IN REMEMBRANCE

It is with deep sympathy that we inform our readers of the passing of Mr. Michael K. Williamson, the editor of the FSME Newsletter, on May 4, 2009.

Mr. Williamson joined the NRC in March 2002, as a General Physical Scientist/Project Manager in the former Division of Industrial and Medical Nuclear Safety. Mr. Williamson was involved in the writing and development of inspection procedures and guidance as well as maintaining the nuclear materials portion of the NRC’s Inspection Manual. He was also involved in the development of guidance that appears in the NUREG-1556 series. Most recently, he was promoted to a Health Physicist/Project Manager in the FSME’s Division of Intergovernmental Liaison and Rulemaking where he served as the lead Project Manager for the Expansion of the National Source Tracking System rulemaking.

Prior to joining the NRC, Mr. Williamson was a Health Physics Technologist in the United States Army and retired after twenty years of service. He served at numerous locations and participated in various projects, such as the Johnston Atoll Plutonium Clean-up Project, and served as the lead technician on various emergency response teams responsible for responding to accidents or incidents involving radiological and biological warfare agents. While in the service, Mr. Williamson received his B.S. degree in Health Care Administration from Southern Illinois University at Carbondale, graduating Magna cum Laude.

Mr. Williamson was a valued employee and friend and he will be greatly missed.
Phase 1 of terminations occurred on November 30, 2007, and Phase 2 on September 30, 2008. NRC is now preparing for Phase 3, the last phase, which will occur on August 7, 2009 (74 FR 5797). This final phase will include Alaska, Connecticut, Hawaii, Michigan, New Jersey, and Canadian licensees that are under NRC jurisdiction.

NARM users in non-Agreement States and US territories are required to:

(1) apply for license amendments for the new byproduct material within six months from the date the waiver is terminated, if they hold an NRC specific byproduct materials license, or

(2) submit a license application for the new byproduct material within 12 months from the date the waiver is terminated.

For existing NRC licensees, it should be noted that NRC will not be amending licenses to include authorization to produce radioactive material using an accelerator; a separate license will be required for these activities. Therefore, existing licensees should submit a new license application to obtain authorization for the production of radioactive materials using an accelerator.

Also, new NRC license applicants that are seeking authorization to produce radioactive materials using an accelerator should submit a separate license application for any other radioactive material authorizations they may be seeking (e.g., manufacturing of...
On March 31, 2009, Virginia became the 36th Agreement State. Last year, it was Pennsylvania. New Jersey has filed an application to become an Agreement State and NRC staff has it under review. A few other States have expressed interest and are laying the groundwork now.

As Director of the Office of Federal and State Materials and Environmental Management Programs (FSME), it is my daily responsibility to acknowledge and make appropriate use of the talents and regulatory expertise of State regulators along with the skills of my own staff and our regional counterparts. I have occasionally been kidded about the length of the office title, but the Federal/State regulatory partnership is unique and it is important for me as the FSME Director to never forget that and leverage all the talents across the nation.

I was particularly encouraged by the attendance of the leadership of the Organization of Agreement States, Inc. (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD) in the March 16, 2009, Commission briefing, in which I outlined some of the program’s recent accomplishments, priorities and areas in which we look for Commission guidance. From December 2008 through December 2009, the Commission calendar had, and will have, a number of meetings involving FSME activities (uranium recovery, low-level waste, source security, the annual Advisory Committee of Medical Use of Isotopes, just to name a few). In many cases, OAS and CRCPD have participated or will be participating. I appreciate the time and energy this requires, but I believe it is highly worthwhile means of providing important context and additional perspectives which allow the Commission to make more informed decisions.

I would also like to acknowledge and credit the States for their continued participation in numerous Working Groups and Steering Committees which provide updated guidance and rulemakings across the FSME program domain. The States continue to enrich the regulatory infrastructure, and now directly regulate about 85% of the nation’s byproduct materials licensees. I look forward to continuing to work with the States, and with over 20,000 of the nation’s licensees to ensure the safe and secure use of radioactive materials.

Charles L. Miller, Director
radiopharmaceuticals, medical use of byproduct material).

NARM users in Phase 2 States should have submitted their license amendments by March 30, 2009, and must submit new license applications by September 30, 2009.


(Contacts: Shirley Xu, Office of Federal and State Materials and Environmental Management Programs, 301-415-7640; e-mail: Shirley.Xu@nrc.gov)

**NRC COMPLETES THE COMMONWEALTH OF VIRGINIA AGREEMENT**

On February 27, 2009, the U.S. Nuclear Regulatory Commission (NRC) approved an Agreement with the Commonwealth of Virginia (Virginia or Commonwealth) under Section 274b of the Atomic Energy Act of 1954, as amended (AEA).

Under the agreement, the NRC will transfer to Virginia the responsibility for licensing, rulemaking, inspection and enforcement activities for:

1. radioactive materials produced as a result of processes related to the production or utilization of special nuclear material (SNM);
2. naturally occurring or accelerator-produced radioactive material (NARM);
3. source material (uranium and thorium); and
4. SNM in quantities not sufficient to form a critical mass.

Virginia becomes the 36th State to sign such an agreement with the NRC. The agreement became effective March 31, 2009.

The NRC transferred approximately 386 licenses to the Commonwealth’s jurisdiction. In addition, the Commonwealth retains regulatory authority for approximately 216 NARM licenses. Approximately 180 of these NARM licenses currently are regulated by both Virginia and the NRC.

By law, NRC retains jurisdiction over commercial nuclear power plants and federal agencies using certain nuclear material in Virginia. In addition, NRC retains authority for the review, evaluation and approval of sealed radioactive materials and devices containing certain nuclear materials manufactured in Virginia and distributed throughout the country.

Before approving the agreement, NRC reviewed Virginia’s radiation control program to ensure it is adequate to protect public health and safety and is compatible with the agency’s own program for regulating the radioactive materials covered in the agreement. An announcement of the proposed agreement was published four times in the Federal Register in November and December 2008, inviting comments from the public. The agency received one comment in favor of the proposed agreement.

The governor’s request and supporting documents, as well as the NRC staff’s assessment are available through the NRC’s Agency-wide Documents Access and Management System (ADAMS). 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 message to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, Maryland.

Thirty-five other States have previously signed such agreements with NRC. They are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts,
Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.

(Contact: Monica Orendi, Office of Federal and State Materials and Environmental Management Programs, 301-415-3938, email: monica.orendi@nrc.gov.)

**NRC ISSUES CONFIRMATORY ORDER TO MATTINGLY TESTING SERVICES**

The U.S. Nuclear Regulatory Commission has issued a Confirmatory Order to Mattingly Testing Services, Inc. of Molt, Montana, to take corrective actions designed to improve compliance with NRC regulations for the possession and use of radioactive materials.

Mattingly has agreed to the terms and conditions of the Confirmatory Order that requires it to take a number of actions including:

1. hiring an independent consultant to evaluate the effectiveness of its radiation safety and compliance programs,
2. hiring an independent consultant to provide training,
3. improving procedures,
4. improving Mattingly’s disciplinary program, and
5. paying a civil penalty in the amount of $8,000.

In addition, the company’s president/radiation safety officer has agreed not to participate in any NRC-licensed activities for two years.

Mattingly has already implemented many corrective actions designed to prevent recurrence. The terms of the Confirmatory Order were agreed to following Alternative Dispute Resolution, which uses a neutral mediator with no decision-making authority to assist the NRC and its licensees in resolving differences regarding enforcement actions.

The actions stemmed from an NRC inspection and investigation initiated in 2007 that identified nine apparent violations of NRC regulations, including failure by company officials to provide complete and accurate information to the NRC staff; failure by a worker to wear a personal dosimeter while performing radiographic operations; and failure to remove from service a device containing radioactive materials after its locking mechanism sustained damage.

Copies of the Confirmatory Order issued by the NRC to Mattingly are available on the NRC web site at: [http://www.nrc.gov/reading-rm/adams.html](http://www.nrc.gov/reading-rm/adams.html).

(Contact: Victor Dricks, Region IV, 817-860-8128, e-mail: Victor.Dricks@nrc.gov)

**LICENSEE BANKRUPTCY AND/OR CHANGE OF CONTROL**

Financial difficulties have unfortunately become a reality for many American businesses, including those engaged in NRC licensed activities. Commonly, financial relief is sought through bankruptcy proceedings or the selling of assets, including the transfer of licensed material or change of control of NRC licensed activities. Often, NRC first becomes aware of a licensee’s financial difficulties when a licensee has not paid their fees to NRC. In other cases, NRC inspectors become aware of the situation when attempting to perform an inspection but instead find an abandoned or permanently shut down licensee facility. Occasionally during an NRC inspection, it is revealed that the entity has undergone a change of control of licensed activities without prior NRC approval. Licensees might not be familiar with NRC regulations that require licensees to take specific actions with respect to bankruptcy proceedings as well as change of control of NRC licensed activities. These regulations have been promulgated, in part, to ensure adequate protection of public health and safety and the security of radioactive material. The discussion that follows presents a brief overview of byproduct material licensee responsibilities regarding bankruptcy or change of control of NRC licensed activities.

The purpose of the bankruptcy notification requirement is to allow NRC to verify the safe disposition of radioactive material possessed by the bankrupt licensee. Often, when seizing assets, trustees or creditors unknowingly take possession of radioactive material. Licensed material handled without proper radiation safety precautions can create a significant public health and safety hazard. NRC regulations require that licensees inform NRC of bankruptcy proceedings. Specifically,
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10 CFR 30.34(h) requires, in part, that licensees notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 of the United States Code. This applies to petitions for bankruptcy filed by or against: (1) the licensee, (2) an entity controlling the licensee or listing the licensee/license as property of an estate, or (3) an affiliate of the licensee. Following NRC notification of bankruptcy proceedings, an onsite NRC inspection is sometimes necessary to verify safety and security and/or proper disposal or transfer of licensed materials.

Control of licensed activities can be described as the authority to make decisions regarding the possession, storage, or use of licensed materials. NRC does not seek to become involved in business decisions made by licensees. However, NRC needs to be informed when authority of NRC licensed activities has changed. Furthermore, control of licensed activities cannot be transferred without written consent from NRC. Specifically, 10 CFR 30.34(b) requires, in part, that no license issued or granted pursuant to the regulations in 10 CFR Part 30 and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the NRC shall, after securing full information, find that the transfer is in accordance with the provisions of the Atomic Energy Act of 1954 (including any amendments thereto) and shall give its consent in writing. Timely notification is expected so that NRC can perform an appropriate review of the change of control. Through this review, NRC can determine whether radiation safety and security over licensed materials will be maintained during and after the change of control. In addition to NRC’s review of licensee-submitted information, an onsite visit of licensee facilities may be required prior to NRC approval of change of control of licensed activities.

When not appropriately managed, bankruptcies and change of control of licensed activities can lead to a potential loss of control of radioactive material and resultant threat to public health and safety. Regardless of financial or organizational issues, licensees remain responsible for the safety, security and control of licensed materials. Failure to notify NRC and/or maintain control of licensed material could lead to enforcement actions. Early notice made to NRC regarding bankruptcy or change of control will enable NRC staff to provide additional guidance regarding the type of information required to complete the review in a timely manner. Under certain circumstances, NRC may be able to assist licensees regarding appropriate transfer or available means for disposal of licensed material.

Further information and guidance regarding these subjects can be found in NUREG-1556, Vol. 15, Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses. This document can be located on NRC’s public web page at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v15/. Additionally, licensees who have questions regarding this subject are encouraged to contact the licensing staff of their appropriate NRC Regional office.

(Contact: Janine F. Katanic, PhD, CHP, Office of Federal and State Materials and Environmental Management Programs, 817-860-8151; e-mail: Janine.Katanic@nrc.gov)

**NRC IS SEEKING PUBLIC COMMENT ON REGULATORY ISSUES AND OPTIONS FOR POTENTIAL CHANGES TO THE AGENCY’S RADIATION PROTECTION REGULATIONS**

In December 2007, the International Commission on Radiological Protection (ICRP) revised and updated their recommendations for radiation protection as ICRP Publication 103. Electronic or paper copies of the recommendations are available for purchase from the ICRP, www.icrp.org. Shortly thereafter, the U.S. Nuclear Regulatory Commission (NRC) staff engaged in a comparative review of the NRC Standards for Protection Against Ionizing Radiation, 10 CFR Part 20, and other NRC regulations, with ICRP Publication 103, and provided the Commission with recommendations for next steps towards alignment. In a Staff Requirements Memorandum (SRM) dated April 2, 2009, the Commission approved the staff’s
recommendation to immediately begin engagement with stakeholders and interested parties to initiate development of the technical basis for possible revision of the NRC’s radiation protection regulations, as appropriate and where scientifically justified. The Commission believes that the current NRC regulatory framework continues to provide adequate protection of health and safety of workers, the public, and the environment. From a safety regulation perspective, ICRP Publication 103 proposes measures that go beyond what is needed to provide adequate protection. In order to ensure that the NRC is well informed of all the benefits and burdens associated with further alignment of NRC’s current radiation protection regulations with ICRP 103, NRC staff will actively engage stakeholders and interested parties on the technical and regulatory issues associated with such changes. The NRC will use public comments gathered over the next two to three years to develop an appropriate technical basis and make suggestions for proposed rulemaking to the Commission. The NRC staff is particularly interested in understanding the perspectives of different organizations and groups on the benefits, burdens, and impacts of possible options for change. The NRC staff has not made any decisions on particular positions or changes at this time. An initial set of key topics for discussion include the occupational dose limits, the application of constraints to the optimization process, and updates of the scientific information and models supporting dose assessment and compliance.

The NRC wishes to interact with many stakeholder and interested parties including the public, licensees, labor unions, public interest groups, state regulatory agencies, scientific professional societies and organizations, the Interagency Steering Committee on Radiation Standards, other federal agencies, and other organizations while developing the technical basis. Plans have already been made to make presentations at the meetings of the Conference of Radiation Control Program Directors, Inc., the Society of Nuclear Medicine, the Health Physics Society, and the American Association of Physicists in Medicine. The NRC is also developing a dedicated Web site for information and public comments on this issue. Comments may also be submitted by e-mail to Regs4RP@nrc.gov.

(Contacts: Dr. Donald Cool, Office of Federal and State Materials and Environmental Management Programs, 301-415-6347; e-mail: Donald.Cool@nrc.gov; or Dr. Kimyata Morgan Butler, Office of Federal and State Materials and Environmental Management Programs, 301-415-0733; e-mail: Kimyata.MorganButler@nrc.gov)

SIGNIFICANT ENFORCEMENT ACTIONS


Medical

St. John Macomb-Oakland Hospital (EA-08-329)

On February 18, 2009, a Notice of Violation (NOV) was issued for a Severity Level III violation. The NOV involved a violation of Condition 11.B of the facility’s license, which authorized a specifically named individual to fulfill the responsibilities of the Radiation Safety Officer (RSO) for the brachytherapy activities. Specifically, as of November 2007, the authorized individual was no longer employed by the consulting firm retained by the licensee and did not fulfill the RSO responsibilities. The licensee failed to appoint a new RSO following the previous RSO’s departure from the consulting firm.

Radiography

Huntington Testing & Technology, Inc. (EA-08-303)

On January 22, 2009, a Notice of Violation (NOV) was issued for a Severity Level III problem. The violations involved the failure to comply with license condition and to provide event notification as required, in a timely manner. Specifically, on August 20, 2008, the licensee had an event where a radiography camera was disabled and failed to function as designed. The lead radiographer and the field Radiation Safety Officer, who were not trained or authorized by the NRC license, conducted source
retrieval activities and shielded-down a source. In addition, the licensee did not notify the NRC until September 3, 2008, two weeks after this event.

Individual Actions

Robert S. Beveridge (IA-08-054)

On February 24, 2009, a Notice of Violation was issued for a Severity Level III violation involving a deliberate submission of information to the licensee knowing that the information was incomplete or inaccurate in some respect material to the NRC and deliberately caused the licensee to be in violation of NRC regulations. Specifically, Mr. Beveridge, the former Radiation Safety Officer (RSO), deliberately entered data into inventory records indicating that the inventory had been completed, when in actuality the inventory had not been completed as required.

(Contact: Michele Burgess, Office of Federal and State Materials and Environmental Management Programs, 301-415-5868; e-mail: Michele.Burgess@nrc.gov)

**GENERIC COMMUNICATIONS ISSUED**

(January 1, 2009 - March 31, 2009)

The following are summaries of U.S. Nuclear Regulatory Commission (NRC) generic communications issued by the Office of Federal and State Materials and Environmental Management Programs. If one of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the NRC library of generic communications is http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html. Please note that this address is case-sensitive and must be entered exactly as shown.

**Bulletins (BLs)**

None.

**Generic Letters (GLs)**

None.

**Information Notices (INs)**

IN 2009-01, “National Response Framework” was issued January 22, 2009. This IN was issued to all holders of operating licenses or certificates for nuclear power plants, research and test reactors, independent spent fuel storage installations, and fuel cycle facilities; all holders of operating licenses for uranium recovery facilities; all holders of licenses or certificates for the following types of facilities undergoing decommissioning: nuclear power plants, research and test reactors, fuel cycle facilities, and uranium recovery facilities.

(technical contact: Michael I. Dudek, Office Of Nuclear Security And Incident Response, 301-415-6500, email: Michael.Dudek@nrc.gov.)

**Regulatory Issue Summaries (RIS)**

None.

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

**SIGNIFICANT EVENTS**

Event #1   Wrong Treatment Site Error Involving High Dose Rate Remote Afterloader

**Date and Place:** February 23, 2009, Pittsburg, Pennsylvania

Nature and Probable Causes: The licensee reported that a female patient received a high dose rate mammosite treatment to the wrong site between February 23 and February 27, 2009. The patient was to receive treatment twice a day for a total of 10 fractions with an expected dose of 3,400 cGy (rad) to the intended site. A dummy wire was inserted into the balloon to check and measure the tube length for dose calculations. A CAT scan was performed daily to verify the position of the treatment site. Treatment calculations were performed, reviewed, and approved, and treatment began on February 23. On February 27, a different therapy physicist was checking the patient’s charts and believed there may have been an error. On March 2, 2009, the original physicist checked the findings and discovered that there had been an error in the placement of the source during treatments. The source had not been fully inserted into the balloon, and was 3 cm from where it should have been. That incorrect source placement resulted in the tumor site only receiving 30% of the intended dose. An unintended site received the total treatment. The patient is being followed for any sequelae (pathological conditions) to the event. The oncologist discussed the event with the patient.
Event #2: Seed Displacement Results in Wrong Treatment Site Error

Date and Place: March 19, 2009, Voorhees, New Jersey

Nature and Probable Causes: The licensee reported that I-125 seeds were implanted outside the target organ during a prostate seed brachytherapy implant procedure performed on March 19, 2009. The incident was discovered while the physicist conducted a post operative dosimetry analysis of the procedure. It was determined that none of the seeds were implanted in the prostate gland. The seeds retained their planned pattern grouping, with the superior end of the seed cloud being approximately 2 cm from the apex of the prostate gland. A dosimetric analysis of the CT image revealed all 93 seeds accounted for and a calculated dose to 90% of the target organ (prescription line) being 224 cGy (rad). The seeds appeared distal to the prostate and the dose appeared to have been maximally confined to soft tissue, including muscle and subcutaneous fat. A complete analysis was requested of the radiation oncologist, who was immediately informed. The license administrator and nuclear medicine manager were notified.

Event #3: Incorrect Isotope and Activity Ordered Resulting in Medical Event

Date and Place: December 29, 2008, (City Not Reported) New York

A medical facility reported that a patient was prescribed 11.1 MBq (300 uCi) of I-123, but was administered 72.5 MBq (1.96 mCi) of I-131 on December 29, 2008. A referring physician requested an uptake study and scan to be followed by an I-131 therapy for thyrotoxicosis. The authorized user (AU) directed the secretary to schedule the uptake study using I-123. However, the secretary scheduled the patient for a whole body scan using I-131. On the day of the study, the nuclear medicine technologist took the patient's history, which included the fact that she still had her thyroid. The technologist failed to seek clarification from the AU and did not review the AU’s approval. The technologist proceeded with the whole body study using the I-131. Upon discovery of the error, the AU had an uptake study performed. The AU notified the patient and referring physician. Results of the uptake study revealed that the patient was thyrotoxic. The AU prescribed a therapy dose of 370 MBq (10 mCi) of I-131. An error in scheduling precipitated this event. The failure of the technologist to seek clarification and review the physician’s order caused the event. Corrective actions included a requirement for verification of the prescription by two technologists and the need to consult with the AU if there are any questions regarding the ordered procedure.

(Contact: Angela R. McIntosh, Office of Federal and State Materials and Environmental Management Programs, 301-415-5030; e-mail: Angela.McIntosh@nrc.gov)
NOTE TO READERS: In an attempt to keep the FSME Licensee Newsletter relevant, useful and informative, feedback on the content of the newsletter is welcome. Readers desiring to contribute articles, self-explanatory diagrams, suggestions for future articles, bulletins, web-site postings, and other items of interest to the FSME Licensee Newsletter readership, should contact Gwendolyn Davis, from the FSME Division of Intergovernmental Liaison and Rulemaking, Rulemaking Branch A. 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. Davis to prevent any interruption of service.

Please send written correspondence and requests to:
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