U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Office of Federal & State Materials & Environmental Management Programs

LICENSEE NEWSLETTER

NUREG/BR-0117, No. 10-02 Summer 2010

PROTECTING PERSONALLY IDENTIFIABLE INFORMATION FROM PUBLIC DISCLOSURE

Personally identifiable information (PII) should **not** be submitted to the NRC unless it is required by NRC regulations or necessary for a requested review. PII is information that can be used to identify or contact a person uniquely and reliably or can be traced back to a specific individual. Also, PII is any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.

Moreover, PII is a person's name, in combination with other information that could make the person's identity easily traceable, such as relatives' name, postal address, home or cellular telephone number, home e-mail address, date or place of birth, social security number, mother's maiden name, personal characteristics, bank account information, driver's license number, or credit card information. If such information were to be obtained and used maliciously, significant harm could be done to individuals whose PII was released. It is important to note that personal identity is distinct from an individual's professional identity (i.e., employee's name, title, work telephone number, official work location, and work e-mail address). PII is not information related to the workplace.

When PII is necessary, any documents submitted to the NRC must be clearly identified as containing sensitive information to avoid public disclosure in the NRC's Agency-wide Documents Access and Management System (ADAMS). Specifically, documents should be marked on the top of the first page and the top of each page containing PII with language substantially similar to "Withhold from public disclosure under 10 CFR 2.390." In addition, the basis (i.e., Personal Privacy Information) for withholding the information from public disclosure should be provided for each document at the top of the page, if the entire page is affected or adjacent to the information if less than a page is affected.

Additional information on this topic can be found in the NRC Regulatory Issue Summary 2007-04, "Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission" (http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2007/ri200704.pdf).

(Contact: Marc Ferdas, NRC Region 1, DNMS, 610-337-5022 or e-mail: Marc.Ferdas@nrc.gov)

INSIDE THIS ISSUE

PROPOSED RULE FOR DISTRIBUTION OF BYPRODUCT MATERIAL

On June 24, 2010, the NRC published a notice of proposed rulemaking on the distribution of byproduct material in the *Federal Register* (75 FR 36211) for public comment. The proposed rulemaking would make the

requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. Also, the proposed rulemaking would redefine the categories of devices to be used under exemptions, make the regulations more explicit regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. The proposal includes a new class exemption for industrial devices and associated distributor requirements. Primarily, this rulemaking is intended to make the licensing processes more efficient and effective. These changes would affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

The rule is posted at http://www.regulations.gov under Docket ID: NRC-2008-0338. The public comment period ends on September 7, 2010.

(Contact: Catherine R. Mattsen, FSME, 301-415-6264 or e-mail: Catherine.Mattsen@nrc.gov)

WELCOME

Dr. Josephine M. Piccone

The FSME staff is delighted to welcome Dr. Josephine M. Piccone as Director, Division of Intergovernmental Liaison and Rulemaking, which was effective on June 20, 2010.

Since joining the NRC in 1985, Dr. Piccone has held positions of increasing responsibility. Dr. Piccone served in a number of senior management positions in the Office of Nuclear Material Safety and Safeguards (NMSS) and as Deputy Director, Office of State and Tribal Programs. In 2005, she was selected by former Commissioner Peter B. Lyons as his Chief of Staff and Executive Assistant. Dr. Piccone earned a bachelor's degree in chemistry from Daemen College, and a master's degree in health physics and a doctor of philosophy in medical radiation physics from Temple University.

The FSME staff is looking forward to working with Dr. Piccone.

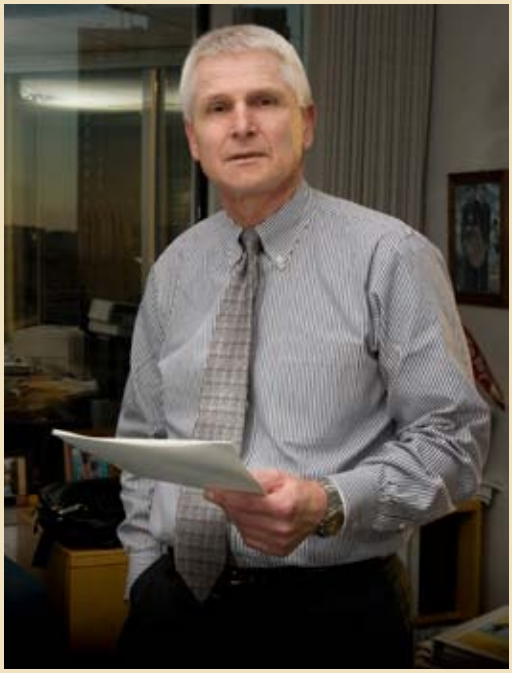
FAREWELL

Mr. Mark Shaffer

The FSME staff would like to congratulate Mr. Mark Shaffer, the former Director of the Division of Intergovernmental Liaison and Rulemaking, for his recent appointment as the new NRC nuclear safety attaché at the U.S. Mission to International Organizations in Vienna, Austria. In his new position, Mr. Shaffer will serve as the nuclear safety issues and programs expert and provide programmatic and policy oversight to the International Atomic Energy Agency's (IAEA) safety program on behalf of the United States.

Mr. Shaffer joined the NRC staff in 1991 and held positions of increasing responsibility. In 2008, Mr. Shaffer became the Director of the Division of Intergovernmental Liaison and Rulemaking in FSME. Additionally, Mr. Shaffer has extensive international experience, including a 6-month assignment at IAEA as Acting Head of the Standards Applications Unit. Mr. Shaffer earned a bachelor's degree in nuclear medicine from Incarnate Word College.

The FSME staff will miss Mr. Mark Shaffer, and we wish him much success in his new position.



FROM THE DESK OF THE FSME DIRECTOR

One of the reasons why I enjoy coming to work every day is that FSME is never a boring place. Our office manages such a broad range of issues and programmatic responsibilities. Usually, I get the chance to meet with staff and counterparts to discuss nuclear materials safety, security, waste management, environmental projects, rulemakings, and corporate issues - all within the course of one business day. Internal NRC statistics nearly always show that FSME has the highest number of items being sent to the Commission for policy decisions, even though we are only considered as a medium-sized office.

In addition, as I mentioned in the previous edition of this Newsletter, FSME and our issues continue to receive attention in the Commission meetings. Whether you hold an NRC or Agreement State license, I am certain that one or more of these Commission meetings has, or will, cover a topic of interest to you.

In early June, FSME took part in a 3-hour briefing to the Commission that presented NRC staff, State regulators, industry, and a public interest group's perspectives on a complex technical issue related to the blending of low-level nuclear waste. This multi-panel format seems to be gaining momentum and is likely to be used more frequently in the future. The Commission seems to favor a broader range of viewpoints to make better-informed regulatory decisions.

In July, FSME conducted a briefing on medical events and brachytherapy regulations in 10 CFR Part 35. Later in the month, I briefed the Commission on a multi-agency Radiation Source Security Task Force report that we will send to the President and Congress. In August, the Organization of Agreement States and the Conference of Radiation Control Program Directors will take their seats before the Commission. In October, our Advisory Committee on the Medical Use of Isotopes and other stakeholders are scheduled to cover a broad range of medical topics.

Chairman Jaczko and the new Commissioners have been quick to act on FSME-related issues. Periodically, I meet with them individually to exchange thoughts on how best to achieve our programmatic goals of safe and secure operations, and environmental protection by 20,000 nuclear materials users under NRC or State regulatory purview. Each of the Commissioners has at least one staff member in his or her office with nuclear materials or waste management expertise. As you are aware, the Commissioners are often busy travelling across the country to visit some of your facilities. The visits allow them the opportunity and experience to see and hear, first-hand, the issues in the real world, and to better understand the impacts of our regulatory decisions on stakeholders.

Of course, none of us is ever likely to feel that the regulatory climate is perfect. Some will always believe that there are unnecessary regulatory burdens. Others may believe that the NRC and FSME are not going far enough to protect people and the environment. Those viewpoints are understandable. As a regulator, I understood a long time ago that my job was not to make everyone happy. My job is to open our regulatory and decision-making processes to allow for all reasonable viewpoints to be expressed and considered. With this exchange, I am able to provide the Commission with the most complete and technically-sound recommendations developed by the FSME staff.

As always, I thank you for your attention to safety, security, and protection of the environment.

Charles L. Miller

Charles L. Miller, Director

DISTRIBUTION OF SOURCE MATERIAL PROPOSED RULE

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 comment period is scheduled to close on November 16, 2010. Associated draft guidance for the proposed rule will be made available prior to the close of the comment period.

This proposed rule would amend the regulations governing the distribution of source material in 10 CFR Parts 30, 40, 70, 170, and 171. The NRC proposed amendments would add new specific licensing and reporting requirements, and fees for the initial distribution of products and materials containing source material for receipt under an exemption or the general license in 10 CFR 40.22, "Small quantities of source material." In addition, the proposed amendments modify the existing possession and use requirements for the general license in 10 CFR 40.22 to better align the requirements with current health and safety standards. Moreover, the proposed amendments revise, clarify, or delete certain licensing exemptions (also known as "unimportant quantities") in order to make the requirements for those exemptions more risk informed.

The proposed amendments are intended to better ensure the protection of the public health and safety in the future; provide the NRC and Agreement States with more complete and timely information on the types and quantities of source material distributed for use under exemption or by general licensees; modify the requirements for possession of certain products under exemptions; and remove obsolete exemptions. These changes may affect licensees who initially distribute source material to exempt persons and general licensees, or use source material under general license.

(Contact: Andrew Carrera, FSME, 301-415-1078 or e-mail: Andrew.Carrera@nrc.gov)

NEW PROPOSED RULE – PART 37 - PHYSICAL PROTECTION OF BYPRODUCT MATERIAL

The NRC is proposing to amend its regulations to establish security requirements for the use and transport of category 1 and category 2 quantities of radioactive material, which the NRC considers to be risk-significant and therefore to warrant additional protection. Category 1 and category 2 thresholds are based on those established in the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources which NRC endorses. The objective of this proposed rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material. The proposed rule addresses access authorization, security during use, and security during transport.

The proposed requirements would apply to NRC or Agreement State licensees (after Agreement State adoption) that are authorized to possess category 1 or category 2 quantities of radioactive material. This includes a wide range of licensees, including pool-type irradiator licensees; manufacturer and distributor licensees; medical facilities with gamma knife devices; self-shielded irradiator licensees (including blood irradiators); teletherapy unit licensees; radiographers; well loggers; broad scope users; radioisotope thermoelectric generator licensees; and licensees that ship or prepare for shipment category 1 or category 2 quantities of radioactive material. Nearly 1,400 licensees are implementing the various orders issued by NRC and the Agreement States and are the entities that

would be impacted by this proposed rule. In addition, some fuel cycle and reactor licensees that possess sources at these levels would be impacted.

Access Authorization

Those licensees that permit unescorted access to category 1 or category 2 quantities of radioactive material would be required to establish and implement an access authorization program. The primary component of the access authorization program is the background investigation. The background investigation is a tool to determine whether individuals are trustworthy and reliable and could be permitted unescorted access to category 1 or category 2 quantities of radioactive material. It is essential to ensure that individuals seeking unescorted access to radioactive material are dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or common defense and security. A background investigation includes several components: fingerprinting and an FBI identification and criminal history records check; verification of true identity; employment history evaluation; verification of education; credit history evaluation; criminal history review; and character and reputation determination.

Another key element of the access authorization program is the use of a reviewing official who will make the determination of whether an individual is to be granted unescorted access to category 1 and category 2 quantities of radioactive material. The reviewing official will also need to undergo a background investigation and will have his/her fingerprints reviewed by the NRC or Agreement State. Other elements of the access authorization program include use of procedures, protection of information, the informed consent of the subject individual, personal history disclosure by the subject individual, and the individual's right to correct and complete the information on which the decision to grant unescorted access is based.

Security Program

The proposed rule would require affected licensees to establish, implement, and maintain a security program. The objective of the security program would be to monitor, and without delay detect, assess, and respond to any actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive materials. A licensee's security program would include a written security plan, implementing procedures, training, use of security zones, protection of information, coordination with the local law enforcement agency (LLEA), testing and maintenance of security-related equipment, security measures, and a program review.

The purpose of a security plan is to establish the licensee's overall security strategy to ensure that all of the required security measures work effectively and are integrated in all facilities and operations where category 1 or category 2 quantities of radioactive material will be used or stored. The plan would, among other things, include a description of the measures and strategies to implement the security requirements and describe any site-specific conditions that affect how the licensee will implement the requirements.

Security Zone

A security zone would be any area established by a licensee to provide physical protection for category 1 or category 2 quantities of radioactive material at a licensed facility. All category 1 and category 2 quantities of radioactive material at the facility would have to be used and stored within a security zone. The purpose of security zones is to isolate and control access to the material to protect it more effectively and deter theft or diversion by providing, among other things, more time for licensees and LLEAs to respond. Isolation measures would protect category 1 or category 2 quantities of

radioactive material by allowing access to security zones only through established access control points. Access control measures would allow only approved individuals to have unescorted access to the security zone, and ensure that other individuals with a need for access are escorted by approved individuals. A security zone effectively defines where the licensee will apply these isolation and access control measures.

Monitoring and Detection

A licensee would be required to establish and maintain the capability to continuously monitor and detect all unauthorized entries into its security zone(s). Monitoring and detection would be performed by either a monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; electronic devices for intrusion detection alarms that would alert nearby facility personnel; visual monitoring by video surveillance cameras; or visual inspection by approved individuals.

A licensee would also need the capability to detect unauthorized removal of the radioactive material. For category 1 quantities of radioactive material, a licensee would need to immediately detect any attempted unauthorized removal through the use of electronic sensors linked to an alarm or continuous visual surveillance. For category 2 quantities of radioactive material, a licensee would need to verify the presence of the radioactive material through

weekly physical checks, tamper indicating devices, actual usage of the material, or other means.

Transportation Security

In the area of transportation security, the proposed rule requires any licensee transferring category 1 and category 2 quantities of radioactive material to a licensee of the NRC or an Agreement State to verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. For transfers of category 1 quantities of radioactive material, the transferring licensee would also be required to verify that the licensee is authorized to receive radioactive material at the address requested for delivery. These verifications would be conducted with the license issuing authority, i.e., the NRC or the appropriate Agreement State or by using the license verification system. (The license verification system is a new web-based system that NRC is developing that may be used to verify the validity of a license issued by either NRC or an Agreement State.) The proposed rule would require preplanning and coordination of shipment information for shipments of category 1 quantities of radioactive material. The shipping licensee (licensee sending the licensed material) would be required to coordinate the departure and arrival times, including the no-later than arrival time, with the receiving licensee (licensee receiving the licensed material). The licensee would also need to preplan and coordinate the shipment information with the State(s) through which the shipment will pass and to provide advance notifications of the shipment. For shipments of category 2 quantities of radioactive material, the proposed rule would require that the shipping licensee verify the shipment no-later-than arrival time and the actual arrival time with the receiving licensee.

The proposed rule would require that any licensee that ships category 1 quantities of radioactive material by road either establish or use a carrier that has established, movement control centers that maintain position information from a location remote from the activity of the transport vehicle or trailer. The control centers would be required to monitor shipments on a continuous and active monitoring basis (24 hours a day, 7 days a week), and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies. For shipments of category 2 quantities of radioactive material the proposed rule would require that a licensee maintain constant control and/or surveillance during transit and have the capability for immediate

communication to summon appropriate response or assistance.

The proposed rule also has requirements for investigations of missing shipments and reporting of missing material.

The category 1 transportation security requirements would also apply to shipments of irradiated reactor fuel weighing 100 grams or less in net weight of irradiated fuel, exclusive of cladding or other structural or packaging material, which has a total external radiation does rate in excess of 1 Sv (100 rem) per hour at a distance of 0.91 m (3 ft) from any accessible surface without intervening shielding.

Requested Input

The NRC is specifically seeking input in the following areas: (1) fingerprinting of reviewing official; (2) background investigation elements; (3) protection of information; (4) LLEA notification at temporary jobsites; (5) reporting requirements; (6) disabling vehicle exemption; (7) license/address verification for transfer; and (8) NRC-approved monitoring plan for railroad classification yard. These issues are discussed in the proposed rule *Federal Register* Notice.

On June 15, 2010, the NRC published the proposed rule in the *Federal Register* (75 FR 33902) for a 120-day public comment period. The comment period ends on October 13, 2010. The *Federal Register* notice lists several methods for submittal of comments.

The NRC is also issuing draft implementation guidance for public comment. On July 14, 2010, the draft guidance document was noticed in the *Federal Register* (75 FR 40756) for a 120-day public comment period. Comments on the draft guidance are due November 12, 2010.

Public Meetings

The NRC is planning to hold two public meetings on the draft implementation guidance in September 2010. The first meeting will be on September 1, 2010, in Austin, TX and the other on September 20, 2010, in Rockville, MD. Information on the meetings will be posted at http://www.regulations.gov under Docket ID NRC-2010-0194, and posted on the NRC's public meeting listing on the NRC website at http://www.nrc.gov/public-involve/public-meetings/index.cfm.

(Contact: Merri Horn, FSME, 301-415-8126 or e-mail: Merri.Horn@nrc.gov)

SAFETY CULTURE MEETING ANNOUNCEMENT

On September 28, 2010, the NRC is planning to hold a 1-day meeting on safety culture at the NRC's hearing facility in Las Vegas, Nevada to discuss the proposed draft final safety culture definition. The meeting will be simultaneously broadcasting to a location inside NRC Headquarters. The objective of the meeting is to obtain consensus on the revised draft safety culture policy statement which was developed from the public, February workshop, and additional comments that have been provided to the staff at the various outreach activities. Also, the meeting will provide an opportunity for stakeholders to offer their comments on the proposed draft final safety culture definition, traits, and policy statement that will be published in the *Federal Register* prior to the meeting for a 30-day public comment period. Additional information on this event or other scheduled workshops can be found, at http://www.nrc.gov/public-involve/public-meetings/index.cfm or http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html.
(Contact: Maria Schwartz, FSME, 301-415-1888 or e-mail: Maria.Schwartz@nrc.gov)

PROTECTION OF CESIUM CHLORIDE SOURCE MEETING ANNOUNCEMENT

Tentatively on November 8, 2010, the NRC is planning to hold a 2-day meeting at The Universities at Shady Grove Conference Center in Rockville, Maryland to solicit public comments on the draft policy statement on the protection of cesium-137 chloride (CsCl) sources. The objective of the meeting is to solicit public input on the major issues associated with NRC's policy involving CsCl to reduce the risk to individuals, society, and the

environment. The NRC will publish the final date and location of the public meeting in the Federal Register, along with an Issue Paper which will serve as a framework for the discussion of the major issues in the meeting. Additional information on this topic and event can be found at http://www.nrc.gov/materials/miau/licensing.html#cc.

During the public meeting, the NRC will conduct roundtable panel discussions, with the opportunity for audience participation, on issues identified in the draft policy statement. The NRC is seeking names of individuals interested in participating in these panels. Nominations by interested individuals or organizations should include the name of the proposed panel member, the issues they are interested in discussing, view point(s) on the issue(s), and affiliation, if any. Roundtable panel participants will be selected with the goal of providing balanced view points on each of the various issues. Please submit nominations by e-mail to CesiumDraftPolicy@nrc.gov by October 8, 2010. Also, the Commission encourages participants to pre-register at CesiumDraftPolicy@nrc.gov, in order to properly plan for the conference facilities. However, pre-registration is not required and registration will be available at the meeting.

(Contact: Dr. John P. Jankovich, FSME, 301-415-7904 or e-mail: John.Jankovich@nrc.gov or Dr. Cynthia Jones, NSIR, 301-415-0298 or e-mail: Cynthia.Jones@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS

The NRC issued significant actions to licensees and an individual for failure to comply with a regulation.

City of South Bend, Indiana (EA-10-014)

On March 10, 2010, a Notice of Violation was issued to the City of South Bend for a Severity Level III violation involving Condition 11.B of the facility's license which authorized a named individual to fulfill the responsibilities of the Radiation Protection Officer. Specifically, as of January 19, 2010, the named individual was no longer employed by the company. The licensee failed to appoint a new Radiation Protection Officer and had not amended the license.

Troxler Electronic Laboratories, Inc. (EA-09-082)

On March 9, 2010, the NRC issued a Notice of Violation for a Severity Level III violation involving the failure to implement 10 CFR 110.20(a)(2) and 10 CFR 110.41(a)(9). Specifically, on November 21, 2008, Troxler Electronic Laboratories, Inc., failed to apply for a specific license and exported byproduct material listed in Appendix L (a moisture density gauge containing Am-241) to an embargoed country (Iraq) listed in 10 CFR 110.28. Further, this failure to apply for a specific export license prevented an Executive Branch review of the export activity as required by 10 CFR 110.41(a)(9).

Medical

Department of Veterans Affairs (EA-10-023)

On June 2, 2010, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of $14,000 to the Department of Veterans Affairs for two Severity Level III violations identified as a result of a medical event that occurred at the San Diego Healthcare System facility. The medical event resulted when iodine-131 was injected into the wrong port of the gastrostomy feeding tube (g-tube) resulting in an underdose to the patient's thyroid and an unintended dose to the patient's stomach. Specifically, the licensee's written procedures did not include directions for administering byproduct material through a g-tube to ensure that the administered dose was in accordance with the written directive as required by 10 CFR 35.41(a)(2). Additionally, two nuclear medicine technologists had not been instructed on administering byproduct material through a g-tube prior to performing the administration in order to ensure that the administered dose was in accordance with the written directive. The second Severity Level III violation involved the

licensee's failure to notify the NRC Operations Center no later than the next calendar day after discovery of a medical event as required by 10 CFR 35.3045(c). Specifically, on September 23, 2009, the licensee had sufficient information, based on patient survey data and the image from the nuclear medicine department, to report the medical event and did not notify the NRC until September 26, 2009.

Yale-New Haven Hospital (EA-10-063)

On May 21, 2010, the NRC issued a Notice of Violation to Yale-New Haven Hospital (YNHH) for a Severity Level III violation involving the failure to develop and maintain written procedures to provide high confidence that each administration was in accordance with the written directive, as required by 10 CFR 35.41. Specifically, YNHH's written procedures did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to initiation of gamma stereotactic radiosurgery (GSR) treatment and did not specify how hospital personnel should respond to unexpected GSR treatment console errors. These procedural inadequacies resulted in a medical event, when YNHH personnel did not verify that the automatic position system coordinates were in accordance with the written directive, during the treatment of a patient undergoing GSR on August 5, 2009.

SSM St. Clare Health Center (EA-10-025)

On April 19, 2010, the NRC issued a Notice of Violation to SSM St. Clare Health Center for a Severity Level III violation involving the failure to implement written procedures to provide high confidence that each administration was in accordance with the written directive as required by Title 10 of the Code of Federal Regulations (CFR), Section 35.41. Specifically, between November 19, 2008, and September 23, 2009, the licensee failed to follow its procedures which required the preparation of final computerized treatment plans for two patients whose prostates had been implanted with radioactive seeds. The seeds were implanted on October 22, 2008, and their computed tomography (CT) studies were performed on November 19, 2008. However, the licensee still had not prepared the final treatment plans for these patients at the time of the inspection.

Individual Actions

Lawrence Grimm (IA-09-068)

On March 1, 2010, an Order was issued to Mr. Lawrence Grimm, a former radiation safety officer at the U.S. Department of Commerce's National Institute of Standards and Technology facility in Boulder, Colorado (NIST-Boulder), prohibiting him from involvement in NRC-licensed activities for a period of 1 year. This enforcement action is based on Mr. Grimm's deliberate failure to provide complete and accurate information to the NRC in a February 15, 2007, license amendment application requesting authorization for NIST-Boulder to possess and use source and special nuclear material, including plutonium. Specifically, Mr. Grimm stated that the doors to the laboratory where the sources were to be stored were equipped with a key-card locking system when, in fact, the laboratory had no key-card locking system, was considered an open laboratory, and was typically not locked. Mr. Grimm also provided inaccurate information regarding internal monitoring of occupationally exposed workers and the use of dosimetry for frequent users of the laboratory, who didn't actually work with the material but who worked in the same laboratories where the materials were stored and used. This represents a violation of 10 CFR 30.10(a)(2), which, in part, prohibits licensee employees from deliberately submitting information to the NRC that the person knows to be incomplete or inaccurate in some material respect.

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.

***Bulletins*:**
None.

***Generic Letters*:**
None.

***Information Notices*:**
None.

REGULATORY ISSUE SUMMARIES

The NRC's regulatory issue summary (RIS) is an informational document used to communicate with the nuclear industry on a broad spectrum of matters having generic applicability. It does not involve a request for action or information unless the request is voluntary.

The NRC issued RIS 2010-04, "Monitoring the Status of Regulated Activities During a Pandemic" on May 25, 2010. This RIS was issued to:

- all holders of operating licenses for nuclear power reactors and research and test reactors under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have ceased operations and have certified that fuel has been permanently removed from the reactor vessel and have no spent fuel stored on-site;
- all NRC fuel cycle facilities licensed under 10 CFR Part 40, "Domestic Licensing of Source Material" or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material" and gaseous diffusion plants certified under 10 CFR Part 76, "Certification of Gaseous Diffusion Plants";
- all holders of site-specific licenses for independent spent fuel storage installations (ISFSIs) under the provisions of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-level Radioactive Waste, and Reactor-related Greater than Class C Waste," and all holders of 10 CFR Part 50 licenses with ISFSIs under the general license provisions of 10 CFR Part 72; and
- all NRC materials licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, under the provisions of 10 CFR Parts 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," 40, and 70.

(Technical Contacts: Milton Concepcion, FSME, 301-415-4054 or e-mail: Milton.Concepcion@nrc.gov; and Yanely Malave, FSME, 301-415-1519 or e-mail: Yanely.Malave@nrc.gov)

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

SIGNIFICANT EVENTS

Event 1: Radioiodine Administration to Patient Determined to be 25 Weeks Pregnant

Date and Place: May 1, 2007, Maryville, Illinois

Event Details: The Illinois Emergency Management Agency recently learned that a patient was administered 3.81 GBq (102.9 mCi) of I-131 as a treatment for reoccurring cancer associated with a previous thyroidectomy that was conducted in 2006. On May 1, 2007, the patient was treated

a second time with I-131and it was later determined that the patient was 25 to 27 weeks pregnant during the second treatment.

The licensee physician stated that he interviewed and counseled the patient. The patient asserted in an interview and signed a statement that she did not believe she was pregnant, but no confirmatory test was conducted. The Illinois Emergency Management Agency calculated the patient's exposure by following ANSI Standard N13.54-2008, which resulted in an estimated dose to the fetus of 86 cGy (rad). The child was delivered after a full term pregnancy without a thyroid, and is receiving thyroid hormone therapy. For corrective actions, the Illinois Emergency Management Agency is considering rulemaking that will require licensees to conduct a pregnancy test for radiopharmaceutical administrations which require a written directive.

Event 2: Wrong Site Treatment Involving Two MammoSite® Brachytherapy Patients

Date and Place: February 14, 2010, Tampa, Florida

Event Details: The licensee reported that two patients received doses to the wrong sites during MammoSite® treatments. The procedure involved a high dose rate remote afterloader unit (Nucletron Model 105.999) that contained an Ir-192 source (AEA Technologies Model 105.002, Serial #D36C-0609). The Ir-192 source used during the first patient's treatment contained 361.1 GBq (9.8 Ci). The Ir-192 source used during the second patient's treatment contained 320.4 GBq (8.7 Ci). It was determined on February 14, 2010, that the source in both cases was positioned approximately 2 to 2.5 cm proximal to the correct patient treatment sites. Both patients were prescribed to receive 340 cGy/fraction for 10 fractions. For Patient A, approximately 25 to 50 % of the planned volume received the prescribed dose A large volume outside the prescribed treatment volume exceeded the prescribed dose. The maximum proximal skin dose was approximately 220% greater than the prescribed dose. Patient A's treatments had been completed in January 2010 before the error was identified.

Patient B was given 8 of 10 fractions prior to the discovery of the error, but the last 2 fractions were delivered correctly. Patient B received at least 50% of the prescribed dose to about 50% of the correct treatment volume. Some areas of the planned volume received greater than 700%. Also, several areas surrounding the treatment site received a 300% to 400% greater dose than anticipated. The proximal skin received about 125% more dose than prescribed. The Florida Bureau of Radiation Control investigated the incident. The mistakes were believed to be caused by inputting the wrong parameters into the program (human error). Corrective actions included improving the review of paperwork and data prior to the start of patient treatment. Both patients and their doctors were notified.

Event 3: Incorrect Catheter Measurement Results in Overdose to Patient During High Dose Rate Remote Afterloader Brachytherapy Treatment

Date and Place: January 18, 2010, Wilmington, Delaware

Event Details: The licensee reported a medical event involving a high dose rate remote afterloader brachytherapy treatment to a patient's left breast. The procedure involved an HDR unit (Nucletron Model 105.999, Serial #31503) and a 247.5 GBq (6.7 Ci) Ir-192 source. The 5 day treatment commenced January 18, 2010, and was completed January 22, 2010.

On February 22, 2010, the patient complained of skin reddening outside the MammoSite® catheter insertion site. It was determined that a measurement error of a multi-lumen catheter caused the licensee to place the radioactive source 10 cm short of the intended position. Using a dummy source wire, the physicist had measured the distance to the tips of the catheters as 115.2 cm. During the measurement, two representatives from the manufacturer were present. The measured distances

were entered into the plan as the position of the first dwell position of the source for each catheter. Later, the physicist was informed of the patient's skin reaction and immediately began an investigation. The physicist determined that the actual distance to the tips of the catheters was 125.2 cm. The patient received an average dose of 1,700 cGy (rad) to approximately 100 cc of the unintended breast tissue. About 7.5 cc of the skin and underlying tissue received a maximum dose of 6,800 cGy (rad). Approximately 35 cc of the intended site received an average dose of 340 cGy (rad) or 10% of the total prescribed dose. Recommendations for corrective actions include: the physicist should make a list of treatment distances for all standard applicators, a therapist or nurse should be included in the patient measurement process and double check the measurements, a new source position simulator assembly and set of transfer tubes should be acquired, and a second measurement of the treatment distance for all patients' catheters should be made prior to the first treatment.

Event 4: Incorrect Seed Placement During Prostate Brachytherapy

Date and Place: January 21, 2010, Philadelphia, Pennsylvania

Event Details: The licensee reported a medical event involving a patient treated for prostate cancer. The treatment included implantation of sixty-five (65) I-125 brachytherapy seeds (Bard Brachytherapy Model STM 1251), containing a total activity of 0.8 GBq (22 mCi), for a prescribed therapeutic radiation dose of 14,500 cGy (rad). The seeds were implanted on January 21, 2010, using real time dosimetry under the ultrasonic guidance. On February 23, 2010, the patient returned to the facility for a 30-day post implant CT scan. The scan showed that the implanted seeds, although in an appropriate pattern, were placed outside the intended target. The licensee determined that the dose to the prostate was only about 500 cGy (rad), and an unintended dose to the penile bulb of approximately 16,100 cGy (rad) was administered,

During the week of March 1, 2010, the Pennsylvania Bureau of Radiation Protection performed a reactive inspection. Initially, a malfunction of the ultrasound unit was suspected, however, the unit was re-evaluated and determined to be working properly. The cause was attributed to human error. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure the urologist and radiation oncologist can clearly identify the prostate gland and the surrounding anatomy. In the future, treatments will be cancelled if the prostate gland and surrounding anatomy cannot be adequately visualized. The radiation oncology group has determined that an additional quality assurance review is warranted, and the Radiation Oncology Department has

suspended prostate brachytherapy treatments.

Event 5: Overdose to Ear During Brachytherapy with High Dose Rate Remote Afterloader Unit

Date and Place: March 11, 2010, Coral Springs, Florida

Event Details: The licensee reported that on March 11, 2010, a patient received approximately nine times the intended dose during the second of 14 high dose rate (HDR) fraction treatments to the ear. An HDR surface applicator (Nucletron Model MicroSelecron V2) and 210.9 GBq (5.7 Ci) Ir-192 source was used during the treatment. The therapist accidently pushed the "auto radiography" button rather than the "treatment" button. Consequently, approximately 2,250 cGy (rad) was administered instead of the intended 250 cGy (rad). Corrective actions included deactivating the autoradiograph function and providing training to technicians concerning the incident. The patient and doctor were notified of the incident.

Event 6: Improper Handling of Br-76 Resulting in Overdose to Finger

Date and Place: February 4, 2010, Saint Louis, Missouri

Event Details: The licensee reported that a technician's left hand ring

badge indicated a dose of 11.9 cSv (rem). The technician's right hand ring badge dose was 4.0 cSv (rem). The licensee received the Landauer dosimetry report on March 9, 2010. Following interviews with the technician and reconstruction of the event, the licensee believes that the individual may have received a dose between 50 and 400 cSv (rem) over a 10 cm^2 area of his fingertips. The exposure to the fingertips was calculated using the Varskin computer code. Between February 4 and February 5, 2010, the technician handled 1.2 GBq (32 mCi) vials of Br-76. Normally, the vials are handled using a long-handle tool with shielding. Due to perceived operational pressures that the technician deemed took precedence over as low as reasonably achievable (ALARA) principles, the technician directly handled the vials on several occasions. The technician had not experienced any observable effects from handling the vials. The whole body deep dose badge reading for the period in question was 0.25 mSv (25 mrem). Corrective actions included retraining radiation workers on proper handling techniques and removing the technician from work involving licensed material.

Event 7: Catheter Kink Resulting in High Dose Rate Remote Afterloader Treatment to Wrong Location

Date and Place: March 23, 2010, Olmstead, Minnesota

Event Details: The licensee reported an administration of two fractions to the wrong location during treatment with a high dose rate (HDR) afterloader unit. The patient was prescribed four fractions of 400 cGy (rad) for a biliary HDR treatment. The HDR unit, a Varian Model VariSource IX(t)® Serial #VS 437; contained a 329.5 GBq (8.9 Ci) Ir-192 source (MS Nordion Model VS 2000, Serial #02-01-0219-001-03101). The catheter had been placed and imaged. A dummy source was pushed into the catheter until it met resistance, which was assumed to be the end of the catheter. In fact, the resistance was actually a tight bend approximately 17 cm short of the end of the catheter. This incorrect distance was used for the treatment distance and the patient was subsequently treated. The following day before administering the treatment, a dummy source was again inserted into the catheter. That dummy source was extended beyond the programmed distance. For the first two fractions, the HDR source was 17 cm from its intended location. This resulted in the tumor receiving only 30% of the prescribed fractional dose and an unintended location, the duodenum, receiving 1,000 cGy (rad). An additional fraction was completed to provide a total tumor dose that was within 90% of the prescribed dose. The patient was informed of the incident on March 24, 2010. Corrective actions included implementing a new procedure that requires that prior to administering the first fraction on each biliary HDR patient that an image must be taken with the measurement cable in place.

Event 8: Improper Shift of Implanted Volume During Prostate Brachytherapy

Date and Place: March 12, 2010, Baton Rouge, Louisiana

Event Details: The licensee reported that a patient being treated for adenocarcinoma of the prostate gland received less than 50% of the prescribed V100 dose during a brachytherapy implant performed on March 12, 2010. The patient also received a dose to an unintended site. The patient was implanted with ninety-five (95) I-125 brachytherapy seeds that contained an activity of 12 MBq/seed (322 uCi/seed). The prescribed dose was 14,500 cGy (rad). The radiation oncologist along with the assistance of the urologist inserted the needles through the appropriate holes in the needle template. The radiation oncologist used the ultrasound to help guide the needle placement. However, while implanting the needles, the oncologist and ultrasound technologist had difficulty clearly visualizing the balloon location (which indicated the prostate base) on the sagittal view of the ultrasound. The patient may have moved during the procedure, which may have caused the balloon and ultimately, the base plane to shift. The radiation oncologist suspected a variance after reviewing the post implant

seed count x-ray. To confirm the implanted seed locations, the patient was asked to return for an early post-implant CT on March 22, 2010. Using those images, a treatment plan was constructed using the treatment planning system's post-plan software. Based on that plan, the entire implanted volume was estimated to have shifted approximately 3 cm inferiorly, resulting in a D90 dose of 1,288 cGy (rad). The patient was informed and supplemental treatment was recommended. The Louisiana Department of Environmental Quality is tracking the incident.

Event 9: Radioiodine Administration to Pregnant Patient

Date and Place: March 16, 2010, Durango, Colorado

Event Details: The licensee administered 1.1 GBq (30 mCi) of I-131 to a pregnant patient on March 16, 2010. A serum blood pregnancy test was performed prior to the administration and the results were negative. On April 26, 2010, the patient took a home urine pregnancy test and discovered that she was pregnant. On April 27, 2010, a blood serum test confirmed the pregnancy. The patient's OB/GYN physician estimated that conception occurred on March 13, 2010. The patient was notified. The fetal dose was estimated to be approximately 8 cSv (rem). The Colorado Department of Health is investigating the incident. The licensee stated that all procedures to prevent this incident were followed. Human chorionic gonadotropin (Hcg) does not detect a pregnancy until 7 to 12 days post conception. The licensee is considering including additional questions during the screening process.

Event 10: Erythema to Thighs Resulting from High Dose Rate Remote Afterloader Treatment

Date and Place: May 4, 2010, Albuquerque, New Mexico

Event Details: The licensee reported that a patient treated for endometrial carcinoma of the vaginal cuff received radiation erythema to her thighs. The patient was prescribed to receive three fractions of 700 cGy (rad) each at a distance of 0.5 cm from the surface of the applicator. The dose to the skin of the thighs occurred during the third fraction, performed on May 4, 2010. The treatment involved a high dose remote afterloader unit (Varian model VariSource, Serial #VS220) and a 129.7 GBq (3.5 Ci) Ir-192 source (Alpha-Omega Services Model VS2000, Serial #02-01-0053-001-010810-10419-81). On May 11, 2010, the patient noticed two dark spots on each thigh. On May 18, 2010, the patient reported the somewhat painful dark spots to the licensee. On May 19, 2010, the patient was examined by the licensee. The prescribing physician did not diagnose the spots as radiation erythema. The patient was asked to return on May 24, 2010. At that time, the physician identified two circular areas with a diameter of approximately 1 cm. On May 26, 2010, the spots were determined to be radiation erythema. The licensee believes that the patient may have moved in a manner that caused the catheter to shift and/or workers may have moved the catheter while trying to better align the stretcher with the treatment device. The average skin dose to the patient's thigh was calculated to be 3,060 cGy (rad). The thigh dose at a depth of 2.5 cm was calculated to be 408 cGy (rad). Corrective actions included procedure modifications to assure that the catheter is correctly positioned prior to the start of treatment. In addition, a special in-service will be held to address the procedure updates.

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SELECTED FEDERAL REGISTER NOTICES

Notice of Issuance and Availability of Regulatory Guide 6.9, Revision 1, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," (NRC–2009–0418), 75 FR 20399, April 19, 2010.

(Contact: Jack W. Foster, FSME, 301- 415-6250 or e-mail: Jack.Foster@nrc.gov)

Notice of Issuance and Availability of Draft Regulatory Guide (NRC–2010–0158), 75 FR 20645, April 20, 2010.

(Contact: Gregory C. Chapman, NMSS, 301-492-3106 or e-mail: Gregory.Chapman@nrc.gov)

Unified Agenda of Federal Regulatory and Deregulatory Actions, 75 FR 21959, April 26, 2010.

(Contact: Cindy Bladey, ADM, 301-492-3667 or e-mail: Cindy.Bladey@nrc.gov)

NRC Region II Address and Main Telephone Number Changes (NRC–2010–0083), 75 FR 21979, April 27, 2010.

(Contact: Judy G. Coleman, NRC Region II, 404-562-4824 or 404-997-4824 or e-mail: Judy.Coleman@nrc.gov)

Draft 2010 Report to Congress on the Benefits and Costs of Federal Regulations; Notice of Availability and Request for Comments, 75 FR 22630, April 29, 2010.

(Contact: Darcel D. Gayle, OMB, 202-395-3741)

List of Approved Spent Fuel Storage Casks: NUHOMSR HD System Revision (NRC–2009–0538), 75 FR 24786, May 4, 2010.

(Contact: Jayne McCausland, FSME, 301- 415-6219 or e-mail: Jayne.McCausland@nrc.gov)

Notice of issuance and availability of Regulatory Guide 6.7, Revision 2, "Preparation of an Environmental Report to Support a Rulemaking Petition Seeking an Exemption for a Radionuclide-Containing Product." (NRC–2009–0492), 75 FR 27599, May 17, 2010.

(Contact: Catherine R. Mattsen, FSME, (301- 415-6264 or e-mail: Catherine.Mattsen@nrc.gov)

Notice of Issuance and Availability of Draft Regulatory Guide, DG–3039, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," (NRC–2010–0181), 75 FR 28073, May 19, 2010.

(Contact: Kevin M. Ramsey, NMSS, 301- 492-3123 or e-mail: Kevin.Ramsey@nrc.gov)

Physical Protection of Byproduct Material,(NRC-2008-0120), 75 FR 33902, June 15, 2010.

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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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