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UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

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

LICENSEE NEWSLETTER

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APPOINTMENT OF MICHAEL WEBER AS DIRECTOR OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS (NMSS) AND ERIC LEEDS AS DEPUTY DIRECTOR, NMSS

Upon the retirement of Jack Strosnider in March 2007, the U.S. Nuclear Regulatory Commission (NRC) appointed Michael F. Weber the Director of Nuclear Material Safety and Safeguards (NMSS). Mr. Weber joined the NRC in 1982 in NMSS where he held a number of progressively more responsible positions including, Chief, Regulatory Issues Section; Chief, Low-Level Waste and Decommissioning Projects Branch; Chief, Fuel Cycle Licensing Branch; Deputy Director, Division of Waste Management; Deputy Director, Division of Fuel Cycle Safety and Safeguards; and Director, Division of Fuel Cycle Safety and Safeguards. In 2002, he was appointed as the Deputy Director, Office of Nuclear Security and Incident Response. In 2006, Mr. Weber became Deputy Director, Office of Nuclear Reactor Regulation (NRR). Mr. Weber has also served as a Technical Assistant to former Chairman Carr and as Executive Assistant to former Chairman Jackson. Of his 25 years at the NRC, he has served about 17 years in NMSS. Mr. Weber is a graduate of the Senior Executive Service Candidate Development Program and received a B.S. degree in Geosciences from the Pennsylvania State University. He received the NRC Meritorious Service Award in 1993, the interagency William A. Jump Meritorious Award in 1996, and Meritorious Executive Rank Awards from President Clinton in 2000 and President Bush in 2006.

Eric J. Leeds was selected as the Deputy Director, NMSS, following the retirement of Margaret Federline in February 2007. Mr. Leeds began his career in the United States Navy where he served

as a nuclear trained officer. In 1984, Mr. Leeds joined the NRC and held a number of progressively more responsible positions in the Offices of Nuclear Reactor Regulation (NRR) and the former Analysis and Evaluation of Operational Data, including serving as a reactor systems engineer, an inspection team member, project manager, technical assistant and senior assistant, and inspection Section Chief. He also served as Chief in both the Licensing and Technical Review Sections, in the Spent Fuel Project Office, NMSS. In 2000, Mr. Leeds was appointed to the position of Branch Chief, Special Projects Branch, Division of Fuel Cycle Safety and Safeguards, NMSS. In 2003, he became Deputy Director, Division of Licensing Project Management, NRR, and in 2004, he was selected as the Director, Division of Preparedness and Response, Office of Nuclear Security and Incident Response. He is a 2001 graduate of NRC's Senior Executive Service Candidate Development Program and holds a B.S. degree in Mechanical Engineering from Villanova University. In 2005, he received the Meritorious Executive Rank Award from President Bush.

(Contact: Dave Pstrak, Office of Nuclear Material Safety and Safeguards, 301-415-7260; e-mail: dwp1@nrc.gov)

DIVISION OF SPENT FUEL STORAGE AND TRANSPORTATION (SFST) MOVES TO NEW LOCATION

The U.S. Nuclear Regulatory Commission has acquired additional office space near its White Flint complex in Rockville, MD, to accommodate its expanding staff. The Office of Nuclear Material Safety and Safeguards (NMSS) will be occupying this office space and will be moving in a phased approach. SFST is the first NMSS division to relocate and did so in late March 2007. The remaining NMSS divisions will move to the same location over the next few months.

SFST is now located at 6003 Executive Boulevard, Rockville, MD. Mail sent directly to staff at this location should be mailed to: U.S. Nuclear Regulatory Commission, Mail Stop 6003 3-D02M, Washington, DC 20555. This information does not change the official addresses for submissions and notifications as stated in the regulations.

The main SFST phone number is (301) 492-3300 and the number for facsimile transmissions is (301) 492-3348. Electronic mail addresses for SFST staff remain unchanged.

For individuals planning to meet or visit with staff at this new location, please contact SFST for directions, parking, and access information.

(Contact: Bernard White, Office of Nuclear Material Safety and Safeguards, 301-492-3303; e-mail: bhw@nrc.gov)

CLARIFICATION ON HOURS CREDITED TOWARD THE TRAINING AND EXPERIENCE REQUIREMENTS IN 10 CFR 35.290 AND 35.390

10 CFR 35.290, "Training for imaging and localization studies," and 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," establish requirements for physicians who are seeking to become authorized users (AU) of unsealed byproduct material for the uses authorized under §35.200 and §35.300, respectively. The U.S. Nuclear Regulatory Commission (NRC) has received inquiries about the interpretation of the type of work experience that could be credited toward the required 700 hours of training and experience (T&E) in 10 CFR 35.290 and 35.390 for physicians seeking to become AUs.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to "classroom and laboratory training" must relate directly to radiation safety and safe handling of byproduct material. NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses for which authorization is being requested.

The "supervised work experience" must include, but is not limited to, the subject areas listed in the applicable T&E requirements in 10 CFR 35.290 and 35.390. The NRC recognizes that physicians in training may not dedicate all of their "supervised work experience" time specifically to the subject

areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited toward the "supervised work experience" category to obtain the required total of 700 hours of T&E, but not to the "classroom and laboratory training" category.

(Contact: Cindy Flannery, Office of Federal and State Materials and Environmental Management Programs, 301-415-0223; e-mail: cmf@nrc.gov)

ENSURING COMPLETENESS IN DOCUMENTING TRAINING AND EXPERIENCE; AND ATTESTATIONS

Individuals seeking to become an authorized user (AU), Radiation Safety Officer (RSO), authorized nuclear pharmacist (ANP), or authorized medical physicist (AMP) under the alternate pathway are required to submit documentation of training and experience (T&E), and a written preceptor attestation stating that the individual has satisfactorily completed the appropriate T&E criteria and has achieved a level of competency (or a level of radiation safety knowledge for proposed RSOs) to function independently. The documentation of T&E, and the attestation can be accomplished either by completing the appropriate NRC Form 313A for the particular authorization that he or she is seeking, or by submitting equivalent documentation.

Recently, the NRC has received a number of deficient NRC Forms 313A from applicants that lacked a significant amount of information required by the regulations, or were not completed correctly. For example, the number of clock hours was not documented for each of the required subject areas in the applicable regulations. Also, there have been cases where applicants have submitted equivalent documentation, in lieu of the NRC Form 313A, and the documentation did not include all of the information from the applicable regulatory requirements. For example, a preceptor did not cite the correct regulation when attesting to the proposed individual's T&E. In another case, a preceptor attested that the proposed RSO completed the required T&E, but did not attest that the individual had achieved a level of radiation safety knowledge sufficient to function independently as an RSO. In yet another case, an attestation was determined to be invalid because the RSO preceptor failed to recognize the T&E requirements, and inappropriately attested that the applicant had satisfactorily completed the requirements to become an RSO when in fact the applicant had not. The pathway under which the applicant was seeking RSO status required the applicant to be listed as an AU on a medical use license, but the applicant had never been an AU. If the attestation had been completed correctly, and had included all of the required information, in accordance with the regulatory requirements, the preceptor RSO could have realized that the applicant had not met NRC's T&E requirements before signing the attestation.

When applying for authorization as an AU, RSO, ANP or AMP under the alternate pathway, medical use licensees are encouraged to refer to the "Licensing Guidance for Using the NRC Form 313A Series of Forms" (even in cases where applicants are electing to use equivalent documentation in lieu of the NRC Form 313A) which provides instructions on all of the necessary information required by the NRC. This guidance can be found on the NRC's public web site at http://www.nrc.gov/materials/miau/licensing-guidance-form313a.pdf. The NRC Form 313A series can be found at http://www.nrc.gov/reading-rm/doc-collections/forms/.

(Contact: Cindy Flannery, Office of Federal and State Materials and Environmental Management Programs, 301-415-0223; e-mail: cmf@nrc.gov)

MEDICAL EVENTS CAUSED BY ERRORS IN UNITS OF MEASUREMENT

In 2006, there were three reported medical events caused by errors in activity units resulting in doses that were 26-28% higher than prescribed. One case was the result of a data entry error in which the intended value of seed activity in units of millicuries (mCi) was actually specified in the treatment planning system in units of air kerma strength (U). More specifically, the intended value of 0.34 mCi per seed was actually entered into the software as

0.34 U per seed, which equates to 0.27 mCi per seed. Based on a lower seed activity, the treatment planning system calculated a higher quantity of seeds needed to deliver the intended dose, but the seeds were ordered with the higher activity of 0.34 mCi per seed. Consequently, a total activity 26% more than intended was implanted into the patient. In the second case, the treatment planning system calculated an activity of 0.394 mCi (0.5 U) per seed, but the licensee ordered 0.5 mCi per seed, resulting in the patient receiving an implant with a total activity 27% higher than intended. The third event was caused by the manufacturer delivering an activity of 0.4 mCi per seed when the licensee actually ordered seeds with an activity of 0.4 U per seed, resulting in the patient receiving an implant with a total activity 28% higher than intended. There have been several additional reported medical events of this type prior to 2006. Although the details of the medical events varied, the root cause for all of these events was human error, not the design of the equipment.

As a measure for prevention of these types of medical events, the units of activity (mCi vs. U) of the seeds received from the manufacturer and the units of activity of the seeds in the prescribed treatment should be double checked prior to implantation. Dual checks should also be made on the correctness of the ordered activity and the total activity received. Precautions can also be taken by developing working procedures that require key processes to be subject to independent confirmation. Licensees are reminded to refer to the software manufacturer for the appropriate methods of data entry. Effective communications between all involved persons (e.g. licensee staff, seed manufacturer, treatment planning software manufacturer) is vital to an effective process.

(Contact: Cindy Flannery, Office of Federal and State Materials and Environmental Management Programs, 301-415-0223; e-mail: cmf@nrc.gov)

CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES FOR NATURALLY OCCURRING RADIOACTIVE MATERIALS AND ACCELERATOR- PRODUCED RADIOACTIVE MATERIALS

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to include jurisdiction over certain radium sources, accelerator-produced radioactive materials, and certain naturally occurring radioactive material, as required by the Energy Policy Act of 2005 (EPAct), which was signed into law on August 8, 2005. The EPAct expanded the Atomic Energy Act of 1954 definition of byproduct material to include any discrete source of radium-226, any material made radioactive by use of a particle accelerator, and any discrete source of naturally occurring radioactive material, other than source material, that the Commission, in consultation with other Federal officials named in the EPAct, determines would pose a similar threat to the public health and safety or the common defense and security as a discrete source of radium-226, that are extracted or converted after extraction for use for a commercial, medical, or research activity. In so doing, these materials were placed under the NRC's regulatory authority. Licensees and individuals who are engaged in activities involving the newly defined byproduct material in both Agreement States and non-Agreement States and United States Territories may be affected by this new authority.

Staff from the Office of Federal and State Materials and Environmental Management Programs (FSME) is providing this information so licensees, and potential new licensees, are informed of changes and new requirements in the EPAct of 2005. The NRC staff is working on several activities that will be needed to support NRC's new regulatory authority. Specifically, the NRC staff is working on finalizing revisions to the guidance in NUREG-1556, Volumes 9 "Program-Specific Guidance About Medical Use Licenses," and 13 "Program-Specific Guidance About Commercial Radiopharmacy Licenses," and developing a new NUREG (NUREG-1556, Volume 21) which is focused on the production of radioactive material using an accelerator.

The NRC will provide stakeholders with an opportunity to comment on these NUREGs in the

Spring of 2007. NRC plans to finalize the licensing guidance as close to the effective date of the final rule as possible. These guidance documents will be noticed in the *Federal Register* and posted to the NRC's NUREG-1556 public web site at the following address:

http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. The NRC staff is also evaluating the need for revisions to several other guidance documents in the NUREG-1556 series, as well as to inspection procedures (IP) 87125, "Materials Processor/Manufacturer Programs," IP 87127, "Radiopharmacy Programs," and Manual Chapter 2800, "Materials Inspection Program." Furthermore, the NRC staff is preparing a set of "Frequently Asked Questions" on radium-226 that will be publicly available. The schedule for completing these additional activities has not yet been finalized. You may access the "NARM Toolbox" at the NRC's FSME website at: http://nrc-stp.ornl.gov/narmtoolbox.html for information on NARM related activities.

(Contact: Torre Taylor, Office of Federal and State Materials and Environmental Management Programs, 301-415-7900, e-mail: tmt@nrc.gov)

STATUS AND PLANS FOR IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY-OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

On August 8, 2005, the President signed into law the Energy Policy Act of 2005 (EPAct) on "Treatment of Accelerator Produced and other Radioactive Material as Byproduct Material." Section 651(e) of the EPAct expanded the definition of byproduct material as defined in the Atomic Energy Act of 1954, as amended (AEA), and placed additional byproduct material under the U.S. Nuclear Regulatory Commission (NRC) jurisdiction as defined in section 11e.(3) and 11e.(4) of the AEA.

On March 20, 2007, the NRC issued a Regulatory Issue Summary (RIS) 2007-05, to inform recipients of the status of the NRC's efforts to implement the requirements of Section 651(e) of the EPAct. The RIS, along with a list a "Frequently Asked Questions" is available for review at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2007/ri200705.pdf. You may also access the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) website at http://nrc-stp.ornl.gov/narmtoolbox.html for additional information on naturally-occurring and accelerator-produced radioactive material (NARM) related activities.

Regulations:

Section 651(e) of the EPAct requires that the Commission issue final regulations establishing requirements for licensing and regulating section 11e.(3) and 11e.(4) byproduct material, while cooperating with the States, and using model State standards to the maximum extent practicable. NRC has made significant progress toward completion of the final regulations, which are currently expected to be published in the Spring of 2007. The final regulations will become effective 60 days after the date of publication, and will be posted to NRC's Public Involvement Rulemaking website, which is located at http://www.nrc.gov/about-nrc/regulatory/rulemaking/public-involvement.html. Throughout the rulemaking process, the NRC has actively worked with both Agreement States and non-Agreement States, through the Organization of Agreement States, and the Conference of Radiation Control Program Directors, as well as with NRC's Advisory Committee on the Medical Uses of Isotopes, other Federal agencies, professional organizations, and the medical community.

Waiver:

As provided for by the EPAct, the Commission issued a waiver on August 31, 2005 (70 FR 51581) to: (1) allow States to continue with their regulatory programs for NARM; (2) allow persons engaged in activities involving NARM to continue with their operations in a safe manner; and (3) allow continued use of radiopharmaceuticals for medical purposes. The waiver is in effect through August 7, 2009, unless the Commission terminates it earlier.

The Commission plans to terminate the waiver in phases, after the final rule is issued, starting from the effective date of the rule and ending on August 7, 2009. During the initial phase of waiver terminations, which will occur in conjunction with the effective date of the final rule, the Commission

intends to terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana.

At this time, the timing and schedule for waiver terminations for the remainder of the non-Agreement States and U.S. Territories have not been established. A notice in the *Federal Register* will be published approximately six months before the effective date of the waiver termination to notify users of their waiver terminations and implementation dates of the rule. NRC staff will notify impacted State regulators individually prior to the publication of the *Federal Register* notice. The NRC also plans to provide additional notification to known entities impacted by the initial phase of waiver terminations following publication of the final rule in the *Federal Register*.

Upon waiver termination, all persons that possess the new byproduct materials in these States, U.S. Territories, or areas of exclusive Federal jurisdiction must be in compliance with NRC regulations, including, for example, meeting the reporting and recordkeeping requirements for the new byproduct material. Such persons will also either be required to: (1) apply for license amendments for the new byproduct material within 6 months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license; or (2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

In conjunction with the effective date of the final rule, the Commission also intends to terminate the waiver for any of the 34 Agreement States that provide a certification from their Governor to the Commission as described in the EPAct and the Commission's Transition Plan mandated by the EPAct (see below). Users of the new byproduct materials in Agreement States should contact their respective Agreement State regulatory agency with any questions related to plans for continuing to regulate these materials.

Transition Plan:

The EPAct requires the NRC to prepare and publish a transition plan to facilitate an orderly transition of regulatory authority with respect to the newly added byproduct material. The transition plan addresses both Agreement and non-Agreement States, and has been coordinated extensively with the States. The NRC anticipates that the final Transition Plan will be published in conjunction with the final regulations in the *Federal Register*, as required by section 651(e) of the EPAct. The RIS provides additional information including where to locate a copy of the draft transition plan as well as NRC plans for publication of the final transition plan.

Supportive Activities:

The NRC staff is also working on several activities that will be needed to support NRC's new regulatory authority. Specifically, the NRC staff is working on finalizing revisions to guidance contained in NUREG-1556, Volumes 9 and 13, and developing a new NUREG (NUREG-1556, Volume 21) which is focused on the production of radioactive material using an accelerator. The NRC staff is also planning to make minor revisions to other guidance documents and procedures to reflect the regulation of the new byproduct material.

(Contacts: Andrew Mauer, Office of Federal and State Materials and Environmental Management Programs, 301-415-3962, e-mail: anm@nrc.gov; or Duane White, Office of Federal and State Materials and Environmental Management Programs, 301-415-6272, e-mail: dew2@nrc.gov)

NRC's FUEL CYCLE INFORMATION EXCHANGE (FCIX) 2007

The Nuclear Regulatory Commission (NRC) is hosting a seminar, The Fuel Cycle Information Exchange 2007 (FCIX 2007), on June 12 and 13, 2007. This will be the second annual hosting of this seminar, 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 will be held in Rockville, Maryland, at the Universities of Maryland at the Shady Grove Campus Auditorium and will be open to the public. We are expecting that NRC staff, licensees and certificate holders, and other interested parties and stakeholders will be making presentations on varying subjects of interest, with opportunity for

follow-up discussion on each subject.

Speakers from the NRC, the Nuclear Energy Institute, fuel cycle licensees and stakeholders have volunteered to address various topics; however, at this early date, the NRC is seeking additional speakers to discuss topics of a broad nature, relative to the nuclear fuel cycle. If you would like an opportunity to discuss an issue, or to offer an additional topic of discussion, please contact the staff member listed below. Additionally we ask that you provide the staff contact with a Microsoft Powerpoint version of your presentation at least 45 days prior to the seminar.

Registration: Preregistration by e-mailing the staff contact listed below is recommended to facilitate the distribution of meeting information and preparation of identification badges; however, on-site registration will be allowed on the days of the meeting.

Dates and location:

June 12, 2007, doors open at 8:00 am; meeting starts at 9 a.m.

June 13, 2007, doors open at 8:00 am; meeting starts at 9 a.m.

Universities of Maryland at the Shady Grove Campus Auditorium,

9630 Gudelsky Drive
Rockville, MD 20850.

Updated information regarding the meeting will be posted on the agency public meeting website at http://www.nrc.gov/public-involve/public-meetings/index.cfm?fuseaction=Search.Detail&MC=20070137&NS=0&CFID=120254&CFTOKEN=54666193

(Contact: James Smith, Office of Nuclear Material Safety and Safeguards, Division of Fuel Cycle Safety and Safeguards, Mail Stop: T8F42, 301-415-6459, Fax: 301-415-5370, e-mail: jas4@nrc.gov)

WEB-BASED COURSE "EVALUATION OF DOSE MODELING FOR COMPLIANCE WITH RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION"

The Division of Waste Management and Environmental Protection developed, through contract with Argonne National Laboratory, a web-based version of a classroom course originally developed in 2004 entitled "Evaluation of Dose Modeling for Compliance with Radiological Criteria for License Termination." The general objective of this course is to familiarize NRC staff with how to review dose modeling aspects of licensee-submitted decommissioning and license termination plans. There are no prerequisites for the course, although familiarity with dose modeling codes such as DandD and RESRAD would be helpful. In addition to sixteen individual course modules on various topics related to decommissioning dose modeling, the course hyperlinks to supporting documents allowing the course to serve as a comprehensive on-line resource to decommissioning staff. The course is available on the Training Web-site with other NRC developed web-based training or can be accessed directly through the following URL: http://grape.nrc.gov/NMSS/Decom/login.cfm.

(Contacts: Cynthia Barr, FSME/DWMEP, 301-415-4015; e-mail: csb2@nrc.gov, and Chris McKenney, FSME/DWMEP, 301-415-6663; e-mail: cam1@nrc.gov)

UNITED STATES ENRICHMENT CORPORATION (USEC Inc.) HIGHLIGHTS

On April 13, 2006, the U.S. Nuclear Regulatory Commission (NRC) issued USEC Inc. a license to construct and operate a gas centrifuge uranium enrichment facility, known as the American Centrifuge Plant (ACP), in Piketon, OH. USEC Inc. submitted its application for the ACP in August 2004. In April 2006, the NRC staff completed its "Environmental Impact Statement for the Proposed American Centrifuge Plant in Piketon, Ohio," NUREG-1834. In September 2006, the NRC staff completed its "Safety Evaluation Report for the American Centrifuge Plant in Piketon, Ohio," NUREG-1851. On April 13, 2007, the Atomic Safety and Licensing Board (ASLB) issued its decision on the mandatory hearing finding that the NRC staff adequately performed its safety and environmental reviews of the USEC Inc. license application and environmental report. In addition, on April 13, 2007, the Department of Energy and the NRC signed a Memorandum of Understanding

(MOU) regarding the regulatory oversight of the ACP. The MOU delineates each agency's regulatory oversight responsibilities, ensures adequate oversight, avoids dual regulation of USEC Inc., and avoids any gaps in oversight.

(Contact: Brian Smith, Office of Nuclear Material Safety and Safeguards, Division of Fuel Cycle Safety and Safeguards, Enrichment and Conversion Branch, 301-4157457, e-mail: bws1@nrc.gov)

GENERIC COMMUNICATIONS ISSUED(December 1, 2006 - March 31, 2007)

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 Angela R. McIntosh, FSME, 301-415-5030; email: arm@nrc.gov.

Bulletins (BL)

None.

Generic Letters (Gl)

None.

Information Notices (IN)

IN 2007-03, "Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 Less Than the Prescribed Dosage Because of Capsules Remaining in Vials After Administration" was issued February 2, 2007. This IN was issued to all NRC medical use licensees, NRC Master Materials Licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical contact: Cindy Flannery, FSME, 301-415-0223; e-mail: cmf@nrc.gov)

IN 2007-08, "Potential Vulnerabilities of Time-Reliant Computer-based Systems Due to Change in Daylight Saving Time Dates" was issued February 28, 2007. This IN was issued to all NRC licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical contact: Matthew Chiramal, NRR/DE, 301-415-2845; email: mxc@nrc.gov)

IN 2007-10, "Yttrium-90 Theraspheres® and Sirspheres® Impurities" was issued 03/13/07. This IN was issued to all U.S. Nuclear Regulatory Commission (NRC) Medical Licensees, NRC Master Materials Licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical contact: Mohammad Saba, FSME, 301-415-7608; e-mail: mss@nrc.gov)

Regulatory Issue Summaries (RIS')

RIS 2007-03, "Ionizing Radiation Warning Symbol" was issued March 1, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission (NRC) licensees, certificate holders, and all Radiation Control Program Directors and State Liaison Officers.

(Technical contacts: John P. Jankovich, FSME, 301- 415-7904; e-mail: jpj2@nrc.gov, and Nima Ashkeboussi, FSME, 301-415-7637; email: naa@nrc.gov)

RIS 2007-04 "Personally Identifiable Information Submitted to The U.S. Nuclear Regulatory Commission" was issued March 9, 2007. This RIS was issued to all holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs, all licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) of the use of source, byproduct, and special nuclear material.

(Technical contact: Russell A. Nichols, OIS, 301-415-6874; e-mail: ran2@nrc.gov)

RIS 2007-05, "Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-Occurring and Accelerator-Produced Radioactive Material" was issued March 20, 2007. This RIS was issued to all NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes.

(Technical contacts: Duane E. White, FSME, 301-415-6272; e-mail: dew2@nrc.gov; Andrew N. Mauer, FSME, 301-415-3962; e-mail: anm@nrc.gov; Donna M. Janda, Region I, 610-337-5371; e-mail: dmj@nrc.gov; Kevin G. Null, Region III, 630-829-9854; e-mail: kgn@nrc.gov; and Rachel S. Browder, Region IV, 817-276-6552; e-mail: rsb3@nrc.gov)

(General Contact: Angela R. McIntosh, FSME, 301-415-5030; email: arm@nrc.gov)

SIGNIFICANT EVENTS

(January 1, 2007 - March 31, 2007)

Event #1: Extremity Overexposure to Radiation Worker

Date and Place: February 6, 2007, Tallahassee, Florida

Nature and Probable Causes: The licensee reported receiving an employee's left hand dosimetry report that revealed an exposure of 50.68 centiSievert (cSv) (rem). The employee had handled various isotopes during the monitored time period. It was determined that the employee's technique in handling radioactive material was not fast enough to minimize exposure to her hands. The licensee made several attempts to improve her handling technique, but could not. The individual terminated employment with the licensee.

Event #2: Medical Event Involving Mammosite Treatment

Date and Place: March 19, 2007 Bakersfield, California

Nature and Probable Causes: The licensee reported that a patient receiving mammosite treatment with a total prescribed dose of 3,400 centiGray (cGy) (rad) to be delivered in 10 fractions over the course of five days, only received 1,700 cGy (rad). The treatment was performed using a Nucletron high dose rate brachytherapy unit (model 105.999) and an Iridium-192 source with an activity of 151.7 gigabecquerels (GBq) (4.1 Curies). The first five fractions were delivered uneventfully. During the last five fractions, the radiation therapy technologist accidentally imported the wrong treatment plan, resulting in an under dose to the treatment area. The dwell position of the source was actually fully outside of the patient, so the tumor received effectively no dose. The licensee is calculating the skin and whole body dose to the patient. The patient and referring physician have been notified and re-treatment has been scheduled. The incident was discovered upon review of the patient's chart when the patient returned for a follow-up exam.

(CONTACT: Angela R. McIntosh, FSME, 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.

Individual Actions

Brandon Fontenot (IA-07-002)

On March 20, 2007, a Notice of Violation for a Severity Level III violation was issued for a violation involving the individual's deliberate misconduct which caused his former employer, Accurate NDE & Inspection, LLC, to be in violation of 10 CFR 20.1801 and 1802, and 10 CFR 30.9. Specifically the individual failed to: (1) secure a radiographic exposure device; and (2) provide complete and accurate information in the daily radiation survey form which was provided to the NRC inspector.

Medical

Mallinckrodt, Inc. (EA-06-280)

On December 27, 2006, a Notice of Violation was issued for a Severity Level III problem involving the failure to close, or check several valves during a planned release of certain radioactive material into a sanitary sewer system, resulting in an inadvertent release of other radioactive material into the system.

Portable Gauges

TRC Engineers, Inc. [Formerly SITE-Blauvelt Engineering, Inc.] (EA-06-286)

On January 30, 2007, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $3,250, was issued for a Severity Level III violation of 10 CFR 30.34 (i), involving the reported theft of a portable nuclear density gauge containing licensed material. The licensee failed to use a minimum of two independent physical controls to secure a portable gauge while it was not under the control and surveillance of their staff, as required. Specifically, the licensee provided one independent barrier by securing the gauge in a locked container and placing it in a locked shed for overnight storage at a temporary job site. However, the licensee failed to provide a second independent barrier when it did not secure the gauge to the shed.

EGS Associates, Inc. (EA-06-288)

On January 10, 2007, a Notice of Violation was issued for a Severity Level III violation involving the failure, on two separate occasions, to provide a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal when not under the control and constant surveillance of the licensee. Specifically, on September 21, 2006, a portable nuclear gauge was not secured within an unlocked company vehicle; and a second gauge was not secured within a locked storage shed.

Andrew Environmental Engineering, Inc. (EA-06-299)

On December 27, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to control and maintain constant surveillance of licensed material that is in a controlled, or unrestricted area and that is not in storage. Specifically, the gauge user left the portable gauge unattended at a job site to answer a phone call, thus failing to control access to the unrestricted area and provide constant surveillance of the gauge.

Pennoni Associates, Inc. (EA-06-252)

On December 21, 2006, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of $3,250 was issued for a Severity Level III problem composed of three violations. The violations involved: (1) the failure to use a minimum of two independent physical controls to secure a portable gauge from unauthorized removal when the gauge was not under the control and constant surveillance of the licensee; (2) the failure to control and maintain constant surveillance of licensed material in an unrestricted area; and (3) the failure to immediately report the loss of licensed material. Specifically, an authorized user loaned a vehicle containing NRC licensed material in a portable gauge to an unauthorized individual. Although the gauge was secured to the vehicle in its locked transport container in the rear seat of the vehicle (one barrier), the second barrier (locked door) was compromised when the authorized user gave the vehicle keys to the unauthorized individual who drove off with the vehicle. As a result, only one independent physical barrier to secure the portable gauge and prevent its unauthorized removal remained. The gauge was then left unsupervised in the public domain for approximately four days. Additionally, the NRC was not notified of the missing gauge as required.

New Jersey Department of Transportation (EA-06-287)

On December 14, 2006, a Notice of Violation was issued for a Severity Level III violation involving the failure to use two independent physical controls that formed tangible barriers to secure a portable gauge, containing NRC licensed material, from unauthorized removal when the portable gauge was not under the control and constant surveillance of the licensee. Specifically, the licensee stored the gauge in a locked transportation case inside a locked wooden box located inside an unoccupied, unlocked building. The wooden box was not under the licensee's control, was not secured, and could be

accessed by unauthorized individuals.

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

SELECTED *FEDERAL REGISTER* NOTICES

(January 1, 2007 - March 31, 2007)

10 CFR Part 110 [RIN 3150-AI02] "Export and Import of Nuclear Material; Exports to Libya Restricted." 72 FR 1426, January 12, 2007.

(Contact: Jennifer Schwartzman, Office of International Programs, 301-415-2317, e-mail: jks1@nrc.gov, or Brooke G. Smith, Office of International Programs, 301-415-2347, e-mail: bgs@nrc.gov)

10 CFR Part 73 [RIN 3150-AH90] "Secure Transfer of Nuclear Materials." 72 FR 3025, January 24, 2007.

(Contact: Frank Cardile, Office of Federal and State Materials and Environmental Management Programs, 301-415-6185, e-mail: fpc@nrc.gov)

10 CFR Part 72 [RIN 3150-AI03] "List of Approved Spent Fuel Storage Casks: Standardized

NUHOMS[reg] System Revision 9." 72 FR 4615, February 1, 2007.

(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 72 [RIN 3150-AI03] "List of Approved Spent Fuel Storage Casks: Standardized

NUHOMS[reg] System Revision 9, Proposed rule." 72 FR 4660, February 1, 2007

(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 73 [RIN 3150-AI04] "Relief From Fingerprinting and Criminal History Records Checks." 72 FR 4945, February 2, 2007.

(Contact: Jared K. Heck, Attorney, Office of the General Counsel, 301-415-1623, e-mail: jkh3@nrc.gov)

"Call for Nominations." 72 FR 15172, March 30, 2007.

(Contact: Ashley M. Tull, Office of Federal and State Materials and Environmental Management Programs, 301-415-5294; e-mail: amt1@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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