the review and to announce another opportunity for a hearing.

DCS previously applied for and received authorization to construct a MFFF. On April 18, 2001, the NRC published a notice in the *Federal Register* (66FR19994), announcing that the NRC had accepted an application for authority to construct a MFFF from DCS. The notice also announced an opportunity for a hearing on the DCS application. On March 30, 2005, the NRC issued a Construction Authorization (CA) to DCS for a MFFF located on the Savannah River Site in South Carolina. The NRC staff's technical basis for issuing the CA is set forth in NUREG-1821, "Final Safety Evaluation Report on the Construction Authorization Request for the Mixed Oxide Fuel Fabrication Facility at the Savannah River Site, South Carolina." The results of the staff's environmental review related to the issuance of the CA are contained in NUREG-1767, "Environmental Impact Statement on the Construction and Operation of a Mixed Oxide Fuel Fabrication Facility at the Savannah River Site, South Carolina -- Final Report."

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THE GLOBAL NUCLEAR ENERGY PARTNERSHIP

In February 2006, the U.S. government announced the Global Nuclear Energy Partnership (GNEP) as part of President Bush's Advanced Energy Initiative to reduce U.S. dependence on foreign sources of energy. This major initiative is considering a new approach to the recycling of spent nuclear fuel using advanced technologies. These advanced technologies would increase resistance to proliferation, recover and reuse fuel resources, and reduce the amount of waste. Under this partnership, the U.S. Government will work with nations such as Russia, Japan, the United Kingdom and France which have advanced civilian nuclear energy programs to expand the use of nuclear power,

consistent with the provisions in the Energy Policy Act, Nuclear Power 2010, and other provisions that have been passed.

In order to reduce nuclear waste, GNEP is considering two recycling technologies, among others: 1) Uranium Extraction Plus (UREX+); and 2) pyroprocessing. UREX+ is an advanced version of PUREX, which is an existing aqueous reprocessing technology used internationally in France and in the United Kingdom. UREX+ does not separate plutonium from other long-lived radioactive elements. The UREX+ process will separate spent fuel into uranium, which can be stored for future use or disposal as low-level waste. In addition, long-lived fission products, such as technetium, and iodine, could be separated for disposal in the proposed repository at Yucca Mountain. Short-lived fission products, such as cesium and strontium, could be extracted and prepared for decay-in-storage until they meet the requirements for disposal as low-level waste. Transuranic elements (plutonium, neptunium, americium, and curium) separated from the remaining fission products could be fabricated into fuel for consumption in a fast neutron reactor. Burning the transuranic elements will significantly reduce the heat load to Yucca Mountain, reducing the need for additional geological repositories this century.

Pyroprocessing is a non-aqueous technology that is based on electrochemical separation. This technique is used to remove uranium, plutonium and other actinides from the spent fuel, while keeping them mixed. This method prevents the plutonium to be used directly in weapons. Pyroprocessing dissolves spent fuel in a chloride salt that is hot enough to melt, rather than water-based acid as used in UREX+. This does not work well for the oxide fuels in thermal reactors, but it is ideal for metallic fuel that may be used in fast-neutron reactors.

According to the U.S. Department of Energy (DOE), reprocessed materials, which retain about 90 percent of the energy content of primary fuel, can be burned in Advanced Burner Reactors (fast-neutron reactors) to produce even more energy. The advantage of those fast reactors is that as they produce power they are also able to consume transuranic elements, potentially eliminating the need for their disposal at Yucca Mountain.

The U.S. will co-sponsor a workshop with the International Atomic Energy Agency (IAEA) and other IAEA Member States in Vienna, Austria, on Dec. 4-6, 2006, to discuss a program to design, build and export grid-appropriate reactors to comply with GNEP purposes. The aforementioned technologies promise to bring the benefits of nuclear energy to the world safely and securely, without all countries having to invest in the complete fuel cycle process.

The DOE plans to work with the industry to design, build and operate a Consolidated Fuel Treatment Center (CFTC) consisting of a commercial-scale Modular Prototype Integrated Recycle Facility and a commercial-scale Prototype Advance Burner Reactor. DOE also intends to retain the lead on research and development in the Advance Fuel Cycle Research Facility.

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RECENT EVENTS IN GAS CENTRIFUGE

Milestones continue to be reached in the area of gas centrifuge (GC) uranium-enrichment facility licensing. After issuing a license to Louisiana Energy Services for the National Enrichment Facility in Hobbs, New Mexico this past June, the staff has been working on several licensing actions involving USEC Inc. (USEC). These licensing actions continue a changeover from the current uranium-enrichment technology used in the United States (gaseous-diffusion process) to the gas-centrifuge process.

On September 11, 2006, the U.S. Nuclear Regulatory Commission (NRC) issued the Safety Evaluation Report (SER), NUREG-1851, for the proposed American Centrifuge Plant (ACP) to be constructed and operated by USEC. In the SER, NRC staff concluded that USEC demonstrated it has adequate safety programs to construct and operate the proposed facility.

The proposed ACP, to be located at the Portsmouth Gaseous Diffusion Plant (GDP) site in Piketon, Ohio, would produce Uranium-235 (U-235) enriched up to 10 weight percent by a gas centrifuge process. If the license is approved, facility construction would begin in 2007, and continue for 5 years through, 2011. The proposed ACP would begin initial production in 2009, and peak production would be reached in 2011.

The final SER, and the recently completed Environmental Impact Statement are the major NRC staff reviews in the licensing process. There are no contentions related to the facility before the NRC

Atomic Safety and Licensing Board. However, a mandatory hearing will take place early next year.

Recent advancements have also been made by USEC's Lead Cascade Facility (LCF), which was licensed in early 2004. The LCF was authorized to introduce uranium hexafluoride gas (UF6) into the system on August 23, 2006. Also located at the Portsmouth GDP site in Piketon, Ohio, the LCF is a gas centrifuge test facility intended to provide operational information on the machines and auxiliary systems as they would be used in commercial application. The authorization to introduce UF6 was made after several license conditions were satisfied. These license conditions required: (1) revising the Portsmouth GDP Emergency Plan to appropriately address the LCF; (2) acceptance and execution of the decommissioning funding mechanism; and (3) NRC completion of an operational readiness review, verifing that management measures to ensure compliance with the performance requirements of 10 CFR 70.61 had been implemented, and confirming that the facility was constructed and operated, safely in accordance with license requirements.

For more information related to gas centrifuge uranium-enrichment facility licensing, visit our website at http://www.nrc.gov/materials/fuel-cyclefac/gas-centrifuge.html.

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UPDATE OF CONSOLIDATED DECOMMISSIONING GUIDANCE (NUREG-1757)

The Division of Waste Management and Environmental Protection (DWMEP) has completed its update of NUREG-1757, "Consolidated Decommissioning Guidance," which provides guidance for planning and implementing license termination under the License Termination Rule (10 CFR Part 20, Subpart E). The staff has published revisions to Volumes 1 and 2 of this NUREG series. The first volume is "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees" (NUREG-1757, Vol. 1, Rev. 2), which provides guidance for planning and implementing the termination of materials licenses. The second volume, "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria" (NUREG-1757, Vol. 2, Rev. 1), provides guidance for compliance with the radiological criteria for termination of licenses.

The revised Volumes 1 and 2 include the finalized guidance of NUREG-1757, Draft Supplement 1, which was published for public comment in September 2005. The guidance is intended for use by NRC staff, licensees, and others. All three volumes of NUREG-1757 are available at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757.

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CONSOLIDATION OF NRC'S DECOMMISSIONING PROGRAM

On October 1, 2006, the project management and oversight responsibility for 14 decommissioning Research and Test Reactors (RTRs), two decommissioning power reactors, and two early-demonstration reactors transferred from the Office of Nuclear Reactor Regulation (NRR) to the Office of Federal and State Materials and Environmental Management Programs (FSME). Additionally, the project management and oversight of uranium-recovery facilities, including decommissioning facilities, was also transferred to FSME. The decommissioning activities were consolidated into the Division of Waste Management and Environmental Protection (DWMEP) as a result of a Staff Requirements Memorandum requesting the staff to evaluate further consolidating the decommissioning program. Based on the evaluation, the staff determined that consolidating the decommissioning program would increase the efficient and effective use of resources and further concentrate the decommissioning technical expertise in one organization. The Decommissioning and Uranium Licensing Recovery Licensing Directorate in FSME now provides decommissioning project management and oversight activities for complex materials sites, power reactors, RTRs, and uranium-mill tailing sites in addition to providing decommissioning programmatic support to the regions and other offices involved in decommissioning activities.

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CLARIFYING IMPROVEMENTS TO 10 CFR 70.72(c)(2)

In a September 27, 2006, *Federal Register* notice (FRN), the U.S. Nuclear Regulatory Commission (NRC) published both a proposed Direct Final Rule (DFR) and proposed rule to clarify a requirement

pertaining to items relied on for safety (IROFS), under Title 10 Code of Federal Regulations (CFR) Part 70. The proposed rulemaking corrected an inconsistency in the regulations pertaining to IROFS. The final rule would be effective by December 11, 2006, unless significant adverse comments on the rule were had been received by October 27, 2006. If significant adverse comments on the rule had been received, then the proposed rule would be modified to address the comments, and a final rule would be published in a future FRN.

Questions had arisen about whether changes involving licensee-identified IROFS that were not needed to meet the performance requirements in 10 CFR 70.61 would require an equivalent replacement of the safety function. Consistent with other parts of the regulation, the staff proposed adding the phrase, "...and is necessary for compliance with the performance requirements of 10 CFR 70.61" to the end of 10 CFR 70.72(c)(2). Thus, the proposed 10 CFR 70.72(c)(2) would be (newly added phrase in bold):

> "The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change . . . does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary **and is necessary for compliance with the performance requirements in §70.61**."

This revision clarified that if an IROFS were not needed to meet the 10 CFR 70.61 performance requirements, a licensee may remove or replace the IROFS without NRC staff's approval and without showing equivalent replacement of the safety function. This change did not affect IROFS needed to meet performance requirements. If a licensee intends to remove or replace an IROFS needed to meet performance requirements, then the licensee must obtain NRC staff pre-approval before making the change, unless the licensee has demonstrated with on-site documentation that the replacement or removal of the IROFS could be done with equivalent replacement of the safety function of the IROFS.

At around the same time that the FRN was published, NRC published the associated Regulatory Issue Summary (RIS) 2006-14 and Enforcement Guidance Memorandum (EGM) 06-005. The RIS informed the Part 70 licensees that the 10 CFR 70.72(c)(2) regulation was proposed to be changed, whereas the EGM informed NRC inspectors how to apply enforcement discretion between the times when the FRN was published and when the rule change became final.

No significant adverse comments on the rule were received by October 27, 2006. So, on December 11, 2006, the DFR became effective as a final rule. Now that the rule change was finalized, both the RIS and EGM are not in effect. One comment was received on the information in the FRN. Staff is developing a 10 CFR 70.72(c)(2) implementation guidance document called an interim staff guidance (ISG). The Division of Fuel Cycle Safety and Safeguards (FCSS)-ISG process includes industry and other stakeholder participation in public meetings as well as a comment/resolution process. The one comment received on the information in the FRN will be addressed as part of the FCSS-ISG process.

(Contact: Harry Felsher, Office of Nuclear Material Safety and Safeguards, 301-415-5521, e-mail: hdf@nrc.gov)

REGULATIONS FOR EMERGING TECHNOLOGIES

The requirements for all new medical uses of byproduct material, or radiation from byproduct material, that are not specifically addressed in subparts D through H of Title 10 Code of Federal Regulations (CFR) Part 35 fall under the regulations in10 CFR 35.1000. The information required by applicants of 35.1000 medical uses is found in 10 CFR 35.12 "Application for license, amendment, or renewal." Section 35.1000 itself does not include specific training and experience (T&E) requirements for authorized users (AU) of emerging technologies because the T&E necessary for the safe use of byproduct material may be unique to each new technology. The specific risks associated with these emerging technologies, additional regulatory requirements, and the T&E requirements are evaluated on a case-by-case basis. Although the new medical use of byproduct material is regulated under 10 CFR 35.1000, licensing guidance for each specific 10 CFR 35.1000 use, including the T&E requirements, is posted on the U.S. Nuclear Regulatory Commission (NRC) web site under the section "Other Guidance," at http://www.nrc.gov/materials/miau/med-use-toolkit.html. Licensing guidance for emerging technologies will be modeled on other medical uses with similar risk. Licensees interested in applying for authorizations for new medical uses should submit applications to the appropriate NRC Regional offices.

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CLARIFICATION OF DOSAGE CATEGORIES FOR UNSEALED BYPRODUCT MATERIAL REQUIRING A WRITTEN DIRECTIVE

Title 10 Code of Federal Regulations (CFR) 35.390, "Training for use of unsealed byproduct material for which a written directive is required," establishes requirements for authorized users (AU) of unsealed byproduct material for the uses authorized under 10 CFR 35.300 "Use of unsealed byproduct materials for which a written directive is required." 10 CFR 35.390 requires a physician seeking to become an AU for uses authorized under section 35.300 to complete work experience that includes administering dosages of radioactive drugs to patients or human research subjects in at least three cases in each of the categories for which the individual is requesting AU status. There are four dosage categories listed in paragraph 10 CFR 35.390(b)(1)(ii)(G):

(1) Oral administration of less than or equal to 1.22 gigabecquerels (Gbq) (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(2) Oral administration of greater than 1.22 Gbq (33 millicuries) of sodium iodide I-131;

(3) Parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 kiloelectron volt, for which a written directive is required; and/or

(4) Parenteral administration of any other radionuclide, for which a written directive is required.

The U.S. Nuclear Regulatory Commission (NRC) has received several inquiries from physicians wishing to be authorized for all four categories. Currently an AU can be licensed only for categories 1, 2, and 3, or any combination thereof. Examples of parenteral administrations that fall within the third category include, but are not limited to, Strontium-89, Phosphorus-32, Yttrium-90 (Zevalin® therapy), Samarium-153, and non-sodium iodide-131 (e.g. Bexxar® and MIBG therapies). NRC is not aware of any radiopharmaceutical administrations that fall under the fourth category and therefore currently does not authorize AUs for that category. Category 3 was intended to include parenteral administrations that were currently being performed at the time that 10 CFR 35.390 was promulgated. At the time that 10 CFR 35.390 was promulgated, there was no way to predict what new therapies involving parenteral administrations of unsealed byproduct material would be developed in the future. Therefore, the fourth category was included in the regulation to cover these potential therapies, to avoid having to again revise the requirements to address these new therapies.

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CLARIFICATION OF THE TRAINING AND EXPERIENCE REQUIREMENTS IN 10 CFR 35.396

Section 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," was specifically developed for authorized users (AU) qualified under other sections of Title 10 Code of Federal Regulations (CFR) Part 35 who are seeking to become AU's under this section. The U.S. Nuclear Regulatory Commission (NRC) has received many inquiries about whether paragraph (d) of 10 CFR 35.396 is a stand-alone criterion for one of the training and experience (T&E) pathways. Section 35.396 establishes three different T&E pathways for a physician seeking to become an AU for parenteral administration of unsealed byproduct material requiring a written directive. The first pathway, described in 10 CFR 35.396(a), is a stand-alone criterion which permits an AU authorized under 10 CFR 35.390 for parenteral administrations (i.e., uses listed in §35.390(b)(1)(ii)(G)(3) or (4)), by his or her training and experience, to be an AU under 10 CFR 35.396. Physicians seeking AU status by the second or third pathways, described in 10 CFR 35.396(b) and (c), respectively, must also satisfy the T&E requirement in paragraph (d) of 10 CFR 35.396. With regard to those pathways, the T&E requirement described in 10 CFR 35.396(d) is not a stand-alone criterion. Rather, paragraph (d) is an additional requirement for the pathways described in 10 CFR 35.396(b) and (c). The T&E requirements established in 10 CFR 35.396 can be found on the NRC web site at http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0396.html.

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IMPROVING PUBLIC UNDERSTANDING OF THE RISKS ASSOCIATED WITH MEDICAL EVENTS

Medical events (ME) are defined in Title 10 Code of Federal Regulations (CFR) 35.3045, "Report

and notification of a medical event." There have been indications to the U.S. Nuclear Regulatory Commission (NRC), that members of the public associate the occurrence of an ME with harm or risk of harm to the patient or patients involved in an event, which is not necessarily the case. In March 2004, the Commission directed the NRC staff to provide recommendations on how to effectively communicate the associated risks, if any, of MEs to the public. The Commission also directed the staff to involve NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in the development of its recommendations.

In February 2005, the Commission approved the NRC staff's recommendations to improve public understanding of the risks associated with MEs. The staff's recommendations were based on input from the ACMUI.

The ACMUI recommended as a general "guiding principle" that NRC consider MEs as a quality assurance (QA) performance index, indicative of technical or QA problems in accurately realizing clinical intentions of authorized user (AU) physicians, but not as an indicator of patient harm, nor the probability of patient harm. NRC endorses this "guiding principle." The ACMUI also suggested that NRC not disclose/release event information to the public until the event has been confirmed to be a reportable ME. In the interest of openness and timeliness, information about events involving medical use and reported as potential MEs is released to the public by NRC when the event has been confirmed to be an ME, or after 5 calendar days have passed, whichever comes first. The ACMUI also suggested footnoting each Event Summary released, to the public as a reportable ME, to indicate that dose thresholds in NRC's ME definitions, if exceeded, are not necessarily indicative of patient harm. This measure has also been implemented.

In summary:

1. NRC's ME definitions provide thresholds for identifying events indicative of technical or QA problems in accurately realizing the clinical intentions (prescriptions) of AU physicians;
2. Thresholds in NRC's ME definitions, if exceeded, are not necessarily indicative of patient harm.

This summary has been incorporated into an NRC fact sheet, available on the NRC public web site, at http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/risks-assoc-medical-events.html.

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DOSE LIMIT FOR PATIENT RELEASED UNDER 10 CFR 35.75

The conditions under which licensees may authorize the release from their control of individuals who have been administered unsealed byproduct material or implants containing byproduct material appear in Title 10 Code of Federal Regulations (CFR) 35.75. One of these conditions is that the total effective dose equivalent (TEDE) to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (mSv) (0.5 rem).

Although licensees typically use the 5 mSv (0.5 rem) TEDE limit to other individuals for determining the appropriateness of releasing a patient (or human research subject) after a single administration or application, the 5 mSv (0.5 rem) TEDE is an annual limit on dose to other individuals. Thus, if multiple administrations or applications in a single year are planned or are potentially anticipated for a patient, the decision about releasing that patient after each of the administrations must be based on the TEDE from all administrations or applications in a calendar year not exceeding 5 mSv (0.5 rem) for the maximally exposed other individual.

The U.S. Nuclear Regulatory Commission's position for 10 CFR 35.75, that the 5 mSv (0.5 rem) TEDE annual limit on doses to other individuals from exposure to the released individual is an annual limit, and that the total dose resulting from multiple administrations to and multiple releases of an individual within a given year must be taken into consideration, will be discussed more fully in a Regulatory Information Summary to be issued in the near future, which can be found at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2006/.

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INCREASED CONTROLS: ANSWERS TO COMMONLY ASKED QUESTIONS

The U.S. Nuclear Regulatory Commission (NRC) has identified fifteen radionuclides, and combinations thereof, that, when possessed in certain quantities, must be protected by the licensee from theft, sabotage, or diversion. In order to minimize risk to public health and safety, NRC

issued an Increased Controls (IC) Order [EA-05-090] on November 14, 2005 to licensees that are authorized to possess the quantities of radioactive material identified in Table 1 of the Order, otherwise known as "Radioactive Materials Quantities of Concern." The Order encompasses six general requirements that pertain to the security of Table 1 quantities. Licensees must implement these requirements to ensure adequate protection of these sources from malevolent use.

Though NRC and Agreement State licensees have always been required to protect radioactive material in their possession, several security concepts behind the IC requirements may be new to licensees. To help licensees interpret and apply the IC requirements, NRC formed the Implementation of Increased Controls Working Group (IICWG), made up of NRC Headquarters and Regional staff, and Agreement State representatives. The IICWG develops guidance to address questions that may arise as regulators and licensees implement the requirements of the Order. For this purpose, the IICWG produced implementing guidance including a series of questions and answers (Q&A). The IICWG continues to answer new implementation questions by means of a living supplemental Q&A document. Licensees are encouraged to review this information to enhance their understanding of the requirements and clarify issues involving their IC program. Should there be need of further clarification, licensees may contact their respective Agreement State agency or NRC Regional office for assistance.

The IC Order and guidance documents can be viewed on the NRC public website at http://www.nrc.gov/reading-rm/doc-collections/enforcement/security. The documents are located under the heading "Holders of Material Licenses Authorized to Possess Radioactive Material Quantities of Concern."

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RUPTURE OF JAMMED SEEDS IN MICK APPLICATORS DURING MANUAL BRACHYTHERAPY TREATMENTS

During the past 3 years, there have been at least six cases in which Iodine-125 seeds ruptured during prostate Brachytherapy treatments. Typically the cause of the seed rupture is operator excessive force applied to the seed cartridge in an attempt to dislodge or implant seeds jammed in the MICK applicator.

In 2005, NRC issued Information Notice 2005-17, "Manual Brachytherapy Source Jamming" for nation-wide distribution, and the Wisconsin Department of Health and Family Services also issued an Information Notice dated June 9, 2005, for Wisconsin licensees. Users are advised NOT to use force when attempting to remove jammed seeds, and to follow the manufacturer's instructions, as provided in the user manual, when dislodging jammed seeds. Also, Mick Radio-Nuclear Instruments, Inc. describes the proper dislodging techniques on its website (http://www.micknuclear.com).

Both Information Notices are available on the NRC website at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2005/in200517.pdf.

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GENERIC COMMUNICATIONS ISSUED (Sep 1, 2006 - Nov 30, 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/ en-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 Monica Orendi, (301) 415-3938, or by e-mail: mlo1@nrc.gov.

Bulletins (BL)

None.

Generic Letters (Gl)

None.

Information Notices (IN)

None.

Regulatory Issue Summaries (RIS')

RIS 2006-19 "Availability of Guidance on Radioactive Seed Localization" was issued September 14, 2006. This RIS was issued to all NRC medical licensees.

(Technical contact: Donna-Beth Howe, FSME, 301-415-7848; e-mail: dbh@nrc.gov)

RIS 2006-20, "Guidance for Receiving Enforcement Discretion When Concentrating Uranium at Community Water Systems" was issued September 14, 2006. This RIS was issued to all community water systems (CWS'), in NRC non-Agreement States, that during the treatment of drinking water, may accumulate and concentrate naturally occurring uranium in media, effluents, and other residuals, above 0.05 percent by weight. CWS' operating in Agreement States should contact their State regulatory agency to determine what requirements apply to their operations.

(Technical contacts: Michael Williamson, Office of Federal and State Materials and Environmental Management Programs, 301-415-6234; e-mail: mkw1@nrc.gov and Gary Comfort, Office of Federal and State Materials and Environmental Management Programs, 301-415-8106; e-mail: gcc1@nrc.gov)

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: Monica Orendi, FSME, 301-415-3938; e-mail: mlo1@nrc.gov)

SIGNIFICANT EVENTS

Event #1: Lost radioactive seeds

Date and Place: October 4, 2006, Spokane, Washington

Nature and Probable Causes: The licensee reported two damaged shipping packages containing cesium-131 (Cs-131) cancer therapy seeds. The shipping company discovered a flattened lead cap in its Spokane, Washington, terminal. A partial label on the cap indicated it came from one of two packages containing 63 Cs-131 seeds with a total activity of 12.2 Gigabecquerels (GBq) (330 millicuries). The second package was found crushed, but essentially intact; all seeds were present and undamaged. Scraps from the first package were found on the runway and on the floor of an airport vehicle. Washington Department of Health (DOH) personnel responded to the scene, and the licensee also dispatched a team to the site. DOH personnel were able to recover three of the 63 seeds from the first package. Several areas of radioactive contamination and radiation exposure were located, with the highest level of contamination at 400 counts per minute, and the highest level of exposure at approximately 25 milliroentgen per hour or 6.54 x 10-5 Coulombs per kilogram per hour (C-kg-1-hr-1). Washington DOH requested that the shipping company's management revise its hazardous material transportation-handling procedures and provide refresher training to staff.

Event #2: Overexposure to Worker

Date and Place: October 20, 2006, Cincinnati, Ohio

Nature and Probable Causes: The licensee reported a contamination incident in its source-handling facility. Two cesium 137 (Cs-137) sources from TN Technology fixed gauges were breached during source disposal operations. One Cs-137 source with an activity of 0.41 Gigabecquerels (GBq) (11 millicuries (mCi)) was breached when an individual cut into the source holder with a band-saw. The other source had an activity of 0.96 GBq (26 mCi) and was breached when the same individual drilled into the source holder. Radioactive contamination was detected on the individual conducting the source-removal operations and throughout the source-handling area. The contaminated areas were controlled-access areas within the facility. Some contamination escaped from the room under two doors leading to the licensee's gauge-manufacturing area, but not into any unrestricted areas. The contamination on the individual was estimated at 0.37 GBq (10 mCi) and was located on the individual's clothing, hair, arms, and hands. The individual was decontaminated on site and sent to a local hospital as a precautionary measure. There was some residual contamination on the individual's finger tips; however, further scrubbing to remove the contamination may have caused a breakdown of the skin. The individual put on gloves in an attempt to sweat out the residual contamination. Two urinalysis samples collected from the employee were negative. The source-handling area was secured and closed to all personnel over the weekend. Preliminary surveys identified 14,000 to 500,000 disintegrations

per minute in large-sample wipe tests of walk-ways in the manufacturing area. It was estimated that approximately 0.37 GBq (10 mCi) of contamination were involved in the source-handling area. The licensee retained a decontamination contractor and an Ohio Bureau of Radiation Protection inspector visited the site to assess the contractor's decontamination efforts and to further investigate the circumstances that caused the incident. The contaminated employee received a whole-body count, and the results revealed the presence of 133.57 Becquerels (3.61 nanocuries) in the lungs. A second whole-body scan was scheduled for 2 weeks from the initial scan. Dose estimates will be prepared by the licensee and its medical consultant after urine samples have been analyzed. Corrective actions taken by the licensee included generating a new procedure for the removal of sources from holders.

Event #3: Overexposure to Radioactive Waste Workers

Date and Place: November 1, 2006, Richland, Washington

Nature and Probable Causes: The licensee reported possible radiation overexposures to four individuals. The individuals were involved in separating sources, lead pigs, and trash from drums. The total americium 241 (Am-241) activity from 12 drums was manifested at 6.8 Gigabecquerels (GBq) (184 millicuries); however, only one drum was open at the time of the incident. Work was being conducted in a ventilated room within a waste-processing building. Two workers inside the room were wearing respirators and the supervisor, not wearing a respirator, was immediately outside the room directing the work. A contamination level above 2 million disintegrations per minute was detected in the room, and the building was evacuated. An air sample in the area revealed an alpha activity of 0.37 microBecquerels per milliliter (μBq/ml) (0.001 picocuries per milliliter). The three workers were taken to a survey area and found to be contaminated on the face. Contamination was also found on the respirators. The workers were decontaminated on site. Air-sample-analysis results for a particulate sample in the building exhaust stack was 340.4 Becquerels per milliliter (Bq/ml) (9.2 nanocuries per milliliter (nCi/ml)) gross alpha. The building was decontaminated, and additional containment tents were installed around the contaminated room. Whole-body counts the next day revealed that the supervisor received an intake of approximately 432.9 Bq (11.7 nCi) of Am-241, with an estimated lung dose of 97.5 centisievert (cSv) (97.5 rem) committed dose equivalent (CDE). The supervisor also had an estimated dose to the endosteal (white bone matter) of 95 cSv (95 rem) CDE. The other two workers were given two lung counts, with results of 248 and 188 Bq (6.7 and 3.2 nCi) for one, and 56 and 19 Bq (1.5 and 0.5 nCi) for the other. A health physics technician working near the supervisor in the outer room was also counted with a result of less than 33 Bq (0.9 nCi). All four workers were given chelating treatments.

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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

St. Peter's University Hospital (EA-06-228)

On November 30, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure licensed material from unauthorized removal or access, and/or maintain constant surveillance of licensed material that was stored in a controlled or unrestricted area. Specifically, on August 2, 2006, an High Dose Reloader (HDR) unit containing Iridium-192 was left unsecured and unattended in that the door to the room housing the HDR was open and no staff member was in the immediate vicinity to maintain constant surveillance, contrary to 10 CFR 20.1801 and 10 CFR 20.1802.

St. Joseph Health Center (EA-06-188)

On October 20, 2006, a Notice of Violation was issued for a Severity Level III violation involving the administration of greater than 30 microcuries of I-131 sodium iodide without a written directive that was signed and dated by an authorized user. Specifically, a technologist administered 5.4 millicuries of I-131 sodium iodide to a patient that was scheduled to receive 15 microcuries of I-131 sodium iodide, without a written directive that was dated and signed by an authorized user before administering the I-131 sodium iodide dose.

Portable Gauges

H&G Inspection Company, Inc. (EA-06-021)

On October 24, 2006, a Confirmatory Order (effective immediately) was issued to confirm commitments made as part of a settlement agreement. The licensee requested Alternative Dispute Resolution following the NRC's May 1, 2006, Notice of Violation and proposed imposition of a civil penalty in the amount of $6,500. The violation involved the willful failure to block and brace a radiographic exposure device during transport. As part of the agreement, H&G has agreed to implement a comprehensive management review and oversight program, and within one year, to write and submit an article for publication by both the American Society of Non-Destructive Testing (ASNT) and the Non-Destructive Testing Managers Association (NDTMA) addressing the value that the new H&G management oversight program adds to overall safe and effective operations. In recognition of H&G's extensive corrective actions, the NRC agreed to reduce the civil penalty originally proposed to $500.

Advantage Engineering, LLC (EA-06-214)

On October 18, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure by the authorized gauge operator to control and maintain constant surveillance of a portable nuclear gauge. Specifically, the gauge, which contained NRC-licensed radioactive material (two radioactive sources), was damaged when it was run over by a bulldozer after the authorized gauge operator had left it unattended for approximately five minutes at a job site.

Quaker Sales Corporation (EA-06-194)

On September 13, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of a portable nuclear gauge resulting in damage to the gauge. Specifically, the gauge was left unattended for approximately 5 minutes while the gauge user was approximately 150 feet away from the gauge. During the time the gauge was not within the user's line of sight, it was run over by a bulldozer.

Triad Engineering, Inc. (EA-06-150)

On September 12, 2006, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of $3,250 was issued. The NOV cites two violations of NRC requirements. The first violation involved the failure of the authorized gauge user (AU) to properly block and brace the gauge in the open bed of his pick-up truck, to secure the gauge with two independent physical controls, and to close the tailgate prior to leaving the field office parking lot. The case containing the gauge fell off the truck onto a public street resulting in the second violation, i.e., the failure to control and maintain constant surveillance of licensed material in an unrestricted area. After bystanders notified the AU that his gauge had fallen off his truck, the AU driver retraced his route and retrieved the gauge. The container and the gauge were not damaged and there was no radiation dose to members of the public as a result of this event.

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

SELECTED *FEDERAL REGISTER* NOTICES (September 1, 2006 – December 31, 2006)

10 CFR Parts 19, 20, and 50 [RIN 3150-AH40] "Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent; Proposed rule." 71 FR 55382, September 22, 2006.

(Contact: Stewart Schneider, Office of Nuclear Reactor Regulation, 301-415-4123, e-mail: sxs4@nrc.gov)

10 CFR Part 70 [RIN 3150-AH96] "Facility Change Process Involving Items Relied on for Safety." 71 FR 56344 September 27, 2006.

(Contact: Dr. Anthony N. Tse, Office of Federal and State Materials and Environmental Management Programs, 301-415-6233, e-mail: ant@nrc.gov)

10 CFR Part 72 [RIN 3150-AH98] "List of Approved Spent Fuel Storage Casks: HI-STORM 100 Revision 3." 71 FR 60659, October 16, 2006.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, 301-415-6219, e-mail: jmm2@nrc.gov)

10 CFR Parts 2, 30, 40, 50, 52, 60, 63, 70, 71, 72, 73, 76, and 150 [RIN 3150-AH57] "Protection of Safeguards Information; Proposed rule." 71 FR 64004, October 31, 2006.

(Contact: Marjorie Rothschild, Office of the General Counsel, 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)

10 CFR Part 35 [Docket No. PRM-35-20] "E. Russell Ritenour, Ph.D.; Receipt of Petition for Rulemaking." 71 FR 64168, November 1, 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 and 32 [RIN 3150-AH48] "National Source Tracking of Sealed Sources; Final Rule." 71 FR 65686, November 8, 2006.

(Contact: Merri Horn, Office of Federal and State Materials and Environmental Management Programs, 301-415-8126, e-mail: mlh1@nrc.gov)

10 CFR Part 72 [RIN 3150-AH93] "List of Approved Spent Fuel Storage Casks: NUHOMS[supreg] HD Addition." 71 FR 71463, December 11, 2006.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, 301-415- 6219, e-mail: jmm2@nrc.gov)

10 CFR Part 20 "Public Meeting on Consideration of Rulemaking To Reduce the Likelihood of Funding Shortfalls for Decommissioning Under the License Termination Rule." 71 FR 74847, December 13, 2006.

(Contact: Kevin O'Sullivan, Office of Federal and State Materials and Environmental Management Programs, 301-415-8112, e-mail: kro2@nrc.gov)

10 CFR Part 72 [RIN 3150-AH98] "List of Approved Spent Fuel Storage Casks: HI-STORM 100 Revision 3; Withdrawal of Direct Final Rule." 71 FR 77586, December 27, 2006.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, 301-415- 6219, email: jmm2@nrc.gov)

(General Contact: Alexandra Greene, Office of Federal and State Materials and Environmental Management Programs, 301-415-5288, e-mail: amg1@nrc.gov)

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