

## FSME TURNS FIVE



On October 1, 2006, the U.S. Nuclear Regulatory Commission (NRC) reorganization plan became effective that established the Office of Federal and State Materials and Environmental Management Programs (FSME) and restructured the Office of Nuclear Material Safety and Safeguards (NMSS). The new office, FSME, was created by merging the former Office of State and Tribal Programs with two of the technical divisions from the old NMSS. The Commission felt that this would “provide for effective organizational focus” for several major areas, including the nation’s fuel cycle strategy and the acknowledged “increasing contribution of Agreement States in the regulation of radioactive materials.” The reorganization

was designed to “elevate the visibility of State and Tribal programs to a major program office level.” The Commission directed the new office to “remain engaged with the States to strengthen their roles in the National Materials Program to make it a truly national program.”

Now here we are in late 2011. Five years have passed since the inception of FSME; we cannot believe it has been that long. Many members of the original FSME leadership team have moved into other endeavors, but the primary mission of this office has not changed. FSME remains committed to effective regulation of nuclear materials and protection of the health and safety, environment, and security of the materials we regulate. We strive to do this

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through our partnerships with the other NRC offices, especially the regions, and with an appreciation for the regulatory excellence of the 37 Agreement States. We also make every effort to be an effective liaison for Tribal issues and a place where concerns from the States or members of the public can be addressed.

Our full office name is admittedly quite a mouthful. But most important, we are quite proud of what we've accomplished in the past half-decade. With that said, we recognize that nobody is perfect and that all organizations need to continue to look for areas in which they can improve. Although we do self-assessments periodically, we also encourage your thoughts about whether or not you believe we are meeting our mission objectives or your ideas for ways we could get better. We want to know your thoughts, so tell us. We are waiting to hear from you.

The FSME Staff

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## SOURCE MATERIAL

On July 26, 2010, the NRC published a proposed rule on the distribution of source material in the Federal Register (75 FR 43425) for public comment. The rulemaking



would provide the NRC with more complete and timely

information on the types and quantities of source material distributed for use either under exemption or by general licensees. In addition, the NRC proposed to modify the existing possession and use requirements of the general license for small quantities of source material in Title 10 of the Code of Federal Regulations (10 CFR) 40.22,

“Small Quantities of Source Material,” to better align the requirements with current health and safety standards. Finally, the proposed rule would revise, clarify, or delete certain source material exemptions from licensing. The rule is expected to impact manufacturers and distributors of certain products and materials containing source material and certain persons using source material under a general license. On November 18, 2010, the NRC published in the Federal Register (75 FR 70618) a notice to extend the comment period to February 15, 2011. The NRC provided the extension to allow members of the public time to review the related guidance that was published in the Federal Register (76 FR 1100) for comment on January 7, 2011. The NRC received 14 comment letters from 9 commenters representing private individuals, industry groups, and individual companies. All comments are publicly available on regulations.gov under docket NRC-2009-0084. The comments all opposed various aspects of the rulemaking and stated concerns about the impacts on analytical laboratories, the costs resulting from new distribution licenses and proposed reductions in possession limits, and the burden associated with reporting. Many of the commenters were concerned that the burdens were not justified by the risks. The commenters also identified many areas for which they believed additional guidance

is necessary. The working group is currently analyzing the comments and evaluating the impacts of the proposed rule.

(Contact: Gary Comfort, FSME, 301-415-8106 or e-mail [Gary.Comfort@nrc.gov](mailto:Gary.Comfort@nrc.gov))

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## WELCOME



*Mr. Brian McDermott*

The FSME staff would like to welcome Mr. Brian J. McDermott, the former Acting Director, Division of Security Policy, Office of Nuclear Security and Incident Response (NSIR), as the new Director, Division of Materials Safety and State Agreements, FSME, which was effective in October 2011.

Mr. McDermott joined the NRC in 1990 as a reactor engineer intern. After graduation from the intern program, he served in Region I as a Reactor Engineer, Resident Inspector, at Susquehanna Steam Electric Station, and as a



## FROM THE DESK OF THE DIRECTOR

The summer edition of this newsletter contained a brief article on page 4 announcing that I had been named as the new Director of FSME. It summarized my previous assignments within the NRC and my educational and military background, so I will not repeat any of that here.

Instead, I'd like to use this space to tell you how enthusiastic I am about joining the FSME team, an organization that has earned a reputation for regulatory excellence since the office was formed in 2006. This reputation for excellence can be attributed to many things, including the hard-working staff and expanded leadership team, which is composed of the Branch Chiefs and divisional and office leadership. The successes are also closely tied to the leadership of my predecessor, Charlie Miller, his former Deputy Director, George Pangburn, and our current Deputy Director, Cindi Carpenter.

From my days in both Headquarters and the regions, I know that all regulators are only as good as the licensees they regulate. In FSME's case, we share that regulatory responsibility with 37 Agreement States. In fact, 20,000 of the 23,000 nuclear materials users are under State regulatory purview. I intend to rely heavily on the States as our partners, and I strive to communicate early and often to move us closer to a true "national materials program."

The reason that I am so eager to join FSME is because I know that this office deals with many different issues and a broad array of challenges. For example, we must continue to make progress on the information technology issues associated with development of an Integrated Source Management Portfolio. We will continue to address complex low-level-waste issues such as blending, depleted uranium, and changes to 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." We have uranium recovery applications to review from a safety and environmental perspective. We will strive to keep our rulemaking actions on schedule while also providing ample opportunities for stakeholder viewpoints to be heard and addressed.

I am a firm believer in the importance of all of the NRC values, which are located at <http://www.nrc.gov/about-nrc/values.html>. Of these, I hold openness and integrity most dearly. I commit to all of you that FSME will model these values and take them into account during the course of our daily duties.

Thanks to all of you for your solid record of safety. Let's continue to work together to ensure the public health and safety and protection of the environment in all operations involving regulated nuclear materials.

A handwritten signature in black ink that reads "Mark A. Satorius". The signature is written in a cursive, slightly slanted style.

Mark A. Satorius, Director

Senior Resident Inspector at Vermont Yankee Nuclear Power Station. He has held a number of progressively more responsible positions in Region I and NSIR. Mr. McDermott received a bachelor's degree in nuclear engineering from Pennsylvania State University and a Master of Business Administration degree from Franklin College.

The FSME staff is looking forward to working with Mr. McDermott.

## FAREWELL



*Mr. Robert J. Lewis*

The FSME staff would like to congratulate Mr. Robert J. Lewis, the former Acting Deputy Director, FSME, for his recent appointment as the new Director, Division of Preparedness and Response, NSIR, which was effective in October 2011.

The FSME staff wishes Mr. Lewis all the best in his new position.

## ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES MEETS

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises the NRC on policy and



*Committee members (left to right):*

*Dr. William Van Decker, Dr. James Welsh, Dr. Bruce Thomadsen, Ms. Laura Weil, Dr. Milton Guiberteau, Dr. Leon Malmud, Mr. Steve Mattmuller, Dr. Pat Zanzonico, Dr. Susan Langhorst, Dr. Orhan Suleiman, Dr. John Suh, and Dr. Christopher Palestro.*

technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance, evaluate certain nonroutine uses of radioactive material, and bring key issues to the attention of the Commission for appropriate action. On September 22, 2011, ACMUI met for two consecutive days at NRC Headquarters to discuss issues such as the Cardiogen generators, the NRC Medical Rulemaking Workshops, and the Permanent Implant Brachytherapy Subcommittee report. The next ACMUI meeting will take place at NRC Headquarters on April 16–17, 2012.

(Contact: Sophie Holiday, FSME, 301-415-7865 or e-mail [Sophie.Holiday@nrc.gov](mailto:Sophie.Holiday@nrc.gov))

## INTERAGENCY JURISDICTIONAL WORKING GROUP

The Interagency Jurisdictional Working Group (IJWG) was initially established in 2001 to determine the



best approach to delineating the responsibilities of the NRC and other Federal agencies and States with regard to low-level source material and materials containing less than 0.005 percent by weight concentration of uranium and/or thorium. In 2003, the IJWG recommended that the NRC's jurisdiction should be limited to uranium and thorium that are extracted or purposely concentrated for their chemical, physical, or radiological properties. This would include source material used in the nuclear fuel cycle. However, at that time, the Commission decided to defer further activities of the IJWG. In 2006, the Commission directed the NRC staff to reassemble the IJWG to determine if the IJWG continued to support the original recommendation. In subsequent deliberations, the IJWG voiced continued support for the overall recommendation, but some members wanted to see the actual legislative proposal before committing the support for their agency or organization. The Commission has decided that the NRC should prepare and, upon the Commission's approval, submit a legislative proposal through the Office of Management and

Budget. On the basis of this path forward, the Commission has determined that the IJWG has successfully completed its objectives and has decided to conclude the working group.

(Contact: Gary Comfort, FSME, 301-415-8106 or e-mail [Gary.Comfort@nrc.gov](mailto:Gary.Comfort@nrc.gov))

## SIGNIFICANT ENFORCEMENT ACTIONS



The NRC issued the following significant actions for failure to comply with regulations.

### **Del Valle Group (EA-11-009)**

On May 11, 2011, the NRC issued a Notice of Violation to Del Valle Group (DVG) for a Severity Level III violation involving the failure to obtain authorization in a specific NRC license to own and possess three portable moisture density gauges, as required by 10 CFR 30.3(a). Specifically, from November 30, 2008, through October 28, 2010, DVG owned or possessed byproduct material (discrete radium-226 sources contained in three portable moisture density gauges) without authorization in a specific or general license issued in accordance with NRC regulations.

### **Luzenac America, Inc. (EA-11-022)**

On July 7, 2011, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$8,500 to Luzenac America, Inc., for a Severity Level III violation involving the failure

to transfer a device containing byproduct material to a licensee authorized to receive it, as required by 10 CFR 31.5(c)(8)(i). Specifically, as of December 2, 2010, Luzenac transferred a fixed nuclear gauge containing byproduct material to a recycling company that was not authorized to receive it.



## MEDICAL

### **Mercy Hospital (EA-11-094)**

On June 8, 2011, the NRC issued a Notice of Violation to Mercy Hospital for a Severity Level III violation involving the failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a). Specifically, between June 18, 2008, and February 23, 2011, the licensee performed approximately 200 high-dose-rate remote afterloader administrations requiring written directives and failed to develop written procedures to provide high confidence that each administration was in accordance with the written directive.



### **Henry Ford Macomb Hospital (EA-11-088)**

On June 24, 2011, the NRC issued a Notice of Violation to Henry Ford Macomb Hospital for a Severity Level III

violation involving the failure to develop, implement, and maintain written procedures to provide high confidence that each brachytherapy treatment was in accordance with the written directive as required by 10 CFR 35.41(a). Specifically, as of December 9, 2010, the licensee's procedure did not include steps to verify that the transfer tube assembly used at the time of the administration was the same length as the one identified in the treatment plan implementing the written directive. As a result, four patients received radiation doses to areas not included within the planned treatment area.

### **Charleston Radiation Therapy Consultants, PLLC (EA-11-115)**

On June 30, 2011, the NRC issued a Notice of Violation to Charleston Radiation Therapy Consultants, PLLC (CRTC) for a Severity Level III violation involving the



failure to meet the physical presence requirements of 10 CFR 35.615(f)(2) during high dose radiation treatments. Specifically, on an indeterminate number of occasions on and before April 28, 2011, neither a CRTC authorized user nor a physician under the supervision of an authorized user was physically present during the entire duration of patient treatments involving the high-dose radiation unit.

## Bozeman Deaconess Hospital (EA-10-258)

On July 8, 2011, the NRC issued a Confirmatory Order (effective immediately) to Bozeman Deaconess Hospital (BDH) to confirm commitments made as a result of an alternative dispute resolution settlement agreement.



During the inspection and investigation, the NRC identified

two willful violations. The violations involved the failure to secure licensed materials from unauthorized removal or access as required by 10 CFR 20.1801, "Security of Stored Material," and to control and maintain constant surveillance of licensed material as required by 10 CFR 20.1802, "Control of Material Not in Storage." In response to these violations, BDH requested an alternative dispute resolution and agreed to take a number of actions as part of this Confirmatory Order. BDH agreed to provide training by an independent third-party organization to hospital staff and managers involved in NRC-licensed activities, modify the internal requirements for new workers' initial and annual refresher training, develop and implement a procedure that allows hospital employees and contractors to raise radiation safety concerns to hospital management, and pay a civil penalty in the amount of \$3,500.

Information about the NRC's enforcement program can be

accessed at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>. Documents related to cases can be accessed through the NRC's Agencywide Document Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov).

(Contact: Michele Burgess, FSME, 301-415-5868 or e-mail [Michele.Burgess@nrc.gov](mailto:Michele.Burgess@nrc.gov))

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## GENERIC COMMUNICATIONS ISSUED

The following are summaries of NRC generic communications issued by FSME. If any of these



documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Web address for the NRC library of generic communications is <http://www.nrc.gov/reading-rm/doc-collections/gen-comm>.

## REGULATORY ISSUE SUMMARIES

The NRC provides a regulatory issue summary (RIS) as an informational document



used to communicate with the nuclear industry on a broad spectrum of matters.

On September 29, 2011, the NRC issued RIS 2011-11, "Regarding Long-Term Surveillance Charge for Conventional or Heap Leach Uranium Recovery Facilities Licensed under 10 CFR Part 40." The RIS reiterated NRC policy on the long-term surveillance charge for applicable uranium recovery facilities.

(Technical Contact: Dominick Orlando, FSME, 301-415-6749 or e-mail [Dominick.Orlando@nrc.gov](mailto:Dominick.Orlando@nrc.gov))

(General Contact: Angela R. McIntosh, FSME, 301-415-5030 or e-mail [Angela.McIntosh@nrc.gov](mailto:Angela.McIntosh@nrc.gov))

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## SIGNIFICANT EVENTS



### Treatment to Wrong Lobe of the Liver

Date and Place: July 7, 2011, Madison, Wisconsin

Event Details: The licensee reported that a patient was administered 1.05 GBq (28.38 mCi) of yttrium-90 microspheres (MDS Nordion model TheraSpheres) on July 7, 2011, to the wrong



lobe of the liver as documented on the written directive. The patient was prescribed to receive 1.04 GBq (28.11 mCi) to the left lobe

of the liver for multinodular hepatic cellular cancer. A treatment plan was created for the left lobe, but, during the procedure, the right lobe was treated with the prescribed dose for the left lobe.

### Dose Administered to Wrong Patient

Date and Place: July 8, 2011, Denver, Colorado

Event Details: The licensee reported that a patient was administered 3.7 GBq (100 mCi) of iodine-131, instead of the prescribed dose of 0.74 GBq (20 mCi), for Grave's Disease. The 3.7 GBq (100



mCi) dosage was intended for another patient. The patient was discharged from the hospital before the error was discovered. The patient's physician and the patient were notified of the error. The patient was given additional instructions about his contact with members of the public.

### Overexposure Resulting in Deterministic Effects

Date and Place: September 19, 2011, Port Lavaca, Texas

Event Details: The licensee reported that a radiography trainee received an exposure to his right hand. It was

determined that the trainee had removed the guide tube from the exposure device (Amersham model 660-D) with his bare hand and saw that the 2.7 TBq (73 Ci) iridium-192 source was protruding from



the device. The individual's fingers had observable deterministic effects, including blistering of the thumb, index, and middle fingers. These effects correspond to a dose range between 20 and 30 Gy (2,000 and 3,000 rads). The trainee's whole-body dosimeter was sent for immediate processing, and the results revealed that the trainee had received a dose of 14 mSv (1.4 rem). The trainee is receiving treatment at a local hospital. The licensee has conferred with the Radiation Emergency Assistance Center/ Training Site concerning this event.

### Overexposure to Workers during Irradiator Source Exchange

Date and Place: October 8, 2011, Raritan, New Jersey

Event Details: The licensee reported a potential radiation overexposure event involving three radiation workers. The three workers were contracted to load a 44.77 TBq (1,210 Ci) cobalt-60 source assembly (International Isotopes Idaho) into an MDS Nordion model Gammacell 220 irradiator at the licensee's facility. During the procedure, the 8-inch tall source assembly was somehow dislodged



from its shielded position, so that approximately 4 inches of the assembly were exposed. In addition, the insertion tool

prevented the workers from quickly reinserting the source assembly. The workers were able to shield the assembly using titanium. They then had to force the assembly into place and broke off the insertion tool. The cobalt-60 source was then confirmed to be in a shielded configuration and safely secured. The total time that the source was unshielded was estimated to be between 25 and 30 seconds. The two workers loading the source received whole-body exposures of 17.5 and 17.2 cSv (rem); and their extremity exposures were determined to be 61.6 and 101.3 rad, respectively. They were wearing thermoluminescent dosimeters and ring badges. The third worker received a whole-body dose of 11.4 cSv (rem). Four additional workers were in attendance during the attempted source exchange. Their estimated whole-body exposures ranged between 1.5 cSv (rem) and 3.5 cSv (rem).

(CONTACT: Angela R. McIntosh, FSME, 301- 415-5030 or e-mail [Angela.McIntosh@nrc.gov](mailto:Angela.McIntosh@nrc.gov))



## SELECTED FEDERAL REGISTER NOTICES

CITATION	SUBJECT	CONTACT	PUBLISHED
76 FR 58543	"Draft Policy Statement on Volume Reduction and Low-Level Radioactive Waste Management" (Reopening of comment period)	Donald Lowman, FSME, 301-415-5452 or e-mail <a href="mailto:Donald.Lowman@nrc.gov">Donald.Lowman@nrc.gov</a>	September 21, 2011
76 FR 60935	"Notice of Application from ExxonMobil Corporation, Highland Uranium Mine and Millsite, To Amend Existing Alternate Concentration Limits and Extend the NRC Long-Term Surveillance Boundary with Respect to Materials License SUA 1139" (Notice of amendment and opportunity to provide comments, to request a hearing, and to petition for leave to intervene)	Thomas McLaughlin, FSME, 301-415-5869, fax number 301-415-5369, or e-mail <a href="mailto:Thomas.McLaughlin@nrc.gov">Thomas.McLaughlin@nrc.gov</a>	September 30, 2011

## TO OUR READERS



In our attempt to keep the FSME Licensee Newsletter relevant, we welcome useful and informative feedback on the contents of the newsletter. If you would like to suggest topics, please contact Vanessa Cox or Gwendolyn Davis from FSME Rulemaking Branch A. Ms. Cox may be contacted at 301-415-8342 or e-mail [Vanessa.Cox@nrc.gov](mailto:Vanessa.Cox@nrc.gov). Ms. Davis may be contacted at 301-415-8165 or e-mail [Gwendolyn.Davis@nrc.gov](mailto:Gwendolyn.Davis@nrc.gov). In addition, to ensure proper delivery of the FSME Licensee Newsletter and to prevent any interruption of service, please report any address changes to Ms. Cox at [FSME\\_Newsletter@nrc.gov](mailto:FSME_Newsletter@nrc.gov).

Please send written correspondence to the following address:



Vanessa Cox, Editor FSME 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  
Washington, D.C. 20555-0001