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. 08-04 Winter 2008

## SOURCE COLLECTION AND THREAT REDUCTION – SCATR

The Conference of Radiation Control Program Directors Inc. (CRCPD) last year implemented the Source Collection and Threat Reduction (SCATR) Program through a five-year cooperative agreement with the U.S. Department of Energy (DOE). This program is designed to assist in the disposition of Atomic Energy Act sources, less than 10 curies and radium sources less than 100 milligrams. Some examples of the type of sources that can be dispositioned through this program are cesium or radium brachytherapy tubes and unused or unwanted gauges.

Through the SCATR Program, licensees are asked to register unwanted discrete radioactive sources at the DOE Off-Site Source Recovery Project (OSRP) website http://osrp.lanl.gov/crcpdscatr.shtml. More than 7,000 sources have been registered with OSRP thus far.

The CRCPD notifies the licensee when an opportunity for disposition arises. Disposition may be adoption by another person, acceptance by a manufacturer, disposal as radioactive waste and storage, if that becomes necessary. The CRCPD may provide at least partial funding for disposition, as in State-organized projects.

In the first year of the program, a State-organized project for collection of unwanted material was successfully conducted in Florida, with arrangements for collection coordinated by the Florida Department of Health's Bureau of Radiation Control. During this project, more than 2,700 sources were dispositioned. The project focused on old cesium-137 brachytherapy devices being held in long-term storage.

Currently, during the second year of the SCATR Program, radium and cesium-137 are being collected from widely separated facilities throughout many States. Although the outlets for cesium-137 recently closed, licensees are still encouraged to register so that accurate assessments can be made of unwanted material. The disposal of radium continues.

CRCPD will continue to promote the registration of unwanted radioactive material and to coordinate licensees, State radiation control programs and brokers for the disposition of material in geographic or State groupings. The CRCPD's Committee for Unwanted Radioactive Material (E-34) continues to promote outlets for radioactive material and waste and to promote the registration of unwanted radioactive material.

Materials eligible for CRCPD/SCATR funding of disposition include:

- Discrete radioactive material, whether naturally occurring, or accelerator or reactor produced that is not already covered under the OSRP Program;

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- Sources licensed by a State or U.S. Nuclear Regulatory Commission, but not on Federal property (specific or general license);
- Unused sources in long-term storage with no foreseeable future use.

More information on the SCATR Program is available at CRCPD's website: http://www.crcpd.org/SCATR/SCATR.html and http://www.crcpd.org/UnwantedRadMat.asp.

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## VIRGINIA WANTS TO BECOME AN AGREEMENT STATE

The U.S. Nuclear Regulatory Commission (NRC) is considering a request from the Commonwealth of Virginia to become an Agreement State. The request from Governor Timothy Kaine seeks to assume part of the NRC's regulatory authority over certain nuclear materials in the Commonwealth. If the NRC approves the request, Virginia would become the 36th Agreement State.

Section 274 of the Atomic Energy Act of 1954, as amended (Act), allows States to assume certain NRC regulatory authority. Under the Act, NRC relinquishes to the States portions of its regulatory authority to license and regulate byproduct materials (radioisotopes), source materials (uranium and thorium), and certain quantities of special nuclear materials. The mechanism for the transfer is an agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with Section 274b of the Act.

When a State takes on this authority and becomes an "Agreement State," NRC continues to provide assistance. This assistance includes conducting training courses and workshops, evaluating technical licensing and inspection issues, evaluating State rule changes, participating in activities conducted by the Conference of Radiation Control Program Directors Inc., and allowing early and substantive involvement of the States in NRC rulemaking and other regulatory efforts. The NRC also coordinates with Agreement States on the reporting of event information and allegations involving Agreement States.

The Commonwealth of Kentucky became the first Agreement State on March 26, 1962. If the proposed agreement is approved, NRC would transfer 386 licenses to the Commonwealth's jurisdiction. Virginia would retain regulatory authority for approximately 216 licenses for naturally occurring and accelerator-produced radioactive materials; of which approximately 180 of these licenses are dually regulated by Virginia and the NRC.

NRC would retain jurisdiction over commercial nuclear power plants and Federal agencies using certain nuclear material in the State. In addition, NRC would retain authority for the review, evaluation, and approval of sealed radioactive materials and devices containing certain nuclear materials within the State.

The current list of Agreement States 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.

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## NRC ISSUES ORDER TO RADIOGRAPHY GROUP

The U.S. Nuclear Regulatory Commission (NRC) has issued a Confirmatory Order to Mistras Holding Group documenting the company's commitments to improve safety practices in radiography work.

The Order was issued to the firm, which operates from multiple locations throughout the country including Illinois and Pennsylvania. It also does business as CONAM Inspection and Engineering Services Quality Services Laboratories, Inc.

The Confirmatory Order makes the company's commitments conditions of its license. If these conditions are not met, the company's NRC license may be terminated; criminal or civil charges may be brought against the company; and fines may be levied.

In January 2007, CONAM reported to the NRC that a radiographer

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# FROM THE DESK OF THE FSME DIRECTOR

The FSME management team met recently to discuss the changing internal and external climate in which we and you (our licensees) operate. Perhaps it is a byproduct of the time, but it seems as though the changes are accelerating in number and in magnitude and that resistance to change is not a viable or prudent option.

Of course, adjusting to change is nothing new. Victor Hugo once said, "Change your opinions; keep to your principles; change your leaves; keep intact your roots." Bertrand Russell said, "Change is one thing. Progress is another." I agree with both of these quotes. That said, changes are inevitable and so, we would do well to try to anticipate them as best we can and plan accordingly.

Externally, we have a change in the Presidential Administration, and changes in several of the Cabinet level agencies (Energy, Homeland Security, Environmental Protection Agency) with whom NRC and FSME interact. This will create new leadership in those agencies, which could result in significant policy changes. Although the NRC is not a Cabinet level agency, it is an independent regulatory agency, likely to be affected by changes also.

Additionally, we have major economic changes occurring throughout the global economy. Most of the readers of this Newsletter are FSME licensees, and I am sure that most of you are feeling the impacts-- some more than others. As I write this, NRC is operating under a Continuing Resolution, and FSME is being held to its lower FY 2008 budget authority. We are receiving our funding only on an incremental basis so we have really had to limit our hiring, re-prioritize our work, and re-focus on our most mission critical tasks. I am guessing that many of you, our licensees, are in the same position, and are making a number of tough management decisions to sustain your competitive positions in your respective industries. From a regulatory standpoint, my focus must be on ensuring that safety, security, and environmental considerations are not forgotten as these tough calls are made.

Within the nuclear reactor industry, the term "safety culture" is well-understood and has long been in application. Because FSME and Agreement State licensees are far more diverse in terms of what you do (compared to reactor licensees), the concept may be newer, and less understood, but it is no less important. Even as we grapple with its definition within an FSME context, I suspect that most of you strive to have the key attributes of a strong safety/security culture in place. It is now our responsibility to share those good practices with one another, and ensure that nothing is compromised in these tight economic, changing times. I stand ready to work with you to address these changes. Based on your past performance, I am confident that we will jointly achieve success.

Charles L. Miller

Charles L. Miller, Director

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may have been overexposed to radiation while performing industrial radiography at a Sunoco refinery in Philadelphia, Pennsylvania. An NRC special inspection identified five apparent violations, including the radiographer's failure to secure the sealed source with radioactive material in the shielded position, his failure to wear a radiation alarm at all times, his failure to stop radiography when a pocket radiation measuring device showed off-the-scale radiation levels, and a failure to make sure that the radiation safety officer named in the NRC license performed the intended function. A subsequent NRC investigation showed that most of the apparent violations were willful or deliberate.

Even though the radiographer was exposed to radiation as a result of the event, the radiation dose received was not in excess of regulatory limits and is not expected to cause adverse health effects. The company took corrective actions following the event, including removing the radiographer from radiography work, implementing new procedures to verify that the radiation source is properly retracted into a shielded position, and briefing all employees at the Pennsylvania facility on the circumstances and causes of the event.

As part of the agreement reached by the NRC and the company, CONAM committed to: increasing the number of audits of its radiographers by 25 percent, revising its audit procedures to address the conduct of audits and documentation of results, disseminating lessons learned through an online training program, creating a safety hotline for radiographers to report safety concerns, and conducting surveys of safety consciousness in the company.

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## LICENSE SUSPENSION AND TRANSFER OF CLEANUP OF THE STEPAN COMPANY SITE TO THE US ARMY CORPS OF ENGINEERS

On November 5, 2008, the NRC published in the Federal Register, a Notice of an October 21, 2008, Confirmatory Order Modifying License (Effective Immediately) for the Stepan Company in Maywood, New Jersey (73 FR 65886, November 5, 2008). The Order became final on November 25, as the Order had set forth and included an opportunity to request a hearing by any person adversely affected by the Order within 20 days of its publication in the Federal Register. Dr. Charles Miller, Director of the Office of Federal and State Materials and Environmental Programs issued the Order after an extensive period of negotiations between the licensee and the staff, and in coordination with the U.S. Army Corps of Engineers (USACE), the State of New Jersey Department of Environmental Protection, and the State Attorney General's Office. The order was prepared consistent with the Memorandum of Understanding (MOU) between the U.S. Nuclear Regulatory Commission and the U.S. Army Corps of Engineers for Coordination of Cleanup & Decommissioning of the Formerly Utilized Sites Remedial Action Program (FUSRAP) Sites With NRC-Licensed Facilities (66 FR 36606, July 12, 2001). Again, consistent with the MOU, and upon a September 25, 2008, USACE written request, the NRC formally initiated Stepan license suspension process in order to facilitate USACE's start of site cleanup in early January 2009.

In 1997, USACE received congressional authority to manage and administer cleanup of FUSRAP sites. The Stepan site was added to FUSRAP in 1984. The Order was culmination of eight years of effort by the NRC, USACE, U.S. Environmental Protection Agency, U.S. Department of Energy, U.S. Department of Justice, the State of New Jersey, and the licensee. In 2003, USACE published a Record of Decision (akin to a decommissioning plan), laying out its plan for the site cleanup. In 2004, the Stepan Company and the Department of Justice, on behalf of the U.S. Government, reached a settlement on roles and responsibilities for the cleanup of the licensed facilities for unrestricted use, allowing the staff to proceed with the eventual suspension of the license to permit USACE's cleanup of the licensed facilities.

The Maywood Stepan site is located in the borough of Maywood, New Jersey. The Stepan Company acquired the facility from the Maywood Chemical Works (MCW) in 1959. Since the acquisition of the facility, the Stepan Company has been manufacturing specialty

chemicals and other products at the Maywood facility. In the late 1960s, the Stepan Company conducted some site cleanup on the original MCW plant site property on both east and west sides of New Jersey State Route 17, adjacent to the facility. In accordance with the NRC regulations at the time (NRC subsequently rescinded the regulation), the waste materials were relocated to three burial areas on property currently owned by the Stepan Company. The principal radioactive contaminants at the site are process wastes from the thorium extracted from the monazite sands using a chemical separation process. The residual alkaline thorium phosphate tailings are stored in three licensed underground storage areas.

Until the license is put in abeyance, the license remains in timely renewal. The NRC and USACE interactions during the period of license abeyance and site cleanup will be guided by the MOU. USACE has no objections to NRC's observing USACE and its contractor's activities during the period of site remediation.

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## AVAILABILITY OF FREQUENTLY ASKED QUESTIONS ON RADIUM-226

TThe Energy Policy Act (EPAct) of 2005 gave the U.S. Nuclear Regulatory Commission (NRC) regulatory authority over certain naturally occurring and accelerator-produced radioactive material (NARM). The NRC published its final rule implementing this authority in the Federal Register on October 1, 2007 (72 FR 55863). The final rule expanded the definition of "byproduct material" in NRC regulations and established requirements for licensing and regulating Section 11e.(3) and 11e.(4) byproduct material, as required by Section 651(e) of the EPAct. These final regulations became effective on November 30, 2007.

As part of the staff's effort on this rule, the staff developed a set of frequently asked questions (FAQs) for radium-226. The purpose of the FAQs is to provide a set of questions and answers for the general public and stakeholders who might have questions regarding NRC's new authority to regulate discrete sources of radium-226. The questions are intended to be broad and address certain aspects of the NARM rule. The FAQs are available at:

http://nrc-stp.ornl.gov/narmtoolbox/radium%20faq102008.pdf.

For more information on NARM-related activities, please go to the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Web site at http://nrc-stp.ornl.gov/narmtoolbox.html.

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## NOTIFICATION OF THE NEXT PHASE OF WAIVER TERMINATIONS IN THE IMPLEMENTATION OF NRC REGULATORY AUTHORITY FOR CERTAIN NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM)

The Energy Policy Act (EPAct) of 2005 gave the NRC regulatory authority over NARM. NRC's final rule implementing this authority was effective November 30, 2007 (72 FR 55863).

A waiver was issued on August 31, 2005, to allow continued use and possession of NARM while the NRC developed its regulatory framework. The NRC has been terminating the waiver in phases. Phase 1 of terminations occurred on November 30, 2007, and Phase 2 on September 30, 2008. NRC is now preparing for Phase 3 which will occur on August 8, 2009. This final phase will include Alaska, Connecticut, Hawaii, Michigan, New Jersey, the Commonwealth of Virginia, and Canadian licensees that are under NRC jurisdiction. If one of these States becomes an Agreement State before August 7, 2009, the Commission will terminate the waiver for the non-Agreement State that enters into an Agreement with the NRC coincident with the effective date of such Agreement.

For existing NRC licensees, NARM use amendments are required within six months from the date of waiver termination. For NARM users in non-Agreement States and US territories without an NRC license, the new license

applications are required within 12 months from the date of waiver termination.

NARM users in Phase 2 States must submit license amendments by March 31, 2009, or new license applications by September 30, 2009.

More information on NARM-related activities can be found on the "NARM Toolbox" at the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Web site at http://nrc-stp.ornl.gov/narmtoolbox.html. One of the more recent documents posted on the NARM Toolbox is a recently issued Regulatory Issue Summary 2008-13, "Status and Plans for Implementation of NRC Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material," issued on June 16, 2008 (http://nrc-stp.ornl.gov/narmtoolbox/ris2008-13.pdf).

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## NEOVISTA, INC.'S EPI-RAD$_{90}$™ (STRONTIUM-90) OPHTHALMIC SYSTEM: AN EMERGING TECHNOLOGY REGULATED UNDER 10 CFR 35.1000

NNeoVista, Inc.'s Epi-Rad$_{90}$™ (strontium-90) Ophthalmic System is an intraocular radiation therapy device that was added to the Sealed Source and Device (SSD) Registry in September 2006 and its SSD registration certificate was last updated in February 2008. Although the Epi-Rad$_{90}$™ System is used for ophthalmic radiation therapy, NRC staff, with the assistance of the Advisory Committee on the Medical Uses of Isotopes, has determined that the design and operation of the Epi-Rad$_{90}$™ System is significantly different from that of strontium-90 (Sr-90) superficial eye applicators that are currently regulated under 10 CFR 35.400, "Use of sources for manual brachytherapy." As such, the NRC has determined that the intraocular use of the Epi-Rad$_{90}$™ System is regulated under the provisions of 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material."

The Epi-Rad$_{90}$™ System is currently being used under the provisions of an Investigational Device Exemption issued by the U.S. Food and Drug Administration (FDA) and therefore can be only used at the limited number of approved FDA investigational sites. Limited specific medical use licensees authorized for Sr-90 eye applicators, or for other materials under 10 CFR 35.400, are not automatically authorized to possess and use the Epi-Rad$_{90}$™ System and therefore must submit a license amendment request and obtain authorization for possession and use of the device. Appropriate licensing guidance for the use of the Epi-Rad$_{90}$™ System has been developed by NRC and posted on NRC's public website at http://www.nrc.gov/materials/miau/med-use-toolkit.html#other. Licensees interested in applying for authorizations for use of the Epi-Rad$_{90}$™ System should submit applications to the appropriate NRC Regional Office.

An amendment is not required for use of the Epi-Rad$_{90}$™ System by NRC broad scope medical use licenses with authorization under 10 CFR 35.1000, unless the possession limit for Sr-90 needs to be increased. For broad scope licenses, the radiation safety committee is required, by 10 CFR 33.13(c)(3), to review, approve, and record the safety evaluation of proposed uses of byproduct material. This safety evaluation must take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures. This review, approval and recording of the Epi-Rad$_{90}$™ System safety evaluation must be completed prior to use of the device.

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## URANIUM RECOVERY COMMISSION BRIEFING

On December 11, 2008, the U.S. Nuclear Regulatory Commission (NRC) held a public Commission Briefing on the status of the NRC's Uranium Recovery Licensing Program (URLP). The all-day briefing included presentations by the NRC staff, as well as, Native American Tribal representatives, Federal and State representatives, and stakeholders. The briefing was attended by approximately 50 staff and interested members of the public and was broadcast via Webcast. The Webcast of the meeting is available at: http://video.nrc.gov/nrcArch.cfm

*Members of the public and the Commission discuss the status of the Uranium Recovery Licensing Program.*

The briefing began with an overview of the status of the URLP by Larry W. Camper, Director of the Division of Waste Management and Environmental Protection (DWMEP). Mr. Camper discussed the scope of the program, the current status of the uranium recovery industry, the staff's activities to prepare for an expected 28 uranium recovery applications by 2012 and the staff's outreach activities to Native Americans, and stakeholders. Over the past few years, the spot price of uranium has been extremely volatile going from about $45 per pound to as high as $130 dollars per pound in mid-2007, which was driven in large part by the need for fuel for new nuclear power reactors. This has increased the production of uranium and subsequent increase in the interest in licensing additional uranium recovery sites in the U.S.

Bill von Till, Chief of the Uranium Recovery Licensing Branch, then discussed the status of the review of current uranium recovery license applications. Currently, four new applications are being reviewed by the staff. In addition, 2 applications for expansions of existing facilities are under review and a review of a restart application was completed in 2008. An additional 24 new, expansion, or restart applications are expected by 2012.

Gregory Suber, Chief of the Environmental Review Branch in DWMEP, then discussed the status of the development of a Generic Environmental Impact Statement (GEIS) for the review of in-situ recovery (ISR) license applications. The GEIS, which in part will assist NRC fulfilling its obligations under the National Environmental Policy Act, evaluates the impacts to several common environmental factors in four geographic areas in the Western U.S. The staff will use the evaluation in the GEIS in the site-specific environmental reviews that are necessary to support the evaluation of each new application. By evaluating these common factors in a GEIS for ISR, the staff expects to save over $4 million and at least 7 Full-Time Equivalent personnel.

Gary Comfort, Sr. Project Manager in the Division of Intergovernmental Liaison and Rulemaking (DILR), then described the status of the NRC's rulemaking on groundwater protection at ISR facilities. The proposed rule would add a new Criterion 14 to Appendix A in 10 CFR Part 40, that would be applicable only to ISR facilities and consist of requirements that NRC has determined are necessary to ensure groundwater protection at the site.

Richard Turtil, Chief of the Intergovernmental Liaison Branch in DILR, then described the NRC's outreach efforts with Native Americans; specifically, the efforts to identify issues of concern, information sharing initiatives, and government-to-government meetings with Native American Tribes. For example, additional scoping meetings were held for the GEIS, specifically to provide Native Americans with an opportunity to provide comments. In addition, NRC has been working with other Federal agencies to develop a 5-year plan to address legacy uranium mine and mill waste on Navajo lands. In 2005, the Navajo Nation passed a law that prohibits the mining of uranium on Navajo lands until all adverse effects from past mining and milling have been eliminated or substantially reduced.

The staff's presentations were followed with presentations by representatives of the U.S. Environmental Protection Agency (EPA) and the Bureau of Land Management (BLM). These presentations centered on the roles of EPA and BLM in the regulation of uranium mining and milling.

During the afternoon sessions, the Commission heard from Native American Tribal representatives and State officials in Wyoming and New Mexico, which have substantial uranium deposits. The Commission also heard from Navajo Allottees, the National Mining Association, the International Forum on Sustainable Options for Uranium Production, and the Natural Resources Defense Council.

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## SAFETY CULTURE AT MATERIALS LICENSEES

On February 3, 2009, the NRC held a public meeting to solicit the views of interested stakeholders on topics related to safety culture and security culture. The meeting was also available through teleconferencing and as a webinar. The attendees included representatives of State governments, materials licensees, and non-governmental organizations. Additional background on these topics is provided in a Federal Register notice (January 23, 2009; 74 FR 4260).

The Commission has directed the NRC staff to complete its evaluation, provide a recommendation to the Commission on how best to update the Commission policy, and provide draft policy statement(s) on safety culture to the Commission for its consideration. As part of its evaluation, the staff should, at a minimum, address the following key areas:

(1) Whether safety culture as applied to reactors needs to be strengthened.

(2) How to increase attention to safety culture in the materials area.

(3) How stakeholder involvement can most effectively be used to address safety culture for all NRC and Agreement State licensees and certificate holders, including any unique aspects of security. The staff should, as part of its public stakeholder outreach, reach out to all types of licensees and certificate holders, including power reactors (including new reactors), research and test reactors, fuel facilities, spent fuel shipping and storage cask vendors, and the materials community, including industrial, academic, and medical users. The assessment should also involve outreach activities to Members of Congress, the Agreement States, and other stakeholders.

(4) Whether publishing NRC's expectations for safety culture and for security culture is best accomplished in one safety/security culture statement or in two separate statements, one each for safety and security, while still considering the safety and security interfaces.

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## MODIFICATION OF THE VARSKIN COMPUTER CODE

The NRC sponsored the development of the VARSKIN code in the 1980s, to assist licensees in demonstrating compliance with Paragraph (c) of Title 10, Section 20.1201, of the Code of Federal Regulations (10 CFR 20.1201), "Occupational Dose Limits for Adults." Specifically, 10 CFR 20.1201(c) requires licensees to have an approved radiation protection program that includes established protocols for calculating and documenting the dose attributable to radioactive contamination of the skin. Since that time, the code has been significantly enhanced to simplify data entry and increase efficiency. VARSKIN 3 is available from the Radiation Safety Information Computational Center. For additional information, see NUREG/CR-6918, "VARSKIN 3: A Computer Code for Assessing Skin Dose from Skin Contamination."

Since the release of VARSKIN 3 in 2004, the NRC staff has compared its dose calculations for various energies and at various skin depths, with doses calculated by the Monte Carlo N-Particle Transport Code System developed by Los Alamos National Laboratory. That comparison indicated that VARSKIN 3 overestimates the dose with increasing photon energy. For that reason, the NRC is sponsoring a further enhancement to replace the existing photon dose algorithm, enhancing the quality assurance program, and correcting technical issues reported by users.

To facilitate this enhancement, or if you are aware of any problems or errors associated with the VARSKIN code, we encourage you to contact us at: http://www.nrc.gov/about-nrc/regulatory/research/contact-us-varskin.html.

(Contact: Mohammad Saba, Office of Research, (301) 415-7608, email: Mohammad.Saba@nrc.gov)

## REPORTING INVENTORIES OF SPECIAL NUCLEAR MATERIALS (SNM) TO THE NRC

On June 9, 2008 the Nuclear Regulatory Commission published the final rule concerning Regulatory Improvements to the Nuclear Materials Management and Safeguards System (NMMSS) in the Federal Register http://edocket.access.gpo.gov/2008/pdf/E8-12830.pdf . The effective date of this rule is January 1, 2009. One of the changes in this

rule is an additional requirement that any NRC or Agreement State licensee, who possesses a gram or more of SNM (plutonium, U-235 contained in enriched uranium, or U-233), report their physical inventory each year to the NRC. The inventory reports are to be submitted between January 1 and March 31 of each year to the operator of the NMMSS database. NRC and Agreement State licensees are already required to report shipments and receipts to NMMSS. Previously, the inventory reporting requirement was for only those licensees that were authorized to possess 350 grams or more of SNM.

The NMMSS compares the reported inventory information with information that the licensee has reported to NMMSS concerning receipts, shipments and inventory adjustments. The rule also requires that if there are any inconsistencies between the reported inventory and records the licensee has submitted previously to NMMSS, the licensee has thirty calendar days to reconcile their records with the NMMSS database. This rule change will apply to NRC and Agreement State licensees who possess, or possessed in the previous year, a gram or more of SNM. The specific regulations that apply to NRC licensees are in 10 CFR 74.13. The specific regulations that apply to Agreement State licensees are located at 10 CFR 150.16 and 10 CFR 150.17 of the published rule.

As NRC and Agreement State licensees prepare to start reporting their inventories, there may be cases when a licensee identifies that its physical inventory does not match up with information that they have reported to the NMMSS database. Many of the inconsistencies may be determined to be the result of on-site inventory adjustments such as small sample use and disposal. The NRC regulations previously did not require that on-site inventory adjustments be reported to the NMMSS database. The licensee will need to report these on-site inventory adjustments to NMMSS as part of their work to reconcile their inventory records with the NMMSS database.

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## SIGNIFICANT ENFORCEMENT ACTIONS

The U.S. Nuclear Regulatory Commission's (NRC's) enforcement program can be accessed via NRC's homepage [http://www.nrc.gov/] under "What We Do." Documents related to cases can be accessed at [http://www.nrc.gov/], "Electronic Reading Room," "Documents in ADAMS." ADAMS is the Agency-wide Document Access and Management System. Help in using ADAMS is available from the NRC Public Document Room, telephone: 301-415-4737 or 1-800-397-4209.

**Medical**

**Bon Secours Virginia Health Source** (EA-08-234)

On October 10, 2008, a Notice of Violation was issued for three Severity Level III violations. The first violation involved a failure to meet 10 CFR 35.41(b)(2) requirement. Specifically, the licensee did not develop and implement written procedures to provide high confidence that each medical administration is in accordance with the written directive, in that the procedures did not address response to high dose rate (HDR) device error messages. The second violation involved a failure to ensure an authorized user (AU) was physically present during initiation of a patient treatment. During continuation of the patient treatment, neither the AU, nor a physician under the supervision of an AU, was physically present. Specifically, the AU was working with another patient in another room and was not involved in the investigation and resolution of an HDR device error message that was received during the patient treatment. The third violation involved a failure to report a medical event as required by 10CFR 35.3045(a)(1)(iii)&(3). Specifically, for an HDR fractional treatment that resulted in a dose delivered to a portion of the treatment site that differed from the prescribed dose by more than 50 rem, and the fractionated dose that differed from the prescribed dose, for a single fraction, by more than 50 percent, the licensee personnel did not provide a verbal or written report to the NRC in a timely manner.

**Bridgeport Hospital** (EA-08-269)

On November 6, 2008, a Notice of Violation was issued for a Severity Level III violation that involved the failure to develop, implement, and maintain written procedures to provide high confidence that each medical administration

will be done in accordance with the written directive, for administrations requiring a written directive. Specifically, changes in procedures for inputting geometric information into the treatment planning system were not performed in accordance with the current version of the vendor's operator manual. An incorrect magnification factor was used in treatment dose calculations and the licensee's calculation double-checks did not include validation of geometric accuracy. As a result, the patients were administered doses that ranged from 45 percent to 62 percent less than the prescribed dose set forth in the written directive.

**Radiography**

**Cal Testing Services, Inc.**
(EA-08-286)

On January 5, 2009, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of $6,500 was issued to Cal Testing Services, Inc. This action is based on a Severity Level III violation of NRC License Condition 20 involving the failure of the licensee to conduct its program in accordance with the statements, representations, and procedures contained in an application (with attachments) provided to the NRC. Specifically, the licensee failed to connect the control cable to the source assembly before cranking the source out of the radiographic exposure device, as required by the licensee's procedures. This event resulted in a disconnected source event.

**Portable Gauges**

**St. Joseph [MO], City of**
(EA-08-266)

On December 11, 2008, a Notice of Violation was issued for a Severity Level III violation. The violation involved the failure to use a minimum of two independent physical controls that form tangible barriers to secure a portable gauge whenever the gauge was not under the control and constant surveillance of the licensee as required in 10 CFR 30.34(i). Specifically, the licensee stored the gauge in a storage room with the key in the door lock rendering the physical barrier ineffective. Additionally, a second independent physical barrier was not provided.

**Montana State University**
(EA-08-279)

On December 4, 2008, a Notice of Violation was issued for a Severity Level III violation. The violation involved the failure to use a minimum of two independent physical controls that form tangible barriers to secure a portable gauge whenever the gauge was not under the control and constant surveillance of the licensee as required in 10 CFR 30.34(i). Specifically, the licensee stored portable gauges at two separate locations on campus using only one independent physical control that formed a tangible barrier to prevent unauthorized removal of the gauges when not under the control and constant surveillance of the licensee.

**Wilcox Associates, Inc.**
(EA-08-215, EA-08-267)

On November 7, 2008, a Notice of Violation was issued for a Severity Level III violation. The violation involved two examples of the failure to use a minimum of two independent physical controls that form tangible barriers to secure a portable gauge whenever the gauge was not under the control and constant surveillance of the licensee as required in 10 CFR 30.34(i). Specifically, the first example involved using a single barrier, only one lock, to secure the gauge transport case to an unlocked closed-bed pickup truck. The second example involved using a single barrier, only one lock, to secure a gauge in a locked cage.

**Kirksville [MO], City of**
(EA-08-205)

On September 22, 2008, a Notice of Violation was issued to the City of Kirksville, Missouri, an NRC licensee. This action is based on a Severity Level III violation of 10 CFR 30.34(i) involving the licensee's failure to maintain a minimum of two independent physical controls that formed tangible barriers to secure a portable gauge from unauthorized removal during a period when the portable gauge was not under the control and constant surveillance of the licensee. Specifically, on multiple occasions, the licensee stored a portable gauge in a laboratory using only a single barrier, the locked laboratory room door. In addition, on multiple occasions, the licensee transported a portable gauge, in its transport case, in the back of a closed-bed pickup truck with only a single barrier, the lock on the bed cover.

**Miscellaneous**

**Crane Army Ammunition Activity - Department of the Army** (EA-08-222)

On October 30, 2008, a Notice of Violation was issued for a Severity Level III problem involving 1) the failure to control radioactive material not in storage as required by 10 CFR 20.1802, and 2) the failure to properly describe the material on shipping papers and properly mark and label the packages in accordance with the requirements of 10 CFR 71.5 and 49 CFR 171.2. Specifically, on May 22 and 29, the licensee shipped depleted uranium in three cardboard boxes to a facility in Virginia as part of their site operation to demilitarize munitions. The boxes were not controlled when not in storage and were not properly marked nor labeled. In addition, the material was not properly described as hazardous on the shipping papers that accompanied the shipment.

**BWX Technologies, Inc.** (EA-08-204)

On October 20, 2008, a Notice of Violation (NOV) and Proposed Imposition of Civil Penalty in the amount of $32,500 was issued to BWX Technologies, Inc. This action is based on a Severity Level III violation of 10 CFR 70.61 involving the failure of the licensee to provide adequate engineered and administrative controls to limit or prevent an acute chemical exposure from a hazardous chemical produced from licensed material. Specifically, the licensee failed to properly label a storage tank containing liquid hydrogen fluoride (HF), and failed to ensure that a Process Operator was adequately trained. As a result, on April 28, 2008, a Process Operator received an ocular exposure to liquid HF while trying to neutralize a spill that could have led to irreversible, or other serious long-lasting health effects. In this case, no permanent vision loss was sustained by the operator. However, under different circumstances, such as a delayed response from the emergency team, the exposure could have resulted in a more severe consequence to the operator.

## GENERIC COMMUNICATIONS ISSUED

(October 3, 2008 – December 8, 2008)

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.

***Regulatory Issue Summaries (RIS)***

**RIS 2008-23, "The Global Threat Reduction Initiative (GTRI) Domestic Threat Reduction Program & Federally Funded Voluntary Security Enhancements For High-Risk Radiological Material"** was issued October 3, 2008. This RIS was issued to all U.S. Nuclear Regulatory Commission Materials Licensees authorized to possess Category 1 or Category 2 quantities of radioactive materials, all Agreement State Radiation Control Program Directors and State Liaison Officers, and Members of the Advisory Committee on the Medical Uses of Isotopes.

(Contact: Doug Broaddus, FSME, (301) 415-8124, e-mail: Doug.Broaddus@nrc.gov; Maria Arribas-Colon, FSME, (301) 415-6026, e-mail: Maria.Arribas-Colon@nrc.gov; and Regional contacts: Judith Joustra, Region I, (610) 337-6942, e-mail: Judith.Joustra@nrc.gov; Kevin Null, Region III, (630) 829-9854, e-mail: Kevin.Null@nrc.gov; Roberto Torres, Region IV, (817) 860-8189, e-mail: Robertoj.Torres@nrc.gov)

**RIS 2008-24, "Security Responsibilities of Service Providers and Client Licensees"** was issued October 3, 2008. This RIS was issued to all U.S. Nuclear Regulatory Commission licensees that hire service providers to install, service, repair, maintain, relocate, exchange, or transport radioactive materials in quantities of concern, service provider licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

(Contact: Doug Broaddus, FSME, (301) 415-8124, e-mail: Doug.Broaddus@nrc.gov)

**RIS 2008-31, Licensing Requirements for Sentinel Lymph Node Biopsy** was issued December 1, 2008. This RIS was issued to all U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master material licensees, and all Agreement State Radiation Control Program Directors and State Liaison Officers.

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

## SIGNIFICANT EVENTS

**Event #1: Medical Event Due to Programming Error**

*Date and Place: September 10, 2008 Jacksonville, Florida*

Nature and Probable Cause: The licensee reported that a patient received 3,400 cGy (rad) to unintended tissue during several breast cancer therapy treatments from 9/10 to 9/17/2008. The patient was being treated with an Ir-192 high dose rate (HDR) afterloader unit. Symptoms of erythema were identified by the patient. The medical physicist reviewed the records and determined that the HDR afterloader was wrongly programmed such that the source stopped 10 cm short of the intended tumor site in the right breast. As a result, the entire dose intended for the tumor was administered to the left breast, which was not intended to be treated.

**Event #2: Medical Event Involving Unintended Dose**

*Date and Place: October 15, 2008 Huntington, West Virginia*

Nature and Probable Cause: The licensee reported that a patient received an unintended dose of 1,786 cGy (rad) to the esophagus. The patient was being treated for a thyroid condition with a capsule containing 5.55 GBq (150 mCi) of I-131. The patient attempted to swallow the capsule on 10/15/2008, but it became lodged in the patient's throat due to an esophageal obstruction. The licensee's staff attempted to aid the patient in swallowing the capsule by having them drink soda and eat applesauce. The capsule eventually passed the obstruction after approximately 2.5 hours. The event was discussed with the patient during a follow-up visit with the physician on 10/22/2008. Potential adverse effects include esophagitis and radiation fibrosis. The NRC retained a medical consultant to review this event.

**Event #3: Overexposure from Failed Equipment**

*Date and Place: October 28, 2008 Tyler, Texas*

Nature and Probable Cause: The licensee reported that a 9.62 GBq (260 mCi) Cs-137 source disconnected from their level measurement gauge (Thermo MeasureTech model 5191). As a result of the source disconnect, four non-radiation workers received annual exposures that exceeded the limit. The individuals received 2.962, 0.960, 0.280, and 0.166 cSv (rem). On 10/28/2008, the licensee noted that the gauge was no longer giving proper readings and a maintenance crew was sent to perform repairs. Radiation surveys revealed elevated levels. DRL contacted the manufacturer and a technician was sent to the facility. The technician identified elevated radiation levels and determined that the source had separated from the operating rod. The source was still located in the gauge housing, but was not shielded. On 10/29/2008, the manufacturer removed the gauge from the tank it was mounted on. The gauge and source were packaged for transportation back to the manufacturer's facility for inspection and repair.

**Event #4: Release of Radioactive Material**

*Date and Place: November 13, 2008 Sweetwater, Texas*

Nature and Probable Cause: The licensee reported breaching a 3.33 GBq (90 mCi) Cs-137 source (AEA Technology model CDC.800) while modifying a piece of calibration equipment. The RSO stated that the source was cut in half with a thin blade saw. Following the incident, the remaining sections of the source were assayed and the activity was 1.78 GBq (48 mCi). A Texas Department of Health Services inspector was dispatched to the scene to investigate. Initial reports stated that 40 or more employees were involved and that contamination was spread by foot traffic through the facility. The licensee contracted Energy Solutions to perform assessment and decontamination activities beginning on 11/14/2008. The inspector identified that contamination levels were fairly low with some spots reading approximately five times background (between 10,000 and 15,000 counts per minute on a scintillation detector). The licensee also contacted the DOE Radiation Emergency Assistance Center/

Training Site for guidance. No employees spread contamination outside the facility. Four employees identified as having potential intakes provided urine samples and received whole body counts at Comanche Peak Nuclear Power Station on 11/19/2008. Three of those individuals had received less than 0.1 mSv (10 mrem) CEDE from the incident. The fourth individual, who cut the source, received 0.3 mSv (30 mrem) CEDE. That individual stated that he covered his mouth with his jacket during the cutting process because it was creating a lot of dust. The licensee intends to provide whole body counts to all of their employees. The whole facility was posted and controlled as a contaminated area. The facility is 60,000 square feet in size. It is divided into several areas, most having their own air handling systems. The contamination appears to be mostly on floor areas outside the work area. No survey information is available in the work area where the source was breached. The RSO stated that approximately 30 percent of the facility has been decontaminated.

**Event #5: Medical Event Due to Improper Preparation**

*Date and Place: December 2, 2008 Dallas, Texas*

Nature and Probable Cause: The licensee reported that a patient prescribed to receive 8,000 cGy (rad) to the 5th intracranial nerve during trigeminal neuralgia treatment only received 10 to 20 cGy (rad) on 12/2/2008. The 7th intracranial nerve, on the other hand, received 1,495 cGy (rad). The 5th intracranial nerve was prescribed 8,000 cGy (rad) and the written directive was completed and signed by all appropriate parties. However, the Elekta Instrument AB gamma knife unit (Leksell Gamma System model 24001), containing 125.8 TBq (3,400 Ci) of Co-60 (General Electric model 43047), was improperly prepared and the wrong nerve was designated for treatment. Fortunately, the authorized neurosurgeon instructed the licensed medical physicist to pause the treatment 9.17 minutes into the 45 minute regime. He then consulted with the neuroradiologist and they determined that the wrong nerve was targeted. The patient was notified and correct treatment was successfully performed on the same day. The clinical staff concluded that the root cause was misidentification of the anatomical target site as listed on the written directive. No untoward effects are expected as a result of the medical event. Corrective actions included procedure modifications requiring that the neuroradiologist provide precise information on the MRI of the correct target site. The written directive will also be modified to ensure the correct site is defined.

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

## SELECTED FEDERAL REGISTER NOTICES

10 CFR Part 35, Medical Use of Byproduct Material--Amendments/ Medical Event Definitions; Extension of Comment Period (AI26), 73 FR 58063, October 6, 2008.

(Contact: Edward M. Lohr, Office of Federal and State Materials and Environmental Management Programs, (301) 415-0253, e-mail: Edward.Lohr@nrc.gov)

10 CFR Part 51, Categorical Exclusions from Environmental Review (AI27), 73 FR 59540, October 9, 2008.

(Contact: Cardelia H. Maupin, Office of Federal and State Materials and Environmental Management Programs, (301) 415-2312, e-mail: Cardelia.Maupin@nrc.gov)

Protection of Safeguards Information (AH57), 73 FR 63545, October 24, 2008.

(Contact: Jason Zorn, Attorney, Office of the General Counsel, (301) 415-8350, e-mail: Jason.Zorn@nrc.gov; or Bernard Stapleton, Office of Nuclear Security and Incident Response, (301) 415-2432, e-mail: Bernard.Stapleton@nrc.gov)

10 CFR Part 72, List of Approved Spent Fuel Storage Casks: NAC-UMS, Revision 5 (AI48), 73 FR 63621, October 27, 2008.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, (301) 415-6219, e-mail: Jayne.McCausland@nrc.gov)

Physical Protection of Byproduct Material: Availability of preliminary draft rule language (RIN AI12), 73 FR 69590, November 19, 2008.

(Contact: Merri Horn, Office of Federal and State Materials and Environmental Management Programs, (301) 415-8126, e-mail: Merri.Horn@nrc.gov)

List of Approved Spent Fuel Storage Casks: MAGNASTOR Addition (RIN AI51), 73 FR 70587, November 21, 2008.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, (301) 415-6219, e-mail: Jayne.McCausland@nrc.gov)

List of Approved Spent Fuel Storage Casks: MAGNASTOR Addition (RIN 3150-AI51), 73 FR 70607, November 21, 2008.

(Contact: Jayne M. McCausland, Office of Federal and State Materials and Environmental Management Programs, (301) 415-6219, e-mail: Jayne.McCausland@nrc.gov)

Regulatory Changes to Implement the Additional Protocol to the US/IAEA Safeguards Agreement (AH38), 73 FR 78599, December 23, 2008.

(Contact: Naiem S. Tanious, Office of Federal and State Materials and Environmental Management Programs, (301) 415-6103, e-mail: Naiem.Tanious @nrc.gov)

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