

FSME
News

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OFFICE OF FEDERAL & STATE

MATERIALS & ENVIRONMENTAL

MANAGEMENT PROGRAMS

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Licensing Decision for Radium-223 Dichloride

Radium-223 dichloride (radium 223) is currently an investigational radiopharmaceutical undergoing clinical trials in the United States. The U.S. Food and Drug Administration has not approved the use of the substance. Algeta ASA (Algeta), a Norwegian drug maker, is developing radium-223 and has plans to make it available for commercial use, pending approval, under a global agreement with Bayer Pharma AG (Bayer). The intended use for radium-223 is for the treatment of skeletal metastases in advanced castration-resistant prostate cancer. Radium-223 naturally self-targets bone metastases by virtue of its properties as a calcium-mimic and kills tumor cells by highly localized short-range alpha irradiation. Radium-223 has the potential to be the first therapeutic radiopharmaceutical administered primarily for its alpha emissions. Therefore, the U.S. Nuclear Regulatory Commission (NRC) staff carefully reviewed the radiation safety aspects of the medical use of radium-223 to determine if the radiopharmaceutical should be licensed under Title 10 Code of Federal Regulations (10 CFR) Part 35, Subpart E, "Unsealed Byproduct Material—Written Directive Required," or 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." On November 20, 2012, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) submitted a report to the NRC to recommend the medical use of radium-223 to be regulated under 10 CFR Part 35, Subpart E. For NRC consideration, Bayer submitted data, which included responses to questions from the NRC staff.

In addition to the ACMUI report and data supplied by Bayer, the NRC staff reviewed technical information obtained during meetings and other correspondences with Bayer and Algeta representatives. The NRC staff learned that unit dosages of radium-223 will be shipped to clinical trial sites from Algeta's manufacturing facility in Norway. Bayer indicated that in the future multidosage vials may be shipped to the United States for commercial distribution to medical use licensees. The current methods of distribution preclude the need for medical use end users to manipulate radium-223.





Before reaching a licensing decision, the NRC staff also discussed and evaluated issues related to such matters as activity measurements, contamination surveys, long-lived contaminants, radon volatility, patient release criteria, training, available dosimetry information, and administrative procedures.

Based on available information, the NRC staff agreed with the ACMUI recommendation and determined that licensing under 10 CFR Part 35, Subpart E is appropriate because the medical use of radium-223 is similar to other commonly used beta and photon-emitting therapeutic radiopharmaceuticals. The staff also has determined that under current regulations, physicians authorized under 10 CFR 35.390, "Training for Use of Unsealed Byproduct Material for which a Written Directive Is Required," or 10 CFR 35.396, "Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive," can be authorized for the medical use of radium-223.

If the NRC becomes aware of future developments related to the production, distribution, or medical use of radium-223 that may negatively impact radiation safety, then the NRC staff may evaluate the information and provide a revised decision.

(Contact: Ashley Cockerham, FSME, 240-888-7129 or Ashley.Cockerham@nrc.gov)

UPDATE ON REVISIONS TO THE RADIATION PROTECTION REGULATIONS

The NRC staff is continuing the process of engaging stakeholders during the development of the regulatory basis for possible revisions to the NRC's radiation protection regulations contained in 10 CFR Part 20, "Standards for Protection against Radiation," and other parts of the NRC regulations, as appropriate and where scientifically justified, to increase alignment with international recommendations. The Commission is seeking to explore implications of greater alignment with the International Commission on Radiological Protection (ICRP) Publication 103. Given that the NRC regulations provide adequate protection, the discussion has been focused on discerning the benefits and burdens associated with revising the radiation protection regulatory framework.

After engaging a wide range of stakeholders on potential issues associated with changes to the radiation protection regulations in light of the 2007 ICRP recommendations, the NRC staff provided a set of policy and technical recommendations to the Commission on April 25, 2012, SECY-12-0064. In response to those recommendations, the Commission issued the staff requirements memorandum (SRM) on December 17, 2012, in SRM-SECY-12-0064, directing the staff to:

- Develop a regulatory basis for revisions to NRC's radiation protection regulations to align 10 CFR Part 20; 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix I "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents; and other portions of the regulations with the most recent methodology and terminology for dose assessment.
- Revise as low as is reasonably achievable (ALARA) guidance for those licensees that could benefit from more effective implementation.
- Continue discussions with stakeholders regarding possible changes to the dose limit for the lens of the eye.
- Continue discussions with stakeholders regarding possible reduction of the dose limit to the embryo or fetus of a declared pregnant worker to 100 mrem (1mSv).





FROM THE DESK OF THE DIRECTOR

One of the unique things about FSME is that our regulatory program encompasses a broad range of issues and programmatic responsibilities from nuclear material safety and security to the Agreement State program, decommissioning, low-level waste, uranium recovery, rulemaking, Tribal interactions, and many other radioactive materials-related issues. During the 2012-2013 fiscal year, several Commission briefings have or will focus on many of FSME's areas of interest.

FSME kicked off the fiscal year with our business line briefing. What is a business line, you ask? Recently, the NRC has moved from budgeting resources solely by office to a more collaborative business line model in which all budgetary interfaces associated with a specific regulatory area are linked. Under this model, FSME is the lead for two business lines: (1) Nuclear Materials Users and (2) Decommissioning and Low-Level Waste. Last October, FSME, along with our business line partners in the Offices of Nuclear Regulatory Research, Nuclear Security and Incident Response, General Counsel, and the regions, led a Commission briefing that provided a strategic programmatic overview of our two business lines. The overview included the expected priorities, near- and longer-term projections and trends, and emerging focus areas for each business line. We will give this briefing to the Commission on an annual basis.

In December 2012, the Advisory Committee on Reactor Safeguards (ACRS) held its annual Commission briefing. The ACRS commented on two topics that could be of interest to our licensees: (1) the revision of 10 CFR Part 20 for conformance with the 2007 International Commission on Radiological Protection (ICRP) recommendations, and (2) the economic consequences associated with the unintended release of licensed nuclear material to the environment. The ACRS letters on these topics appear in the Agencywide Documents Access and Management System (ADAMS) under Accession Nos. MLI2289A915 and MLI2317A004, respectively.

In January 2013, the Commission held a briefing on public participation in NRC's regulatory decisionmaking. This Commission briefing discussed several topics of interest to FSME's stakeholders, Federal partners, and the Tribal Nations, including the effectiveness of Webstreaming, teleconferencing, and other tools, 10 CFR 2.206, "Requests for Actions under the Subpart," petitions for enforcement action process, the rulemaking petition process, and the NRC's interactions with States and Tribes. Clearly, the Commission wants to actively engage the public and licensees to hear various viewpoints as part of its decisionmaking.

In February 2013, FSME conducted a briefing on uranium recovery, which included a diverse external panel with representatives from the U.S. Environmental Protection Agency, Department of the Interior, U.S. Geological Survey, Wyoming Department of Environmental Quality, Oglala Sioux Tribe, National Mining Association, and Natural Resources Defense Council. In April 2013, the Organization of Agreement States and the Conference of Radiation Control Program Directors will take their seats before the Commission. We also are actively planning the NRC's annual Agency Action Review Meeting; during which NRC senior managers meet to discuss NRC licensee performance and evaluate the process used by the agency to ensure the operational safety performance of licensees.

Although the Commission agenda for the rest of 2013 is not yet finalized, the current draft includes a number of other FSME-related topics. Many of the briefings may include external stakeholders, including licensee representatives. Whether you hold an NRC or Agreement State license, I am certain that one or more Commission meetings have, or will, cover a topic of interest to you. Besides Commission meetings, the FSME staff is very willing to set up public meetings and support courtesy "drop-in" visits when you are in the area. We want to hear from you! If you missed a Commission meeting that is of interest, the transcript and meeting materials (dating back to 1996!) are posted on the NRC public Web site. Until next time...


Mark Satorius, Director



- Continue discussions with stakeholders on alternative approaches to improve individual protection and reduce future exposures to workers at, or near, the current dose limits, to address concerns about the cumulative risk incurred through exposures over multiple years.
- Improve reporting of occupational exposure by the NRC and Agreement State materials licensees and some medical occupations into the NRC Radiation Exposure Information and Reporting System.

The Commission disapproved the following:

- The staff's recommendation to develop a regulatory basis to reduce the occupational total effective dose equivalent limit from 5 rem (50 mSv) per year to 2 rem (20 mSv) per year.
- The elimination of traditional units of exposure from the NRC regulations. Both traditional and international units should be maintained.

As the regulatory basis is developed, the NRC staff will coordinate and conduct extensive discussions with other Federal and State government partners; the regulated community; and the public on the policy issues described above. The NRC staff looks forward to hearing from you during this period of regulatory basis development. The planned completion date for the regulatory basis is December 2015.

More information on the revisions to the NRC's radiation protection regulations and guidance can be accessed at <http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html>.

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

THE NRC'S AGREEMENT STATE PROGRAM VERSUS STATE LIAISON OFFICER PROGRAM

Below are some facts about essential and collaborative NRC programs, the Agreement State (AS) Program and the State Liaison Officer (SLO) Program.

Agreement State Program

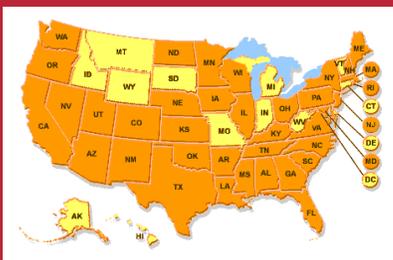
Section 274 of the Atomic Energy Act (AEA) of 1954, as amended, provides for a special Federal-State regulatory framework for the control of byproduct, source and small quantities of special nuclear material.

By signing an agreement with a State, the NRC relinquishes its authority over byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials, as long as the State program is adequate to protect public health and safety and compatible with the NRC's program.

State Liaison Officer Program

Section 274 of the AEA of 1954, as amended, recognized that State governments have an interest in nuclear energy activities and directed the Commission to establish programs for cooperation with the States.

The NRC's responsibility is to license and regulate the nation's civilian use of byproduct, source, and special nuclear material. The NRC's regulatory areas cover reactors, materials, and wastes. The States are responsible for informing and protecting citizens in the event of an emergency.



Agreement State Program

The AS Program was established with the passage of the 1959 amendment to the AEA. On March 26, 1962, the first agreement was signed with Kentucky.

The NRC has entered into agreements with 37 states. Presently, these 37 Agreement States regulate approximately 20,000 radioactive material licensees.

The NRC's Regional State Agreements Officers (RSAOs) were created in each region with materials program responsibilities to serve as the primary contact between the NRC and Agreement States.

Under the AS Program, the NRC provides assistance to those States interested in 274b Agreements, conducts training courses and workshops, evaluates technical licensing and inspection issues from Agreement States, evaluates State rule changes, and provides early and substantive involvement of the States in NRC rulemaking and other regulatory efforts.

FSME's Agreement State Program Branch has the overall responsibility for the AS Program including the management of the Integrated Materials Performance Evaluation Program (IMPEP).

Under Section 274 of the AEA of 1954, as amended, the NRC retains authority for ensuring that AS Program provides adequate protection of public health and safety. As such, the NRC established and implements IMPEP to evaluate the NRC's materials and AS Program and determine its adequacy to protect public health and safety and its compatibility.

For information about the AS Program, please visit: <http://nrc-tp.ornl.gov/rulemaking.html> or contact: Duncan White, Branch Chief, Agreement State Programs Branch, 301-415-2598 or Duncan.White@nrc.gov.

State Liaison Officer Program

In 1976, the SLO Program was established, as a result of recommendations from several State organizations, including the National Governors Association.

Each State Governor appoints an individual to serve as the SLO, and that person functions as the primary communication channel between the State and the NRC. There are 51 SLOs in total, one for each of the States plus the Commonwealth of Puerto Rico.

The NRC's RSAOs are the main points of contact for the SLOs, and they maintain regular communications with their State counterparts.

The SLO Program covers all NRC's program areas of interest to the States. The NRC strives to establish cooperation relationships with the SLOs and keep them appropriately informed and engaged on relevant NRC activities.

FSME's Intergovernmental Liaison Branch has the overall responsibility for the SLO Program and has many resources available to serve the entire agency.

The NRC and the States have complementary responsibilities for protecting public health and safety and the environment. The NRC respects States' interest in nuclear energy activities and views cooperative relationships with States to be essential in accomplishing the agency's mission.

For more information about the SLO Program, please visit: <http://www.nrc.gov/about-nrc/state-tribal/fst-liaison.html> or contact: June Cai, Senior Liaison Project Manager, Intergovernmental Liaison Branch, 301-415-5192 or June.Cai@nrc.gov.



POST-INVESTIGATION ALTERNATIVE DISPUTE RESOLUTION

The NRC's alternative dispute resolution (ADR) program is expanding the scope of post-investigation ADR for a 1-year pilot period. For purposes of discussing this expansion, it is necessary to distinguish between early ADR and post-investigation ADR. In early ADR, a licensee or contractor engages in mediation with its employee; whereas, in post-investigation ADR, the NRC engages in mediation with the subject of a potential enforcement action.

The scope of the current post-investigation ADR program is limited to discrimination and other wrongdoing cases after the NRC's Office of Investigations has completed an investigation that concludes that discrimination or other wrongdoing occurred. The ADR pilot program will expand the scope of post-investigation ADR to include all escalated nonwillful (traditional) enforcement cases with proposed civil penalties. The pilot program will not include violations associated with findings assessed through the Reactor Oversight Program (ROP).

Since its implementation, the staff has evaluated the NRC's use of ADR in its enforcement program and found it to be effective, timely, and generally positively viewed by both internal and external stakeholders. The NRC's use of ADR has resulted in opportunities for improving public safety by including broader and more comprehensive corrective actions in the resultant agreements than might have been achieved through the traditional enforcement process.

A December 16, 2010 tasking memorandum, "ADR Implementation and Assessment" (ADAMS Accession No. MLI2030A228), raised the question of whether to expand the ADR program. In response to this memorandum, the NRC published a *Federal Register* notice (FRN), (76 FR 64124; October 17, 2011), to solicit views on various aspects of the ADR program, including whether it should be expanded. On November 8, 2011, the NRC staff held a public meeting during which both internal and external stakeholders expressed support for the expansion of the ADR program to the extent possible.

In the November 28, 2012, SECY-12-0121, "Status Update, Tasks Related to Alternative Dispute Resolution in the Allegation and Enforcement Programs," the staff informed the Commission of its intent to expand the post-investigation ADR program. The staff offered the expansion as an option for escalated nonwillful (traditional) enforcement cases with proposed civil penalties for a 1-year pilot period. The FRN on the pilot program should be published in March 2013.

(Contact: Maria Schwartz, OE, 301-415-1888 or Maria.Schwartz@nrc.gov)



DECOMMISSIONING WORKSHOP

The FSME Reactor Decommissioning Branch and the International Atomic Energy Agency (IAEA) Decommissioning and Remediation Unit held a Research Reactor Decommissioning Demonstration (R2D2) Project Workshop on December 3-7, 2012 in Buffalo, NY. The R2D2 Project is an ongoing IAEA program to assist developing countries in decommissioning shutdown research reactor facilities. The workshop was entitled “Workshop on Project Management – Decommissioning Dismantling,” and was hosted by the State University of New York at Buffalo (UB) at its Buffalo Materials Research Center (BMRC).

Participants from 10 countries—Argentina, Brazil, Egypt, Indonesia, Libya, Malaysia, the Philippines, Romania, Serbia, and Vietnam—attended the 5-day workshop. The participants were employed by regulatory agencies and reactors in their countries.

The workshop included technical presentations on the U.S. research reactor (RR) decommissioning process, the current status of the UB RR decommissioning, case studies on six U.S. RR decommissioning projects, and IAEA decommissioning standards and activities. Additionally, Mark Roberts, Senior Inspector from NRC Region I, made a presentation on the decommissioning research reactor inspection process.

The week’s activities included practical exercises at the BMRC facility that allowed participants to observe actual decommissioning work, such as the following:

- dismantling and demolishing of a former electronics room
- dismantling of a ventilation rabbit hood
- performing radiological characterization surveys
- removing and dismantling of reactor pool components

The participants provided oral presentations on their observations of the practical activities.

On the subject of project management, participants held a significant discussion on the roles and responsibilities of the regulator, operator or licensee, and the decommissioning contractor. The discussion focused on the responsibility for safety and compliance with requirements, stop work authority, contracting instruments and decommissioning costs and schedules.

Finally, the participants were able to attend and observe a public meeting sponsored by the university to discuss BMRC decommissioning. UB staff members presented the decommissioning plan, NRC and NY State regulatory approval processes, oversight and inspection, the final release of the site for unrestricted use and the license termination process. Their presentation included an overview of the decommissioning activities, demolition and schedule. Participants observed the interactions with the public including an extensive question and answer session.

The R2D2 workshop concluded with very positive feedback from participants and university hosts.

(Contact: Theodore Smith, FSME, 301-415-6727 or Theodore.Smith@nrc.gov)



SIGNIFICANT ENFORCEMENT ACTIONS

The NRC issued significant actions for failure to comply with a regulation.

Department of the Army (EA-12-014)

On April 5, 2012, the NRC issued a Notice of Violation to the Department of the Army (Army), for a Severity Level III violation. The violation involved the Army's failure to provide a radiation monitor that was equipped with personnel access door locks to prevent access to the radiation room of the panoramic irradiator at the Redstone Arsenal facility, when radiation levels were high, as required by 10 CFR 36.23(c), "Access Control." Specifically, from September 24, 1996 to February 17, 2012, the Army's radiation room personnel access door was not integrated with the radiation monitor to prevent the door from opening when radiation levels were high.

Cambridge Isotope Laboratories, Inc., Andover, MA (EA-12-177)

On October 31, 2012, the NRC issued a Severity Level III Notice of Violation (NOV) to Cambridge Isotope Laboratories, Inc. (CIL). The violations involved CIL's failure to adhere to the regulations in 10 CFR 110.20, "General License Information," and 10 CFR 110.24, "General License for the Export of Deuterium." Between 2007 and 2011, CIL did not file an application with the Commission for specific export licenses to export deuterium, a material subject to NRC licensing jurisdiction in accordance with 10 CFR 110.9, "List of Nuclear Material under NRC Export Licensing Authority," when exporting this material in excess of the quantities covered by the general license requirements of 10 CFR 110.24. During this time, CIL exported deuterium in: (1) excess of the 200 kilogram (kg)/year limit set by 10 CFR 110.24(a) to China and Japan in the years 2010 and 2011, and (2) excess of the 5 kg/year limit set by 10 CFR 110.24(b) to restricted destinations per 10 CFR 110.29, "Restricted Destinations," of India and Israel, in the years 2007-2011, without applying for and obtaining NRC specific licenses.

Detector Electronics Corporation, Minneapolis, MN (EA-12-181)

On October 19, 2012, the NRC issued a Notice of Violation to Detector Electronics Corporation for a Severity Level III violation. The violation involved the failure to obtain a specific authorization to export byproduct material to Iraq, an embargoed country, as required by 10 CFR 110.20(a), "General License Information;" 10 CFR 110.23(a), "General License for the Export of Byproduct Material;" 10 CFR 110.5, "Licensing Requirements;" and 10 CFR 110.28, "Embargoed Destinations." Specifically, on April 20, 2007, September 25, 2009, December 21, 2010, and June 24, 2011, the licensee exported flame detectors with electron tubes containing krypton-85 to Iraq, an embargoed destination, and did not have a required specific authorization to export byproduct material to Iraq.

Information about the NRC's enforcement program can be accessed at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>. Documents related to cases can be accessed through ADAMS at <http://www.nrc.gov/reading-rm/adams.html>. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

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



SELECTED FEDERAL REGISTER NOTICES

January 8, 2013

78 FR 1155, Low-Level Waste Disposal, (Proposed Rule - Regulatory basis and preliminary rule language; second request for comment; correction)

Contact: Andrew Carrera, FSME, 301-415-1078 or Andrew.Carrera@nrc.gov

TO OUR READERS

In our attempt to keep the FSME Licensee Newsletter relevant, we welcome feedback on the contents of the newsletter. If you would like to suggest topics, please contact Vanessa Cox, of the FSME Rulemaking and Project Management Branch by phone at 301-415-8342 or by e-mail at Vanessa.Cox@nrc.gov. In addition, to ensure proper delivery of the FSME Licensee Newsletter and to prevent any interruption of service, please report any e-mail address changes to Ms. Cox at FSME_Newsletter@nrc.gov.

Please send written correspondence to the following address:

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

The NRC Wants To Hear From You!

*Tribal Protocol Manual
Tribal Consultation
Policy Statement*

The U.S. Nuclear Regulatory Commission is looking for comments and suggestions as we develop a Tribal Consultation Policy Statement and a Tribal Protocol Manual. We have asked Tribal governments and organizations, members of the public, and other interested parties to comment.

Details can be found online at:
<http://www.nrc.gov/about-nrc/state-tribal/tpm.html>
or
www.regulations.gov
(search for Docket ID NRC-2012-0235)

The NRC licenses and regulates the nation's civilian use of nuclear materials. Our goals are to ensure the adequate protection of public health and safety, promote the common defense and security, and protect the environment. Additional information about the NRC can be found at www.nrc.gov.

If you have any questions or need additional assistance, please call 301-415-2326