

REGION IV OFFICE RELOCATION



On December 19, 2011, NRC's Region IV office officially relocated to a new location in Arlington, Texas. The new location is approximately 1 mile from the previous location. Among other enhancements, the new location provides improved spaces for public meetings, upgraded technological infrastructure, expanded emergency response capabilities, and accommodated design for current as well as anticipated future needs of the Region IV staff.

Effective immediately, the Region IV physical address/ mailing address is:

U.S. Nuclear Regulatory
Commission-Region IV1600
East Lamar Boulevard
Arlington, Texas 76011-4511

The Region IV toll-free telephone number was unaffected by the office relocation and remains at (800) 952-9677.

To reach a member of the Region IV staff, one can dial the toll-free telephone number provided above and follow the prompts. Additionally, one can dial the new Region IV main switchboard telephone number at (817) 200-1100 and follow the prompts.

Often, NRC licensees and other stakeholders are accustomed to contacting Region IV staff members directly either by telephone or submitting documents by facsimile. With very few exceptions, the Region IV office relocation resulted in a telephone prefix change

INSIDE THIS ISSUE

Region IV Office Relocation	1
Welcome.....	2
General License Restriction Rule	2
From the Desk of the Director	3
Significant Enforcement Actions	4
Generic Communications Issued.....	6
Significant Events	7
Selected <i>Federal Register</i> Notices.....	8
To Our Readers	9

for Region IV staff's land-line telephone and facsimile lines from the previous telephone exchanges [(817) 860-8XXX and (817) 276-6XXX] to a new exchange 817-200 -1XXX, where XXX is the 3-digit extension for the Region IV staff member. For example, the new facsimile number that can be used to send reciprocity requests and materials licensing amendments is (817) 200-1263, where 263 was the existing 3 digit extension for the facsimile device. In the event of any difficulty in reaching a Region IV staff member using the new

telephone exchange, please dial the main switchboard number or the toll-free number and follow the prompts.

Cellular telephone numbers as well as e-mail addresses for Region IV staff were unaffected by the office relocation.

(Contact: Dr. Janine F. Katanic, FSME, 817-200-1151 or Janine.Katanic@nrc.gov)

WELCOME



Ms. Tamara Powell

The FSME staff would like to welcome Ms. Tamara Powell as the new FSME Allegation Coordinator.

Ms. Powell joined the NRC in 2000 as a summer hire in Incident Response Operations, while attending the University of Maryland. In 2001, Ms. Powell joined the Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards as a General

Engineer in the Mixed Oxide Branch.

Since 2004, she has worked in the Technical Support Branch as a Nuclear Process Engineer. She is one of a few staff members in the agency that has qualified as both a nuclear criticality safety (NCS) reviewer and NCS inspector. She was also the first female to qualify as an NCS inspector.

Ms. Powell received a Bachelor of Science degree in nuclear engineering from the University of Maryland and a graduate certificate in nuclear criticality safety from the University of Tennessee.

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

GENERAL LICENSE RESTRICTION RULE

On January 25, 2012, the NRC published a withdrawal of proposed rule and closure of petition for rulemaking notice in the Federal Register (77 FR 3640). The NRC is closing the petition for rulemaking (PRM-31-5) submitted by the Organization of Agreement States, Inc. The petition requested that the NRC amend its regulations to strengthen the regulation of radioactive materials by requiring a specific license for higher-activity devices that are currently available under a general license, and change the compatibility designation of applicable regulations from category B to category C. The petition also addresses a request filed by the Florida



Department of Health, Bureau of Radiation Control, to change the compatibility category of a certain part of the applicable regulation from category B to category C. In response to the petition, the NRC developed a proposed rule that would have changed the compatibility of the applicable regulations, and would have limited the quantity of byproduct material contained in a generally-licensed device to below one-tenth of the International Atomic Energy Agency Category 3 thresholds. After further review, the NRC has decided to withdraw the proposed rule and to change the compatibility designation of the applicable regulations from category B to category C.

(Contact: Solomon Sahle, FSME, 301-415-3781 or Solomon.Sahle@nrc.gov)





FROM THE DESK OF THE DIRECTOR

Having been on-board as the FSME Director only since the end of October, I have had just a short time to get familiar with the responsibilities of this office. Already I see my 2012 calendar is filling up with a series of important Commission briefings, topical meetings, reviews of papers on which the Commission will be voting, and a series of trips and speeches.

Having previously been a Regional Administrator, I am use to a full slate of activities and major responsibilities. However, the breadth of FSME topics is a bit surprising to me. For example, in 2012 FSME will play a leading or supporting role in numerous Commission briefings, and policy papers related to low-level waste regulation; the nuclear medical program; materials security; safety culture; radiation protection standards; materials control and accounting regulations; data collection issues associated with released nuclear medicine patients; transportation

standards; site remediation; and Agreement State adequacy and compatibility. This is just a partial list.

Clearly, we will be involved in a wide range of topics and issues. In nearly all of the above areas, FSME staff and management have been, or will be, receiving comments and input from all interested stakeholders, including other regulators, the regulated communities, the affected localities, including the States and Tribes, and members of the general public. Whenever we brief our Commission, we strive to assemble panels with representative cross-sections of stakeholders, with the primary goal of giving our Commission a full understanding of the issues and options from various perspectives.

As a interested reader of this newsletter, you know the numerous ways to make your voice heard on the issues that most concern you. The FSME staff includes comment periods in proposed rulemakings and conducts meetings around the country on complex rulemakings and major policy papers to receive input. Once Commission policy-decisions are reached, FSME usually issues parallel guidance to affected licensees and may supplement that with regional workshops to ensure a common understanding of the key implementation issues. The FSME and NRC public Web sites are good sources for this type of information.

I wish everyone a happy new year as we work together to protect public health and safety, the environment, and ensure the security and control of nuclear materials.

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

Mark A. Satorius, Director



SIGNIFICANT ENFORCEMENT ACTIONS

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

Warner Brothers, LLC (EA-11-209)

On November 8, 2011, the NRC issued a Notice of Violation to Warner Brothers, LLC, for a Severity Level III violation involving the failure to file NRC Form 241, "Report of Proposed Activities in Non-Agreement States," at least 3 days prior to engaging in licensed activities within NRC jurisdiction, as required by 10 CFR 150.20, "Recognition of Agreement State Licenses." Specifically, on December 6, 2006, and July 7, 2008, Warner Brothers LLC, which only holds a Massachusetts license, used a portable gauge containing a sealed source at temporary jobsites within the State of Connecticut, without obtaining a specific license issued by the NRC or filing NRC Form 241 with the NRC, as required.

Escanaba Paper Company (EA-11-061)



On October 17, 2011, the NRC issued a Notice of Violation to

Escanaba Paper Company for a Severity Level III violation involving the failure to ensure that only persons specifically licensed by the NRC or an Agreement State perform services involving the dismantling and non-routine maintenance or repair of components related to the radiological safety of a gauge. Specifically, on May 9, 2011, the licensee performed non-routine maintenance on a fixed level gauge by using a rod to change the position of the shutter, contrary to NRC License No. 21-17630-01, Condition 17.B. The licensee was not specifically licensed by the NRC or an Agreement State to perform this service.

Associated Specialists, Inc. (EA-11-179)



On September 21, 2011, the NRC issued a Notice of Violation to Associated Specialists (ASI), Inc., for Severity Level III violations involving the licensee's failure to: (1) limit operation with a temporary radiation safety officer (RSO) to a period of 60 days, in accordance with 10 CFR 35.24(c); and (2) ensure that its authorized user (AU) provided adequate

supervision to licensee staff who were involved in the receipt, possession, use, transfer or preparation of byproduct material in accordance with 10 CFR 35.27. Specifically, after ASI's RSO left the company on June 8, 2010, the AU functioned as the temporary RSO until October 13, 2010, a period greater than 60 days. From August 16, 2009, until April 19, 2011, the AU had limited oversight of the program, such that ASI personnel under the supervision of the AU had not spoken to him and had not received instructions associated with ASI's written radiation protection procedures, NRC regulations, ASI's license conditions, and the requirement that supervised individuals follow the instructions of the supervising authorized user for medical uses of byproduct material.

Carmeuse Lime, Inc. (EA-11-145)



On September 2, 2011, the NRC issued a Notice of Violation to Carmeuse Lime, Inc., for three Severity Level III violations. The first violation involved the failure to have the individual specifically authorized by Condition 12.A of the license to fulfill the

duties and responsibilities as the radiation safety officer. Specifically, the individual left the company in 2007, and the licensee failed to appoint a new radiation safety officer and amend its license. The second violation involved the failure to conduct a physical inventory every 6 months, or at other intervals approved by the NRC, to account for all sealed sources and/or devices received and possessed under the license as required by Condition 15 of the license. The third violation involved the failure to test each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or at intervals specified in the certificate of registration as required by Condition 16.B of the license.

Professional Service Industries, Inc. (EA-10-161)



On August 18, 2011, the NRC issued an Immediately Effective Confirmatory Order to Professional Service Industries (PSI), Inc., confirming commitments reached as part of an alternative dispute resolution mediation settlement agreement. The NRC identified eight apparent safety violations as well as apparent security violations

involving the performance of industrial radiography in the Rock Springs, Wyoming, area. In addition, the NRC indicated that willfulness on the part of an office manager and a radiographer appeared to have been a factor in two of the apparent violations. PSI made no admission that they deliberately violated any NRC requirement. As part of the agreement, PSI agreed to take several corrective actions involving increased management oversight and individual accountability including, but not limited to: (1) developing and implementing a disciplinary program managed by the corporate staff that provides a graded approach for radiation safety and security infractions; (2) enhanced routine and refresher training for staff; (3) annual safety culture training for radiation safety officers; (4) enhanced annual audits of the radiation safety program; and (5) advance notification if PSI will be working in NRC jurisdiction under reciprocity. PSI also agreed that a Confirmatory Order with a Notice of Violation and \$15,000 civil penalty would be issued in order to avoid further action by the NRC. Prior to any enforcement action by the NRC, the licensee voluntarily terminated its NRC license for radiography but maintains Agreement State licenses for radiography and an NRC license for other non-radiographic, regulated activities.

U. S. Department of the Army (EA-10-129)

On August 1, 2011, the NRC



issued a Notice of Violation to the Department of the Army (Army) for a Severity

Level III violation involving the failure to implement 10 CFR 40.3, "License Requirements." Specifically, from April 1978, when NRC license SUB-459 expired, to the present, the Army continued to possess depleted uranium (DU) associated with the Davy Crockett weapons system in the form of spent fragments of spotting rounds (obtained from 1962 to 1968, and expended prior to 1968) at firing ranges located at the Army's two installations in Hawaii, Schofield Barracks and Pohakuloa Training Area. In addition to the two installations in Hawaii, the Army has also identified the presence of spent DU spotting rounds at other Army installations across the United States.



Medical

William Beaumont Hospital (EA-11-163)

On September 2, 2011, the NRC issued a Notice of Violation to William Beaumont Hospital for a Severity Level III violation involving the failure to develop written procedures to provide high confidence that each administration was

in accordance with the written directive as required by 10 CFR 35.41(a). Specifically, as of May 5, 2011, the licensee's written procedures for yttrium-90 treatments did not specify how personnel should administer a treatment using a fine bore catheter and a high concentration of microspheres in order to prevent blockage within the catheter.

Crittenton Hospital (EA-11-165)

On September 2, 2011, the NRC issued a Notice of Violation to Crittenton Hospital for a Severity Level III violation involving the failure to develop written procedures to provide high confidence that each administration was in accordance with the written directive as required by 10 CFR 35.41(a). Specifically, between September 2009 and January 2011, the licensee failed to address in its written procedure the need to verify that the step size used in the treatment plan was correctly translated into the high dose rate remote afterloader unit. As a result, the device's control unit default step size of 2.5 mm was used instead of the 5 mm used in the treatment planning system.

Liberty Hospital (EA-11-109)

On July 22, 2011, the NRC issued a Notice of Violation to Liberty Hospital for a Severity Level III violation involving the failure to develop written procedures to provide high confidence that



each administration was in accordance with the written directive as required by 10 CFR 35.41(a). Specifically, as of October 6, 2010, the licensee's procedure did not require the position of the prostate to be verified prior to seed placement. As a result, the prostate received 16.9 Gray (Gy) as opposed to the prescribed dose of 125 Gy.



Individual Actions

Christopher A. Moore (IA-11-037)

On November 9, 2011, the NRC issued a Notice of Violation to Christopher A. Moore, former Radiation Safety Officer at Cardinal Health PET Manufacturing Services, Inc., in St. Louis, Missouri, for a Severity Level III violation involving 10 CFR 30.10, "Deliberate Misconduct." Specifically, on June 16, 2010, Mr. Moore caused Cardinal Health PET Manufacturing Services, Inc., an applicant for an NRC license, to be in violation of 10 CFR 20.1502(a)(1) which requires that a licensee (in this case, an applicant) monitor the occupational exposure to adults, who are likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). The nature of Mr. Moore's position made him subject to 10 CFR 20.1502(a)(1). However, Mr. Moore deliberately removed his extremity (ring) dosimetry on two separate

occasions prior to handling a chemical cartridge containing approximately 4 curies of fluorine-18.

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 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 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 January 17, 2012, the NRC issued RIS 2012-01, "Availability of Safety Culture Policy Statement." The RIS informed the addressees of the availability of the Commission safety culture policy statement.

(Contact: Cindy Flannery, FSME, 301-415-0223 or Cindy.Flannery@nrc.gov)

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

SIGNIFICANT EVENTS



Radiation Therapy Dose Administered to Pregnant Patient

Date and Place:
October 6, 2011,
Wynnewood, Pennsylvania

Event Details: The licensee reported that a pregnant patient received 2.73 GBq (73.7 mCi) of iodine-131 for thyroid therapy treatment on

October 6, 2011. The patient had taken a pregnancy test on October 5, 2011, and results were negative. The patient discovered she was pregnant and contacted the licensee on October 26, 2011. It was determined that the embryo/fetus was 10 days old at the time of treatment. The estimated dose to the embryo/fetus is 17.4 cSv (rem). The State of Pennsylvania performed a reactive inspection to review the licensee's procedures and investigate the event. No corrective actions were required beyond current practices.

Medical Event Involving High Dose Rate Remote Afterloader



Date and Place:
January 6, 2012, Toledo, Ohio

Event Details: The licensee reported a medical event involving a high dose rate afterloader (Varian, serial #VS0054) containing a 148.37 GBq (4.01 Ci) iridium-192 source. The patient was thought to have received four treatments to the cervix; each fraction prescribed 400 cGy (rad). The physician noticed reddening of the skin to the upper thigh during examination on January 6, 2012. The licensee investigated the equipment and identified a constriction (corrosion) in the entry of the tandem used in the

Fletcher Suite Device, where the device narrows at the end. It is believed that during the fourth fraction, when the catheter was inserted into the tandem, it snagged on the constriction causing the starting point of the source to be displaced by 9 cm. Preliminary calculations indicate a skin dose of 1,251 cGy (rad) to the right thigh and 1,273.9 cGy (rad) to the left, when no skin dose was intended. The dose to the treatment site during the fourth fraction was 194.2 cGy (rad) instead of the prescribed 400 cGy (rad). The total dose to the treatment site from all four fractions was 1,394.2 cGy (rad) instead of the prescribed 1,600 cGy (rad). The patient and referring physician were notified of the event. The licensee stated that the catheter used prior to the procedure is no longer made by Varian. The licensee was using a replacement catheter that was slightly larger in diameter and thicker than the original. The old catheter did not get caught on the constriction in the tandem, but the new catheter did. The licensee's corrective actions included marking the new catheters to provide a visual indication of full insertion into the tandem

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





SELECTED FEDERAL REGISTER NOTICES

CITATION	SUBJECT	CONTACT	PUBLISHED
76 FR 70913	"Retrospective Review Under Executive Order 13579" (Initial plan for retrospective analysis of existing rules)	Cindy Bladey, ADM, 301-492-3667 or Cindy.Bladey@nrc.gov	November 16, 2011
76 FR 72082	"Miscellaneous Administrative Changes" (Final rule)	Angella Love Blair, ADM, 301-492-3671 or Angella.Love-Blair@nrc.gov	November 22, 2011
76 FR 76327	Installation of Radiation Alarms for Rooms Housing Neutron Sources" (Petition for rulemaking; request for comment)	Cindy Bladey, ADM, 301-492-3667 or Cindy.Bladey@nrc.gov	December 7, 2011
76 FR 76625	"Association of State and Territorial Solid Waste Management Officials; Denial of Petition for Rulemaking" (Petition for rulemaking; denial)	Gregory Trussell, FSME, 301-415-6445 or Gregory.Trussell@nrc.gov	December 8, 2011
76 FR 77431	Decommissioning Planning During Operations" (Draft regulatory guide to request comments)	James C. Shepherd, FSME, 301-415-6712 or James.Shepherd@nrc.gov	December 13, 2011
77 FR 3640	Withdrawal of Proposed Rule and Closure of Petition for Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control" (Withdrawal of proposed rule and closure of petition for rulemaking)	Solomon Sahle, FSME 301-415-3781, or Solomon.Sahle@nrc.gov	January 25, 2012

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 and to prevent any interruption of service, please report any address changes to Ms. Cox at 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



Federal Recycling Program



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
WASHINGTON, DC 20555-0001

OFFICIAL BUSINESS