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Protecting People and the Environment

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

LICENSEE NEWSLETTER

Contents ***Page***

FROM THE DESK OF THE FSME DIRECTOR

With this edition of the Licensee Newsletter, we have decided to add a new feature, an open letter from me, the Director of the Office of Federal and State Materials and Environmental Management Programs (FSME). I will try to use this space to keep you posted on items and issues of general interest since I view this as an important communications tool between our office, and you, our licensees, and other key stakeholders.

For this first letter, I would like to share my philosophy on FSME's role as Federal regulator for nuclear materials, waste and environmental activities. First, I would like to acknowledge the fact that FSME and our regional partners regulate only about 4,500 nuclear materials users, while the 34 Agreement States regulate nearly 18,000 users. With Pennsylvania's application already in the queue, and with New Jersey and Virginia also moving in the direction of becoming Agreement States in the near future, the U.S. Nuclear Regulatory Commission (NRC) role will continue to evolve. In this context, I want everyone to know that I take seriously my responsibility to share information with the States and leverage our talents as regulators with theirs. I think we at the NRC do many things well, and I know that the States do too.

Last Summer, when the Commission approved the NRC reorganization that created FSME out of the former Office of State and Tribal Programs and parts of the Office of Nuclear Material Safety and Safeguards, they did so to elevate the visibility of State and Tribal programs to a major program office level and they directed me to remain engaged with the States to strengthen their roles in the program to make it a truly national materials program. I pledge to you all that I will do everything I can to make that a reality.

The American public needs to know that all 22,000 plus nuclear materials licensees across the country are using nuclear material in a safe and secure manner, regardless of whether they reside in an Agreement State or a non-Agreement State. Licensees need to know that there will be a consistent and predictable regulatory environment regardless of the regulator.

One of the ways I think this can happen is through dialogue and communication at all levels. The FSME managers and staff, and our regional counterparts, are committed to outreach. We want to hear from other regulators, from local stakeholders, and from licensees if our regulatory

approaches can be improved. We will use our website, this Newsletter, generic communications, Federal Register Notices, Information Notices, Bulletins, licensee workshops, etc., and we will travel across the country to engage with interested stakeholders at all levels, as much as we can. That is our commitment. We encourage you as licensees, regulators, or interested stakeholders to let us know if we are on track, or if we need to do better. While we may not always agree, we want to do everything we can to explain our regulatory decisions and to operate in an open regulatory environment.

Charles Miller

Appointment of Patrice M. Bubar as Deputy Director, Division of Intergovernmental Liaison and Rulemaking

Patrice M. Bubar has been selected as Deputy Director, Division of Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs. Ms. Bubar is a member of the Special Executive Services and was most recently the Deputy Assistant Secretary for Corporate Safety Analysis at the U.S. Department of Energy (DOE). She began her government career in 1978 with the Environmental Protection Agency where she spent 13 years in the Water, Superfund, and Radiation Programs. Since 1991, Ms. Bubar has served in a number of senior positions at DOE, including Director, Rocky Flats Program Office; Associate Deputy Assistant Secretary for Integration/Disposition; and Deputy Assistant Secretary for Integrated Safety Management. Ms. Bubar received a B.S. degree in Environmental Engineering from the University of Pittsburgh.

Ms. Bubar has interacted with the NRC on many waste and materials issues. She was DOE's executive lead on the May 2003 report jointly prepared by the NRC and DOE entitled "Radiological Dispersal Devices: An Initial Study to Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging and Disposition." She also worked on waste disposal issues with NRC including Greater Than Class C and Scrap Metals Recycling. Ms. Bubar has worked on international activities with the NRC and other Federal agencies and currently serves as the Vice-Chair of the Joint Convention on Waste and Spent Fuel.

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

MONITORING VISIT AND PUBLIC MEETING REGARDING DOE'S DISPOSAL OF INCIDENTAL WASTE AT IDAHO NATIONAL LABORATORY

On April 24-25, 2007, the U.S. Nuclear Regulatory Commission (NRC) staff conducted its first monitoring visit at the U.S. Department of Energy (DOE) Idaho National Laboratory Tank Farm Facility (INL TFF). The NRC staff also hosted a public meeting in Idaho Falls, Idaho on April 25, 2007, to discuss NRC's roles and responsibilities under the Ronald Reagan National Defense Authorization Act for FY 2005 (NDAA). The NDAA requires DOE to consult with NRC on its waste determinations at INL and requires NRC to monitor DOE disposal actions to assess compliance with 10 CFR Part 61, Subpart C, performance objectives for low-level waste.

The INL TFF was established in 1953 to store incidental waste as part of DOE's effort to recover fissile uranium by reprocessing spent nuclear fuel. There are a total of 15 stainless steel waste storage tanks in TFF. Among them, eleven larger tanks with 300,000 gallon capacity are also housed in reinforced concrete vaults. DOE intends to close the TFF in phases and the closure process comprises tank system cleaning and stabilization activities. DOE tank cleaning began in 2002, and the final TFF closure is planned for 2012.

This monitoring visit was primarily focused on waste storage tank grouting activities and DOE's radiation protection program to protect workers and the public from radiation exposure during tank closure operations. After a tour of the INL TFF site, reviews of DOE's records, and interviews with DOE and its contractor personnel, NRC staff concluded that DOE has an adequate quality assurance program pertaining to tank grouting operations and an adequate radiation protection program in place to protect its personnel from radiation exposures. Another site visit is planned for later this year as grouting operations at the TFF proceed.

The purpose of the public meeting was to provide the public with a better understanding of NRC's activities in implementing the NDAA and in reviewing DOE's waste determination for the INL TFF. NRC staff presented an overview of NRC's implementation of the NDAA, the history of NRC's involvement in DOE waste determinations, and the criteria for waste determinations under the NDAA. NRC staff also presented an overview of the

October 2006 Technical Evaluation Report which documented the staff's review of DOE's draft waste determination for the INL TFF, as well as planned NRC monitoring activities of DOE waste disposal operations at the INL. The NRC staff answered and discussed a wide range of questions and comments from the public pertaining to DOE's waste disposal and tank closure activities. The public meeting was well attended and included representatives from the Snake River Alliance, the Idaho Department of Environmental Quality, DOE, and the office of U.S. Senator Larry Craig.

(Contact: Xiaosong Yin, FSME/DWMEP, 301-415-7640, Fax: 301-415-5397, Mail Stop: T8 F5; e-mail: xxy@nrc.gov)

Agency Announces 2007 Fee Schedule

The NRC has announced the licensing, inspection, and annual fees it will charge licensees and applicants this fiscal year.

Congress requires that the agency recover most of its annual appropriated budget through two types of fees, one for specific services and the other for generic regulatory expenses and other costs. The fees are paid to the U.S. Treasury and go into the general fund.

For fiscal year 2007, NRC must recover 90 percent of its budget, less the amounts appropriated from the Nuclear Waste Fund for high-level waste activities and from general funds for waste-incidental-to-reprocessing and generic homeland security activities. For FY 2007, the amount to be recovered is approximately $670.5 million, about $45 million more than in 2006.

The final rule establishes a single hourly rate of $258 for activities in both the Nuclear Reactor Safety Program and the Nuclear Materials and Waste Safety Program. This represents an increase from $217 for the reactor program and $214 for the materials program, and it reflects a revised estimate of staff hours spent on specific activities, such as licensing actions, inspections, and regulatory development.

Annual fees will increase for power reactor licensees, but will decrease for most other types of licensees. You can read more about the fees at http://www.nrc.gov/reading-rm/doc-collections/news/2007/07-069.html.

RadMap: EPA's New Emergency Response Tool

RadMap is the U.S. Environmental Protection Agency's (EPA) new interactive desktop tool featuring a Geographic Information Systems (GIS) map with quick access to information on long-term radiation monitoring locations across the country. Designed for use by emergency responders, RadMap provides access to key information about the monitors and the area surrounding them. There is currently information on a few hundred monitors in RadMap including monitoring systems sponsored by EPA, some States and DOE facilities. We would welcome NRC participation and will seek participation of additional States as well.

Registered users can download RadMap onto their desktop computer, a critical feature should other systems fail during an emergency. In the event of a radiation release, RadMap can help emergency responders collect information, develop assessments, and determine the placement of deployable monitors. Users can zoom in on an area of the map to identify information about the monitor and to characterize the monitor location.
RadMap provides easy access to:

- Monitor locations
- Points of contact for specific monitoring systems
- Data being collected and how often
- Real-time and long-term data, where available online
- Information on population centers from the 2000 census
- Geographic features such as nearby roads and bodies of water
- Distances from point to point

RadMap helps fulfill one of EPA's critical homeland security responsibilities under the National Response Plan, and addresses recommendations made by both the Conference of Radiation Control Program Directors and EPA's Science Advisory Board (SAB).

EPA is working to make RadMap a complete and useful emergency response tool. If you would like to see how RadMap works, would like additional information or can provide information to help complete the map, contact Jacolyn White at white.jacolyn@epa.gov, or give her a call at 202-343-9474.

Clarification of the Two Part Requirement of Written Directives for Brachytherapy Procedures (Except High Dose-Rate Remote Afterloaders)

Written directives are required for higher-risk procedures to ensure that there is a high degree of confidence that the radiation dose from byproduct material will be administered according to the directions of the authorized user (AU) physician. During some recent inspections that have been conducted in response to reported medical events, the NRC inspectors have found that several licensees are not aware that the written directive requirements for manual brachytherapy and low, medium, and pulsed-dose rate remote afterloader brachytherapy require that the written directive be completed in two parts [see 10 CFR 35.40(b)(6)]. For other administrations requiring a written directive (e.g., high-dose rate remote afterloading brachytherapy), the entire written directive must be completed before the administration.

For certain types of manual brachytherapy (e.g., permanent implant manual brachytherapy), the number of sources used is often not known until the procedure is being performed. Therefore, the written directive requirements for manual brachytherapy as well as low, medium, and pulsed-dose rate remote afterloader brachytherapy [10 CFR 35.40(b)(6)], allow for a portion of the written directive to be completed after the procedure has begun.

The first part of the written directive must be completed before implantation of the sources, and must include the following information: the patient's name, treatment site, the radionuclide, and dose. The written directive must be signed and dated by the AU physician before the radiation therapy treatment begins.

The second part of the written directive is completed after implantation, but before completion of the procedure, and must include the following information: the radionuclide, treatment site, number of sources, and the total source strength and exposure time (or the total dose).

As stated in 10 CFR 35.40(b)(6)(ii), the second part of the written directive must be completed before completion of the procedure, which is the time when the sources are removed from the patient for temporary manual brachytherapy, and low, medium, and pulsed-dose rate remote afterloader brachytherapy. In cases of permanent implant manual brachytherapy, "completion of the procedure" is more difficult to define. Consequently, the written directive requirements in 10 CFR 35.40(b)(6) will be revised for permanent implant brachytherapy.

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

Authorized User Training: Options Available Under the Alternate Pathway for Meeting the Classroom and Laboratory Training Requirement

Physicians seeking to become authorized users (AU) for the medical use of unsealed byproduct material are required to complete a specified total number of hours of training and experience (T&E). For physicians seeking AU status under the alternate pathway (the pathway for approval that is granted based on NRC's evaluation of an individual's training and experience) the regulations further specify that the minimum number of those total hours of T&E are to be devoted to "classroom and laboratory training." The remainder of the required total hours of T&E are spent on "supervised work experience."

Proposed AUs have options that add flexibility to the manner in which they can meet the requirement for the minimum number of hours in "classroom and laboratory training."

The required "classroom and laboratory training" may be obtained in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Applicants may also fulfill the "classroom and laboratory training" requirement in a setting other than the traditional classroom setting. NRC broadly interprets "classroom and laboratory training" to include various types of instruction, including online training. NRC will evaluate training on a case-by-case basis, however, as long as the training 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, NRC generally will accept such training.

Another option that adds flexibility in meeting the requirement for the minimum number of hours in "classroom and laboratory training" is that some of the clinical laboratory experience may be credited toward the "classroom and laboratory training." All

hours credited to "classroom and laboratory training" must include one of the subject areas listed in the applicable regulations and it must relate directly to radiation safety tasks or hands-on use of byproduct material for the uses for which authorization is being sought. Any training that is obtained in a clinical laboratory setting that is credited toward the "classroom and laboratory training" cannot also be credited toward the "supervised work experience" category of the specified total number of T&E hours. For instance, if an applicant received a given number of hours in a clinical nuclear medicine laboratory in the subject area of instrumentation and credited those hours to that required topic under the "classroom and laboratory training" category of the T&E, those same hours, although applicable to the subject matter, could not also be credited toward the required topic of performing checks for proper operation of survey meters under the "supervised work experience" category of the T&E.

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

New Medical List Server

NRC is aware that some stakeholders may benefit from more timely notification of the issuance of medical-related generic communications, newsletters, and Federal Register Notices. To serve the needs of these stakeholders, the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) has established a new list server that will send automatic e-mail notifications of the publication of these items.

Individuals may subscribe or unsubscribe to the new list server by sending an e-mail to medical-gc@nrc.gov, with "Subscribe" or "Unsubscribe" in the subject line. For guidance pertaining to the use of the list server, NRC staff asks that users be mindful of the points listed below.

- Do not reply to e-mails sent from the list server e-mail address medical-gc@nrc.gov. It is intended for subscribing and unsubscribing to the list server only.
- Questions pertaining to the list server itself should be sent to Med-listserverquestions@nrc.gov.
- Questions pertaining to the content of generic communications, Federal Register notices and newsletter articles should be directed to the technical contact(s) identified in the applicable document.

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

GENERIC COMMUNICATIONS ISSUED (April 1, 2007 - June 30, 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 McIntosh, 301-415-5030 or by e-mail: arm@nrc.gov.

Bulletins (BLs)

None.

Generic Letters (Gls)

None.

Information Notices (INs)

IN 2007-13, "Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities" was issued April 4, 2007. This IN was issued to all licensees authorized to possess a critical mass of special nuclear material.

(Technical Contact: Dennis Morey, NMSS, 301-415-6107; e-mail: dcm@nrc.gov)

IN 2007-16, "Common Violations of the Increased Controls Requirements and Related Guidance Documents," was issued May 2, 2007. This IN was issued to all licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005, and December 22, 2005.

(Technical Contact: Joshua Palotay, FSME, 301-415-6231; e-mail: jxp5@nrc.gov)

IN 2007-19, "Fire Protection Equipment Recalls and Counterfeit Notices," was issued May 21, 2007. This IN was issued to all holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have

certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities.

(Technical Contacts: Naeem Iqbal, NRR, 301-415-3346; e-mail: nxi@nrc.gov; and Dennis Andrukat, NRR; e-mail: dwa1@nrc.gov)

IN 2007-20, "Use of Blank Ammunition," was issued June 11, 2007. This IN was issued to all power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants.

(Technical Contact: Joseph Willis, NSIR, 301-415-6869; e-mail: jxw3@nrc.gov)

Regulatory Issue Summaries (RIS's)

RIS 2007-07, "Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities," was issued April 5, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Christian Einberg, FSME, 301-415-5422; e-mail: cee1@nrc.gov)

RIS 2007-09, "Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications," was issued May 4, 2007. This RIS was issued to all holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).

(Technical Contact: Jeremy Smith, NMSS, 301-492-3340; e-mail: jas5@nrc.gov)

RIS 2007-10, "Subscriptions to New List Server for Automatic Notifications of Medical-related Generic Communications, Federal Register Notices And Newsletters," issued May 15, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers

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

RIS 2007-14, "Fingerprinting Requirements for Licensees Implementing the Increased Control Order," was issued June 5, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission licensees that have received the Increased Controls requirements, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Nima Ashkeboussi, FSME, 301-415-7637; e-mail: naa@nrc.gov)

RIS 2007-15, "Unescorted Access to Materials for Non-Manufacturer and Distributor Service Providers," was issued June 5, 2007. This RIS was issued to all U.S. Nuclear Regulatory Commission licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

(Technical Contact: Nima Ashkeboussi, FSME, 301-415-7637; e-mail: naa@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The 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," "ADAMS Documents". Help using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

Portable Gauges

Hirata & Associates, Inc. (EA-06-300)

On June 5, 2007, a Notice of Violation was issued for a Severity Level III violation involving the failure to use a minimum of two independent physical controls that formed tangible barriers to secure portable gauges from unauthorized removal when the gauges were not under the control and constant surveillance of licensee personnel.

U.S. Engineering Laboratories, Inc. (EA-07-035)

On May 22, 2007, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of $9,750 was issued for a Severity Level III violation involving the failure to secure licensed material from unauthorized removal resulting in the loss of a portable nuclear density gauge. The gauge was missing for approximately 5-months before it was found in the public domain in Philadelphia, Pennsylvania. A second NOV involved the failure to

immediately report the loss of the licensed material to the NRC.

Medical

Englewood Hospital and Medical Center (EA-06-309)

On April 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 problem involving the submittal of inaccurate information to the NRC in support of a request to amend the license to add an individual as an Authorized Medical Physicist.

Mercy Hospital (EA-07-018)

On April 5, 2007, 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 High Dose Rate Afterloader. The device was stored in a treatment room, and access to which was not restricted as required.

Milton A. Hershey Medical Center (EA-07-048)

On April 4, 2007, a Notice of Violation was issued for a Severity Level III violation involving the failure to secure from unauthorized removal or limit access to radioactive material located in the nuclear medicine department hot lab, which is a controlled area. In addition, the licensee did not control and maintain constant surveillance of this licensed material.

Industrial Radiography

Accurate NDE and Inspection, LLC (EA-06-281)

On March 20, 2007, a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $13,000 was issued for a Severity Level III problem. The violations involved the failure to secure from unauthorized removal or limit access to a radiographic exposure device that was being improperly stored on an offshore platform, which was in a controlled area or unrestricted area; the failure to wear required personnel dosimetry during radiographic operations; and the failure to provide complete and accurate information on documents provided to an NRC inspector. Because willfulness was associated with the problem, the NRC considered whether credit was warranted for Identification and Corrective Action in accordance with the civil penalty assessment process in the NRC Enforcement Policy, and determined that in this case, it was not.

Individual Actions

John Branyan (IA-07-010)

On May 22, 2007, a Notice of Violation was issued for a Severity Level III violation involving the individual's deliberate misconduct which caused his former employer, U.S. Engineering Laboratories, Inc., to be in violation of 10 CFR 20.2201. Specifically the individual failed to report a portable nuclear density gauge as lost or missing when the location of the gauge was unknown for approximately 5-months. The gauge was subsequently found in the public domain.

Lee-Cheng (Jean) Peng (IA-07-023)

On April 30, 2007, a Notice of Violation was issued for a Severity Level III violation involving the deliberate submittal of information that the individual knew to be inaccurate, to an NRC licensee. The licensee subsequently submitted the inaccurate information to the NRC causing the licensee to be in violation of NRC regulations.

Ching Chong Yang, Ph.D (IA-07-022)

On April 30, 2007, a Notice of Violation was issued for a Severity Level III violation involving the individual's deliberate misconduct that caused two NRC licensees to be in violation of 10 CFR 30.9. Specifically, the individual submitted information to each licensee that he knew to be inaccurate in violation of 10 CFR 30.10. The licensees subsequently submitted the inaccurate information to the NRC causing them to be in violation of NRC regulations.

SIGNIFICANT MEDICAL EVENTS

The NRC's enforcement program can be accessed via NRC's homepage [http://www.nrc.gov/] under "Public Meetings and Involvement." Documents related to cases can be accessed at [http://www.nrc.gov/], "Electronic Reading Room" "ADAMS Documents." 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.

Event 1: Brachytherapy Medical Event Due to Error with Treatment Planning System

Date and Place: March 7, 2007, New York.

Nature and Probable Causes: The licensee reported a brachytherapy misadministration event to the New York State Department of Health. The event involved a 31 year old female patient with a history of vaginal cancer. The treatment involved the use of both Cesium-137 and Iridium-192 seeds. The licensee ordered 11 ribbons of Iridium-192 seeds from Best Industries. Each ribbon contained 8 seeds with an activity of 1.855 milligram radium equivalent (3.19 millicuries, or 118 Megabecquerels) per seed. The patient was to be administered a total dose of 2,500 centigray (rads) via interstitial brachytherapy, to be delivered to the 50 centigray (rad) isodose line for a total treatment time of 50 hours.

On March 6, 2007, a Syed template was used to place the Iridium-192 seeds into the patient, and the Cesium-137 seeds were placed into the patient using a tandem applicator. Late in the morning of March 7, 2007, the medical physicist performed a manual check of the treatment plan calculations, and discovered that the hand calculations indicated a significantly higher dose rate than what was generated using the treatment planning software. The ensuing investigation, which took several hours, revealed that the original treatment plan was in error. At 5:30 p.m. on March 7, 2007, after 27 hours of treatment, the seeds were removed from the patient.

The patient received an estimated dose of 4,590 centigray (rad) to the treatment site, rather than the intended 2,500 centigray (rad). The rectal dose was 7,300 centigray (rad). The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient is being treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber

The primary cause was the use of an inappropriate Dose Rate Factor (DRF) in the treatment planning system. The value used corresponded to the DRF for air kerma, however, the seed strength entered was in milligram radium equivalent. Other causes and/or contributing factors include: (1) Failure to check the treatment pre-plan before the seeds arrived although there was time to do so; failure to double check the calculations either prior to the implant or shortly thereafter; (2) the use of a treatment planning system that underwent acceptance testing for Cs-137 and I-125, but not Iridium-192; and (3) lack of recent experience preparing a treatment using Iridium-192. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years. Due to their recent lack of experience, it would have been prudent to obtain additional review or outside review.

Event 2: Overdose Due to Pharmacy Error

Date and Place: April 24, 2007, Ashville, North Carolina

Nature and Probable Causes: The State of North Carolina was notified on April 26, 2007, of an event that involved a mis-drawn and mislabeled dose from a pharmacy in Ashville, North Carolina. The written directive from the hospital was for 30 microcuries for a diagnostic thyroid scan, but 33.9 millicuries was delivered labeled as 33.9 microcuries. The dose was administered on April 24, 2007, and the error was found on April 26, 2007. The patient and physician were notified, and the licensee is following up with the pharmacy. No information is available on any potential medical impact of the misadministration on the patient.

The licensee missed the error because although the numbers were read, the units were not verified (microcuries vs. millicuries).

Event 3: Exposure to Embryo/Fetus

Date and Place: May 29, 2007, St. Louis, Missouri

Nature and Probable Causes: The licensee reported that cancer treatment to a patient using I-131 resulted in a dose to an embryo/fetus. The patient was seen by her prescribing physician on May 22, 2007, concerning cancer treatment with I-131. The licensee conducted a pregnancy test on the patient with negative results. The patient was advised not to get pregnant prior to the treatment. On May 29, 2007, the treatment was using 4.64 gigabecquerel (125.5 millicuries) of I-131. On May 30, 2007, the patient stated that she performed a home pregnancy test with positive results. The licensee performed another test on May 30, 2007, with positive results. Staff calculated a dose to the patient's uterus as an approximation for the dose received by the embryo/fetus. The dose was estimated to be between 25 and 34 cGy (rad). The risk to the embryo/fetus is being determined by the

licensee. The possible effects will be discussed with the patient at a future date.

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

SELECTED FEDERAL REGISTER NOTICES (May 1, 2007 - June 30, 2007)

"Report to Congress on Abnormal Occurrences Fiscal Year 2006; Dissemination of Information" 72 FR 25339, May 4, 2007.

(Contact: Andrew L. Bates, Office of the Secretary, 301-415-1963; e-mail: alb@nrc.gov)

10 CFR Part 72 [RIN 3150-AI13] "List of Approved Spent Fuel Storage Casks: NAC-MPC Revision 5; Direct Final Rule" 72 FR 26535, May 10, 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-AI13] "List of Approved Spent Fuel Storage Casks: NAC-MPC Revision 5; Companion proposed rule" 72 FR 26568, May 10, 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 51 [Docket No. PRM-51-12] "State of California; Receipt of Petition for Rulemaking" 72 FR 27068, May 14, 2007.

(Contact: Michael T. Lesar, Office of Administration, 301-415-7163 or Toll Free: 800-368-5642)

10 CFR Parts 11 and 25 [RIN 3150-AH99] "Access Authorization Fees" 72 FR 27408, May 16, 2007.

(Contact: Emily Banks, Office of Administration, 301 415-0320; e-mail: erb@nrc.gov)

10 CFR Parts 26, 60, 63, 73, and 74 [RIN 3150-AI06] "Geologic Repository Operations Area Security and Material Control and Accounting Requirements" 72 FR 27766, May 17, 2007.

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

10 CFR Part 1[RIN 3150-AI17] "Emergency Preparedness Policies Developed for Nuclear Materials Facilities" 72 FR 28449, May 21, 2007.

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

10 CFR Part 1 [RIN 3150-AI17] "Emergency Preparedness Policies Developed for Nuclear Materials Facilities" 72 FR 28455, May 21, 2007.

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Jenny C. Tobin, Office of Federal and State Materials and Environmental Management Programs, 301-415-2328; e-mail: jct1@nrc.gov.

(General Contact: Gwendolyn Davis, Office of Federal and State Materials and Environmental Management Programs, 301-415-8165; e-mail: gxd@nrc.gov)

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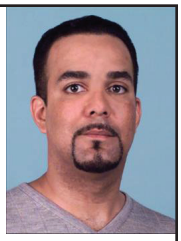

Michael K. Williamson, Editor
FSME-NMSS Licensee Newsletter
Office of Federal and State
Materials and Environmental
Management Programs

U.S. Nuclear Regulatory Commission
Two White Flint North, Mail Stop: T-8-F42
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