

THE 23RD ANNUAL REGULATORY INFORMATION CONFERENCE



On March 8-10, 2011, the NRC held the 23rd Annual Regulatory Information Conference (RIC) at the Bethesda North Marriott Hotel and Conference Center in Rockville, MD. The 3-day conference was sponsored by the Office of Nuclear Reactor Regulation (NRR) and the Office of Nuclear Regulatory Research (RES). This year, the RIC drew rave reviews as the best attended conference to date. More than 3,000 attendees from the nuclear industry, Congress, international agencies and members of the public gathered to discuss nuclear safety and security topics and significant regulatory activities.

The RIC began with opening remarks from NRR Director Eric Leeds, the keynote address by NRC Chairman Gregory Jaczko, and remarks from Executive Director

for Operations William Borchardt. Over the course of the conference, others speakers included Commissioner Kristine Svinicki, Commissioner George Apostolakis, Commissioner William Magwood, Commissioner William Ostendorff, and many other senior NRC managers and technical experts, as well as industry representatives.

In his keynote address titled, "Meeting Our Mission in Challenging Times," Chairman Jaczko stated that, "For the first time since 2007, we open the RIC with a Commission operating at full strength...The RIC is an invaluable forum for us to share information and exchange views about recent developments and emerging issues central to nuclear safety and security...I want to highlight priority number one at the NRC – the safety and security

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of the existing reactor fleet and nuclear materials. As I have mentioned in many speeches throughout the year, we cannot allow complacency to take root in our regulatory culture. Whether through the Institute for Nuclear



Power Operations' (INPO) efforts, licensee initiatives, or agency diligence, safety must be the number one priority."

In two of the many informative sessions, the FSME staff presented discussions on radiation protection and low-level waste management. The radiation protection session addressed topics that included; the effects of the International Commission on Radiation Protection Publication 103 on 10 CFR Part 20; and current initiatives relating to cesium-137 chloride sources. Also, the session included a presentation on the Nuclear Energy Agency's viewpoint on emerging issues in radiation protection and the radiation protection program at the U.S. Environmental Protection Agency. The session slides can be access at: https://ric.nrc-gateway.gov/docs/abstracts/SessionAbstract_5.htm.

The low-level waste management session addressed the NRC's current and planned activities to update regulations and guidance on the disposal of low-level radioactive waste (LLW). The presenters discussed the current issues related to new emerging waste streams, such as large volumes of depleted uranium, as well as proposed waste management techniques, including large-scale blending of LLW. Additionally, the session included a discussion of options that the staff is considering for revising LLW regulations in 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," to make

them more risk informed and performance based, so that they closely reflect current and expected LLW management practices. The session slides can be access at: https://ric.nrc-gateway.gov/docs/abstracts/SessionAbstract_11.htm.

The conference also included a variety of technical posters and tabletop presentations, and tours to the NRC's Incident Response Center.

THE NRC BLOG

On January 31, 2011, the NRC launched a new communications tool, The NRC Blog. The NRC Blog was established to increase collaboration and interaction with the public, in support of the Open Government initiative. The blog is intended to serve as a vehicle for informing stakeholders, raising awareness about the agency and its mission, and providing opportunity to hear from the public. The blog features posts from the NRC staff about various topics of interest to the public, as well as moderated public comments.

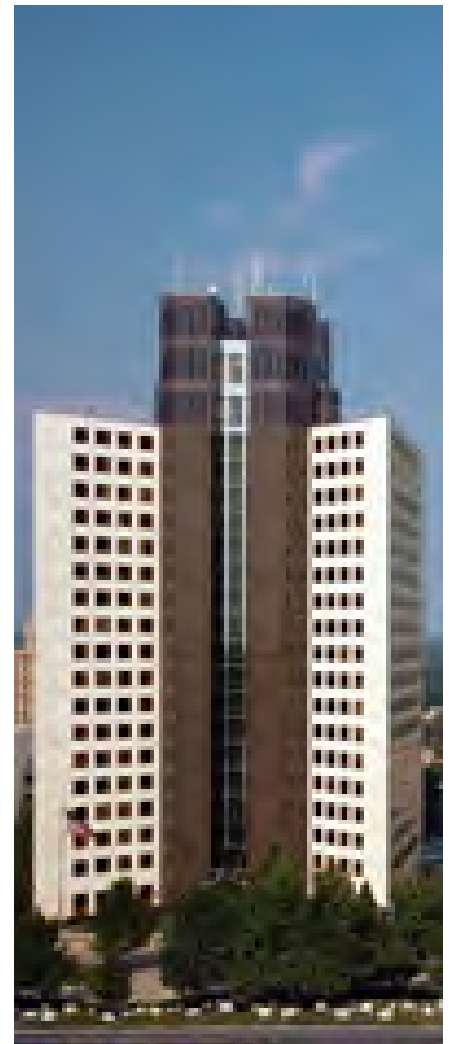
The Office of Public Affairs administers and maintains the blog, works with bloggers to ensure that they understand and follow blog procedures and style, suggests topics of interest as appropriate, reviews posts for policy and legal issues and appropriateness, and edits posts to ensure the use of plain language.

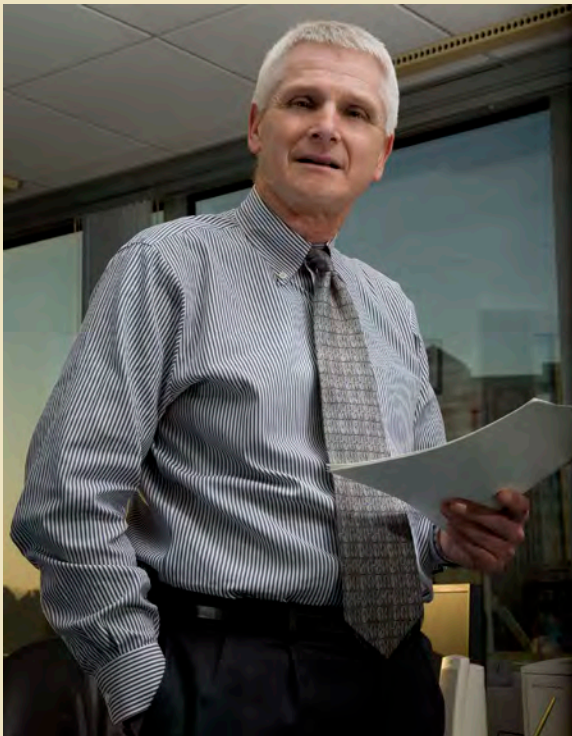
The NRC Blog is attracting thousands of readers who want to know more about the agency.

In the first month, over 22,000 people accessed the blog which included 13 posts and 83 posted comments.

The NRC Blog does not replace formal communications, such as *Federal Register* notices or meeting notices, and will not accept allegations or comments on rulemakings. The complete comment guidelines are available on the blog.

The NRC Blog can be accessed directly at: <http://public-blog.nrc-gateway.gov> or by clicking on the blog icon on the NRC website. It can also be accessed on mobile devices such as smart phones by entering the Web site address in the mobile devices' Web browser.





FROM THE DESK OF THE FSME DIRECTOR

For more than 31 years, I have worked at the NRC. In that time, I have served in a number of staff and management positions. Early in my career, I worked primarily in the reactor arena, serving as a project manager, technical assistant, and first line supervisor. Later, I was fortunate enough to serve in several management positions including emergency response and radiation protection, and served as a Deputy Director for Incident Response Operations. I was also given the opportunity to be the Deputy Director for spent fuel licensing and inspection activities. In other words, I was lucky enough to be involved in issues and projects involving most of what NRC regulates.

That being said, I have really enjoyed the past 8 years of my career. Within this timeframe, I was selected as the Director of the Division of Industrial and Medical Nuclear Safety, and in October 2006, was given the privilege of

being the first Director of the new Office of Federal and State Materials and Environmental Management Programs (FSME).

In these past years, the nuclear materials and waste management programs have really matured. I am proud of what we have all accomplished to enhance public health and safety and protect the environment. Most of the credit for this is due to the consistent and strong performance of over 20,000 Agreement State and NRC licensees, the States and regions who work closely with those licensees, and the general public who plays such an important role in helping us stay on the right track and telling us when we are over-regulating or not doing enough.

Now, it is time for me to step down. Before I do, I would like to thank the FSME staff and management. I will always carry fond memories of you with me. Moreover, when we started this office in 2006, I was concerned about how the cultures of several different organizations (the former Office of State and Tribal Programs, and several divisions of the Office of Nuclear Materials Safety and Safeguards) might mesh. That concern quickly abated as all of the FSME staff and our management team collaborated nicely and we soon developed our own office identity.

As my career was drawing to a conclusion, I was asked by Bill Borchardt, our Executive Director of Operations, to lead one last time. Following the events in Japan at Fukushima, I delayed my departure in order to lead a Task Force to determine what lessons that we might learn from the event and provide recommendations to the Commission about insights regarding the U.S. Reactor fleet, including any changes that should be made. So, I have come full circle, ending my career at the NRC where it started, in reactors.

It is always tough to leave a place where you have cultivated so many strong affiliations and lasting friendships. But I take consolation in knowing that as I retire, I leave the program in good hands. As always, I know you will keep public health and safety, and protection of the environment at the forefront of all that you do. Farewell.

Charles L. Miller
Charles L. Miller, Director

WELCOME



Ms. Deborah Jackson

The FSME staff would like to welcome Ms. Deborah Jackson as the new Deputy Director, Division of Intergovernmental Liaison and Rulemaking, which was effective in March 2011.

Ms. Jackson joined the NRC in 1987 as a project engineer in the Office of Nuclear Reactor Regulation (NRR). She has held a number of progressively more responsible positions in NRR, the Office of Nuclear Regulatory Research, and the Office of Nuclear Material Safety and Safeguards. Prior to joining the NRC, Ms. Jackson worked as a design engineer and construction inspector for the nuclear power industry. Ms. Jackson graduated with a bachelor's degree in mechanical engineering from Howard University.

The FSME staff is looking forward to working with Ms. Jackson.



FAREWELL



Mr. Mark Thaggard

The FSME staff would like to congratulate Mr. Mark Thaggard, the former Deputy Director, Division of Intergovernmental Liaison and Rulemaking, for his recent appointment as the new Deputy Director for Emergency Preparedness, Division of Preparedness and Response, Office of Nuclear Security and Incident Response, which was effective in March 2011.

Mr. Thaggard joined the NRC in 1989 as a hydrologist in the Office of Nuclear Material Safety and Safeguards (NMSS). He has held a number of progressively more responsible positions in NMSS, FSME, and the Office of New Reactors (NRO). Prior to joining the NRC, Mr. Thaggard worked for the Southwest Florida Water Management District and the U.S. Geological Survey. Mr. Thaggard received a bachelor's degree in geology from the University of South Florida, a master's degree in environmental science from the University of South Florida, and another master's degree in applied mathematics and environmental

engineering from John Hopkins University.

The FSME staff wishes Mr. Thaggard all the best and knows that he will succeed in his new position.

DECOMMISSIONING FINANCIAL ASSURANCE



The Commission has approved a final rule to improve decommissioning planning and reduce the likelihood that a facility operating under its jurisdiction will become a "legacy site." A legacy site is a common term used for a facility with an owner who cannot complete the decommissioning work for financial reasons. The final rule should be published in the *Federal Register* in late spring of 2011, after the Office of Management and Budget completes its review.

To reduce the number of future legacy sites and enhance assurance that adequate funding will be available for decommissioning each site, the final rule clarifies the actions that the licensees are required to perform during operations to minimize contamination of the site, and keep doses as low as reasonably achievable (ALARA) before, during, and after the decommissioning process. Licensees are already required by existing regulations to apply operating procedures and controls during facility operations to evaluate potential radiological hazards and minimize and control waste generation, consistent with ALARA principles.

The new rule clarifies that these ALARA principles require all licensees to conduct their operations to minimize the introduction of residual radioactivity into their sites, including subsurface soil and ground water. Currently, 10 CFR 20.1406 requires only applicants for standard reactor design certifications, standard design approvals, and manufacturing licenses to describe in their applications how their facility designs will “minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.” The new rule will amend this provision to apply it not only to those applicants, but to licensees with operating reactors and materials facilities as well.



Certain operational events, such as slow, long-term leaks, particularly those causing subsurface soil and ground-water contamination, can significantly increase the cost of decommissioning. To assure that a facility’s decommissioning fund will adequately cover these costs, the owner must have a reasonably accurate estimate of the extent of residual radioactivity at the facility site.

Currently, 10 CFR 20.1501(a) requires licensees to conduct radiation surveys that “may be necessary” and are “reasonable under the circumstances” to “evaluate the magnitude and extent of radiation levels; ... [c]oncentrations or quantities of

radioactive material; and; ... [t]he potential radiological hazards.” The new rule will revise this provision by replacing its undefined term “radioactive material” with “residual radioactivity,” a term already defined in 10 CFR Part 20 to include subsurface contamination within its scope.

When the new rule takes effect, both 10 CFR 20.1406(c) and 10 CFR 20.1501(a) will incorporate the term “residual radioactivity” to include subsurface contamination. These changes serve to reinforce the intended link between minimizing contamination and conducting surveys. Also, they are consistent with NRC policy that licensees conduct operations to minimize waste generation, which will later facilitate the decommissioning of the site. This clarification may require some licensees to perform site surveys to determine whether residual radioactivity is present in the subsurface soil or groundwater. Moreover, the licensees will maintain records of these surveys for decommissioning purposes.

The final rule will also impose tighter controls on the financial instruments used to provide assurance that adequate funding will be available to cover decommissioning costs. Decommissioning power reactor licensees, for example, will have to report additional information on spent fuel management and storage costs. Among other things, the rule will eliminate the escrow account and line of credit as approved financial assurance mechanisms. It will also modify other financial assurance requirements, including those on self-guarantee of future decommissioning funding.

(Contact: Robert MacDougall, FSME, 301-415-5175 or e-mail: Robert.MacDougall@nrc.gov)

SAFETY CULTURE

On March 7, 2011, the Commission approved the publication of a policy statement on safety culture. This policy statement, along with



two other policy statements, “Freedom of Employees

in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation” (61 FR 24336; May 14, 1996) and “Policy Statement on the Conduct of Nuclear Power Plant Operations” (54 FR 3424; January 24, 1989), describes the Commission’s expectations on safety culture and emphasizes the importance that the NRC places on the development and maintenance of a positive safety culture for all NRC-regulated activities. In addition to approving the safety culture policy statement, the Commission directed the NRC staff to ensure that the individuals and organizations performing regulated activities have the necessary support to effectively employ the policy statement as they deem appropriate. The safety culture policy statement is scheduled to be published in the *Federal Register* after it is reviewed by the Office of Management and Budget.

The policy statement describes the Commission’s expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees,

certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The policy statement defines **nuclear safety culture** as *the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment*. This definition includes safety and security issues. The policy statement also includes a set of traits that describe important areas of a positive safety culture, while acknowledging that other traits may also be important in a positive safety culture. The safety culture policy statement notes that the traits were not developed for inspection purposes. The traits included in the policy statement are: (1) Leadership Safety Values and Actions, (2) Problem Identification and Resolution, (3) Personal Accountability, (4) Work Processes, (5) Continuous Learning, (6) Environment for Raising Concerns, (7) Effective Safety Communication, (8) Respectful Work Environment, and (9) Questioning Attitude. The policy statement indicates that it is the Commission's expectation that all individuals and organizations performing or overseeing regulated activities involving nuclear materials should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizations.

Information on safety culture and NRC activities relating to safety culture can be found at

the NRC's safety culture Web site: <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

(Contact: James Firth, FSME, 301-415-6628 or e-mail: James.Firth@nrc.gov)

REVISIONS TO MEDICAL USE REGULATIONS

Expanded 10 CFR Part 35 Rulemaking

The NRC has begun to work on major revisions to the regulations governing the medical use of byproduct material regulations in 10 CFR Part 35. In 2002, the NRC revised the entire medical use regulations; however, the training and experience requirements were not finalized until 2005. The revisions focused on those medical procedures that posed the highest risk to workers and patients. They were structured to be more risk-informed and performance based. In implementing the regulations in 10 CFR Part 35, the NRC staff and Advisory Committee on the Medical Uses of Isotopes (ACMUI) identified 28 issues that should be considered in the rulemaking process. These issues include several regulatory or technical complexities (e.g., amending preceptor attestation requirements and allowing assistant/associate radiation safety officers on a medical use license). In addition to the 28 identified issues, the proposed "expanded" rule will consider issues that were raised in a petition for rulemaking, the Ritenour petition (PRM-35-20). The proposed rule is due to the Commission by March 2012 and the final rule by September 2013.



Medical Event Definition Rulemaking

On August 6, 2008, the NRC published in the *Federal Register* (73 FR 45635) for public comment a proposed rule to modify both the written directive (WD) requirements in 10 CFR 35.40(b)(6) and the medical event (ME) reporting requirements in 10 CFR 35.3045 for permanent brachytherapy



implants to convert the dose results from dose-based to activity-based. Most of the 57 comment letters received were primarily not supportive of the rulemaking. In 2008, the NRC received a substantial number of MEs involving permanent implant brachytherapy. Based on staff's evaluation and an independent NRC medical consultant's analysis of those MEs, the staff concluded that a number of them would not be categorized as MEs under the proposed rule. This would be inconsistent with the original regulatory intent.

Additionally, the evaluation of the circumstances and data from the MEs reported in 2008 prompted the staff to reevaluate the regulations related to the training requirements and time frames for licensees to assess the dose to the permanent implant brachytherapy treatment site. In SECY-10-0062, "Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated May 18, 2010, the staff recommended that a revised proposed rule be published for public comment.

In SRM-SECY-10-0062, dated August 10, 2010, the Commission disapproved the staff's

recommendation to publish the re-proposed rule. The Commission directed the staff to work closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and the broader medical and stakeholder communities to develop an event definition that will protect the interests of patients and allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users. Additionally, the staff was directed to hold a series of stakeholder workshops to discuss issues associated with the ME definition.

Please see the information on the planned workshops in the article below.

(Contact: Neelam Bhalla, FSME, 301-415-6843 or e-mail: Neelam.Bhalla@nrc.gov, for rulemaking, and Michael Fuller, FSME, 301-415-0620 or e-mail: Michael.Fuller@nrc.gov, for the workshops)

PUBLIC WORKSHOPS ON MEDICAL EVENT DEFINITION AND OTHER RULEMAKING ISSUES

The NRC will hold a series of public workshops to solicit stakeholder input on topics associated with the medical event (ME) definition, including sections involving



reporting and notifications of MEs for permanent implant

brachytherapy and other medical issues that are currently being considered for rulemaking.

The facilitated workshops will specifically cover the following issues:

- definition of medical event associated with permanent implant brachytherapy,
- relaxation of preceptor attestation requirements and extension of grandfathering to certain certified individuals,
- inclusion of the associate/assistant radiation safety officers (RSOs) on NRC medical licenses,
- addition of molybdenum breakthrough testing and reporting requirements,
- consideration of other items under rulemaking as identified in the *Federal Register* Notice (FRN).

The first 2-day workshop will be held on June 20, 2011, in New York, NY. The NRC also plans to hold a second 2-day workshop in August 2011 in Houston, TX. The specific dates and location will be posted at <http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/> when the information becomes available. Each of the meetings will include a panel of participants, who will be selected in a convening process to represent the diversity of stakeholders. In addition to the panel, the NRC is encouraging attendance and participation by all interested individuals. The meeting agenda will specifically include opportunities for viewpoints to be expressed from individuals in attendance who are not members of the panel. The NRC plans to transcribe the meetings.

The meeting notice was published in the *Federal Register* (76 FR 29171) and provided background information, issues that have been identified, and questions that have

been posed by the NRC staff for consideration.

Information about the specific meeting venues, hotel accommodations, and access to public transportation is available on the Location/Lodging page, <http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/location.cfm>. We encourage you to keep checking the workshop's Web site, <http://www.blsmeetings.net/NRCMedicalRulemakingWorkshop/>, for the most current agenda and links to subsequent documents as they become available. Documents relevant to the workshop will also be continually posted on this site.

(Contact: Varughese Kurian, FSME, 301-415-7426 or e-mail: Varughese.Kurian@nrc.gov)

EQUIPMENT FAILURE CAUSES PUBLIC RADIATION EXPOSURE

On March 4, 2011, the NRC provided an inspection report to a licensee regarding an inspection that was conducted



in response to an event that involved a malfunctioning fixed nuclear gauge. On December 17, 2009, the licensee reported the event to the NRC indicating that high radiation levels were found in the vicinity of a fixed gauge, Berthold Technologies model LB-7440-D, which contained a cesium-137 source with an activity of 150 mCi. The high radiation levels were discovered when a radiation worker approached the gauge location to prepare for its relocation. The worker used a radiation survey instrument to

measure the exposure in the area and found a reading exceeding 200 mrem/hr. Normally, these gauges only emit radiation levels less than 1 mrem/hr. Two other survey instruments were used to verify that the radiation readings were correct. The radiation worker moved the shutter actuator of the gauge to the closed position, but the radiation field did not change. Therefore, the radiation worker left the area and contacted an authorized gauge service provider, Berthold Technologies, who dispatched a service engineer to perform repairs. The service engineer removed the source head of the gauge and discovered that the source capsule had become unscrewed from the source holder and had fallen into the tapered cylindrical hole intended to provide a pathway for the radiation beam. It was determined that the source holder became detached due to the absence of the lock washer, which the Sealed Source and Device Registry (SSDR) required to be placed between the sealed source and the source holder.

The licensee had the source heads inspected on the other 43 fixed gauges of the same model that they possessed and found that 35 of the gauges were missing the required lock washer. However, none of the sealed sources in the 35 gauges were detached. In 1991, the gauges were purchased from and the sources were installed by Berthold Systems Incorporated (BSI), which is no longer in business. The sealed source and interior of the failed gauge had apparently not been inspected or serviced since the original purchase and installation that occurred in 1991. Therefore, the absence of the lock-washers

was not known to the licensee until after the investigation into the event that occurred on December 17, 2009. It should be noted that the licensee also hired a consultant to perform a dose assessment of the workers in the area and determined that six individuals, who were not radiation workers, received estimated doses in excess of the 100 mrem per year regulatory limit for members of the public. The six individuals' doses ranged from 109 to 146 mrem. No immediate health effects were believed to result from their exposure.

Due to this event, the NRC searched its event database for any similar events with the Berthold Technologies model LB-7440-D fixed gauge. The NRC has not determined that there is a generic issue or defect with this fixed gauge, but has determined that users of this gauge should be aware of this incident and the potential issues. More detailed information is discussed in NRC Inspection Report 03006794/2010-001 dated March 4, 2011, (ML11066A002).

(Contact: Duane White, FSME, 301-415-6272 or e-mail: Duane.White@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS



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

Carro & Carro Enterprises, Inc. (EA-10-272)

On February 11, 2011, the NRC issued a Notice of Violation to

Carro & Carro Enterprises, Inc. (CCE) for a Severity Level III violation involving CCE's failure to obtain a specific NRC license to own and possess a portable moisture density gauge, which contained byproduct material. Specifically, from November 30, 2008, through June 28, 2009, CCE owned and/or possessed byproduct material, a discrete radium-226 source contained in a portable moisture density gauge, without a specific license issued in accordance with NRC regulations.

Superior Well Services, Ltd. (EA-10-077)



On February 8, 2011, the NRC issued an Immediately

Effective Confirmatory Order to Superior Well Services, Ltd. (SWS) to confirm commitments made as a result of an Alternate Dispute Resolution (ADR) mediation session held on January 4, 2011. After receiving the NRC's Notice of Violation and proposed civil penalty of \$34,000 dated October 21, 2010, SWS requested an ADR to discuss the five violations that were categorized into two Severity Level (SL) III violations. The first SL III violation involved three violations related to the temporary loss of two radioactive well logging sources. The second SL III violation involved two violations related to the deliberate failure to conduct radiological surveys and the creation of inaccurate survey records. Prior to the ADR mediation session, SWS took a number of actions on their own to address the violations. These actions were intended to ensure that the corrective actions were effective and the lessons learned from these events were extended

to the well logging industry. In recognition of these actions taken by SWS, as well as the corrective actions already taken, the NRC agreed to reduce the civil penalty originally proposed to \$17,000.

McConnell Dowell (American Samoa), Ltd. (EA-10-174)

On October 6, 2010, the NRC issued a Notice of Violation to McConnell Dowell (American Samoa), Ltd., for a Severity Level III violation involving the receipt, possession, and use of byproduct material without a specific or general license as required by 10 CFR 30.3(a). Specifically, from 2008 to July 25, 2010, the licensee received, possessed and used two portable nuclear gauges in American Samoa, an area of exclusive Federal jurisdiction, without a specific license issued by the NRC.

Chicago Testing Laboratory, Inc. (EA-10-113)

On August 24, 2010, the NRC issued a Notice of Violation to Chicago Testing Laboratory (CTL), Inc., for a Severity Level III violation involving the possession and use of byproduct material without a



specific or general NRC license prior to conducting licensed activities in a non-Agreement State where the NRC maintains jurisdiction. Specifically, on multiple occasions between July 6, 2006, and August 30, 2009, CTL, an Agreement State licensee, possessed and used devices containing sealed sources in a non-Agreement State without a specific license.



Medical

Sanford Medical Center
(EA-10-182)

On December 10, 2010, the NRC issued a Notice of Violation to Sanford Medical Center for a Severity Level III violation involving the failure to secure the high dose-rate remote (HDR) afterloader brachytherapy unit in accordance with License Condition 19.A and Section 3.3.1.1 of Standard Operating Procedure, NM-X2, "Radiation Safety Procedures for the Nucletron Microselectron HDR, Version 2." Specifically, on June 15 through July 29, 2010, the licensee failed to secure the HDR afterloader unit from unauthorized use, removal or access from its storage area when the unit was not in use because a mechanical locking mechanism failed to function as designed, leaving the unit unsecured.

Bristol Hospital, Inc. (EA-11-008)



On February 17, 2011, the NRC issued a Notice of Violation to Bristol Hospital, Inc. for a Severity Level III violation involving the failure to notify the NRC Operations Center of two medical events, in accordance with 10 CFR 35.3045(c), which requires a report within the next calendar day of discovery. Specifically, on January 12, 2010, Bristol Hospital experienced two medical events involving patients receiving less than the intended prescribed dose during two different permanent prostrate brachytherapy seed implants. The administered doses differed from the prescribed doses by 50 rem to an organ or tissue and the total doses differed by greater than 20% from the prescribed doses. As of March 1, 2010, Bristol Hospital personnel had information

available to determine that those medical events had occurred on January 12, 2010, and should have therefore reported the events by March 2, 2010. However, the licensee did not verbally report the medical events to the NRC until June 2, 2010, when the NRC asked questions concerning the circumstances during an inspection.

Earth Engineers, Inc. (EA-10-062)

On June 28, 2010, the NRC issued a Notice of Violation to Earth Engineers, Inc., d.b.a. Heynen Engineers (EEI) for two Severity Level III violations. The first violation involved a failure to comply with the conditions of the NRC Order Revoking License, which was issued on June 4, 2009. Specifically, the licensee did not pay fees within 30 days or transfer the licensed material to an authorized recipient within 60 days from the date of the Order. The second violation involved a failure to afford the NRC an opportunity to inspect the EEI facility, as required by 10 CFR 19.14(a). Specifically, on October 7, 2009, the licensee did not provide the NRC access to the nuclear portable gauge to inspect the condition of the gauge. Between November 2, 2009, and January 27, 2010, the NRC made several attempts to contact the licensee, but the licensee did not provide access to the EEI facility.

Correction

In the 2010 winter edition of the FSME Licensee Newsletter, the company name of the significant enforcement action (EA-10-062) was erroneously stated. Earth Engineering, Inc. (EA-10-062) is retracted due to misprint of the licensee name.

Individual Actions

Mark M. Ficek (IA-10-028)

On September 2, 2010, the NRC issued an Order Prohibiting Involvement in NRC Activities (Effective Immediately) to Mr. Mark M. Ficek, president of Mattingly Testing Services, Inc., for multiple deliberate violations of NRC requirements and orders. The Order (IA-10-028) specified that Mr. Ficek was prohibited from engaging in all NRC-licensed activities for a period of 7 years, and that Mr. Ficek was required to notify the NRC upon initial involvement in NRC-licensed activities for an additional 3 years after the 7 year prohibition period expired.

Specifically, the NRC found that Mr. Ficek, (1) failed to implement the requirements of Confirmatory Order (EA-08-271), which dispositioned a number of willful violations through alternative dispute resolution in 2009, including conducting an assessment of the licensee's safety programs and providing safety training to the licensee's staff; (2) failed to establish and maintain a prearranged response plan with the local law enforcement agency (LLEA), as required by Increased Controls Order (EA-05-090), Appendix B, Section IC-2(b); (3) provided false information material to an NRC inspector during a site visit on March 6, 2007, in violation of 10 CFR 30.10(a)(2), regarding the licensee's effort to establish a prearranged response plan with the LLEA; (4) provided false information material to an NRC investigator while under oath on October 22, 2009, in violation of 10 CFR 30.10(a)(2), regarding the licensee's effort to establish

a prearranged response plan with the LLEA; and (5) violated the provisions of Confirmatory Order (IA-08-055) Section V.1 which specified that Mr. Ficek was prohibited for 2 years from the date of the Order (March 6, 2009) from engaging in NRC-licensed activities. Although suspended from engaging in NRC-licensed activities for 2 years, Mr. Ficek (i) directed the activities of an NRC-required independent consultant; (ii) assumed the duties of the Radiation Safety Officer to determine the reporting requirements of an event involving a lost radiographic exposure device; (iii) applied, on behalf of the licensee, for reciprocity to use radioactive materials in an Agreement State pursuant to Mattingly's NRC license; and (iv) continued to answer employees' questions about radiation safety issues and purchased radiographic exposure devices.

The NRC's enforcement program can be accessed at: <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html> under Recently Issued Significant Enforcement Actions. 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.

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

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 Internet address for the NRC library of generic communications is <http://www.nrc.gov/reading-rm/doc-collections/gen-comm>.

Regulatory Issue Summary



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 January 25, 2011, the NRC issued RIS 2011-01, "NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations other than Private Residences," to all NRC medical-use licensees, NRC master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

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SIGNIFICANT EVENTS

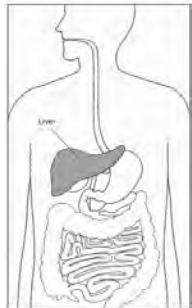
Administration of Iodine-131 to Embryo/Fetus



Date and Place:
January 12, 2011,
Portsmouth,
Virginia

Event Details: The licensee reported that a pregnant patient received 3.7 GBq (100 mCi) of I-131 on January 12, 2011, from a thyroid ablation. She was given a pregnancy test just before the dose was administered and the result was negative. On January 27, 2011, it was determined that the patient became pregnant near the time of therapy. A dose calculation estimated that the dose to the embryo/ fetus was 21.3 cGy (rad).

Overdose of Y-90 Microspheres to Left Lobe of Liver



Date and Place:
January 19, 2011,
Philadelphia,
Pennsylvania

Event Details: The licensee reported that a patient received 4.73 GBq (127.8 mCi) of Y-90 microspheres (MDS Nordion Model TheraSpheres) to the left lobe of the liver, instead of the prescribed of 1.42 GBq (38.4 mCi). As a result, the left lobe of the liver received 25,700 cGy (rad) instead of the intended 11,900 cGy (rad). The cause of the event was determined to be human error. There was a transcription error when the order form was prepared. The error was not recognized upon receipt of the Y-90, because the activity, as measured in a dose calibrator, was compared to the activity

indicated on the order form rather than the activity on the written directive. The event may result in an increased risk of atrophy to the left liver lobe. Corrective actions included generating a computer spreadsheet that populates fields based on initial calculations, written directives, and order forms. In addition, several procedure modifications were implemented to ensure that the correct dosage is ordered and received.

Overdose of Y-90 Microspheres to Left Lobe of Liver

Date and Place: March 9, 2011, Ann Arbor, Michigan

Event Details: The licensee reported that a patient received a calculated dose of 15,940 cGy (rad) to the left lobe of the liver, instead of the prescribed dose of 7,440 cGy (rad). An authorized user (AU) planned two liver infusion treatments, using Y-90 microspheres (MDS Nordion Model Theraspheres), for a patient with unresectable hepatocellular carcinoma. The first treatment to the right lobe of the patient's liver was successfully performed on December 15, 2010. The AU then ordered a 7,440 cGy (rad) dose for the left lobe of the patient's liver. The medical physicist calculated a corresponding activity of 2.24 GBq (60.5 mCi) of Y-90 to be infused into the patient's left liver lobe. However, in determining the Y-90 activity needed, the physicist used the liver segment volumes for the right lobe and medial segment combined, instead of that for the left lobe. That error resulted in an over dose of approximately 114.25% more than prescribed.

Overdose of P-32 to Two Pediatric Patients

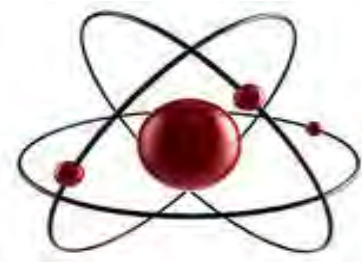
Date and Place: February 15, 2011, Dallas, Texas

Event Details: The licensee reported two medical events discovered as the result of a general chart review. The first event occurred approximately 4 months prior to the licensee's report and the second event occurred approximately 2 months prior to the licensee's report. In the first event, the patient was administered a dose of 56,500 cGy (rad) of P-32 albumin, instead of the prescribed dose of 30,000 cGy (rad). In the second event, the



patient was administered a dose of 50,700 cGy (rad), instead of the prescribed dose of 20,000 cGy (rad). The doses were administered to tissue surrounding the extremity joints of the two patients. The licensee suspects that the radiopharmacy supplied incorrect concentrations of P-32.

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SUGGESTED FEDERAL REGISTER NOTICES

CITATION	SUBJECT	CONTACT	PUBLISHED
76 FR 1100	Implementation Guidance for Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions; Draft Guidance Document for Comment	Gary Comfort, FSME, 301-415-8106 or e-mail: Gary.Comfort@nrc.gov	January 3, 2011
76 FR 6085	Draft Regulatory Guide, "Reporting and Recording Safeguards Events" (Notice of availability of draft guidance for public comment)	Phil Brochman, NSIR, 301-415-6557 or e-mail: Phil.Brochman@nrc.gov	February 3, 2011
76 FR 6086	Draft Regulatory Guide "Applying for Enhanced Weapons Authority, Applying for Preemption Authority, and Accomplishing Firearms Background Checks under 10 CFR Part 73" (Notice of availability of draft guidance for public comment)	Phil Brochman, NSIR, 301-415-6557 or e-mail: Phil.Brochman@nrc.gov	February 3, 2011
76 FR 6087	Draft Weapons Safety Assessment on the Use of Enhanced Weapons; Notice of Availability and Request for Comment	Phil Brochman, NSIR, 301-415-6557 or e-mail: Phil.Brochman@nrc.gov	February 3, 2011
76 FR 24831	Site-Specific Analyses for Demonstrating Compliance with Subpart C Performance Objectives (Notice of availability of preliminary proposed rule language and public meeting)	Andrew Carrera , FSME 301-415-1078 or e-mail: Andrew.Carrera@nrc.gov	May 3, 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 Vanessa.Cox@nrc.gov. Ms. Davis may be contacted at 301-415-8165 or Gwendolyn.Davis@nrc.gov. In addition, to ensure proper delivery of the FSME Licensee Newsletter, please report any address changes to Ms. Cox to prevent any interruption of service at FSME_Newsletter@nrc.gov.

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