

INTER-AGENCY TASK FORCE REPORT



On August 11, 2010, the NRC submitted the Radiation Source Protection and Security Task Force (Task Force) quadrennial report to President Barack Obama and Congress. The report outlines the federal government's efforts over the past 4 years to enhance the security of radioactive sources.

The Task Force was established under the Energy Policy Act of 2005, with the NRC as the lead agency, to evaluate and provide recommendations on the security of radiation sources in the United States from potential criminal or terrorist threats, including acts of sabotage, theft or use in a radiological dispersal device. The Task Force consists of representatives from 14 federal agencies and 2 state organizations.

The legislation mandated that the Task Force provide a report to the President and Congress in 2006 and every 4 years thereafter. The first report in 2006 described efforts to strengthen regulatory controls and made several recommendations to enhance the overall security of risk-significant radioactive materials.

In the 4 years since the first report, the Task Force met routinely to discuss progress and evaluate the protection and security of risk-significant radioactive materials. The 2010 report presents the status of the recommendations and actions from the 2006 report as well as new recommendations in the following areas:

- coordination and communication improvements among government agencies and the public

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- advances in the security and controls of radioactive sources
- recovery and disposition of unused radioactive sources, and
- alternative technologies that could perform all or some of the functions of radiation sources.

The Task Force will continue to meet to implement and monitor the progress of efforts to improve the security of radioactive sources and identify any gaps that may arise.

Additional information on the Task Force, including the 2010 and 2006 reports, is available on the NRC Web site at <http://www.nrc.gov/security/byproduct/task-force.html>.

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SAFETY AND SECURITY CULTURE

On September 17, 2010, the NRC published a revised draft safety culture policy statement in the Federal Register (75 FR 57081; <http://edocket.access.gpo.gov/2010/pdf/2010-23249.pdf>). The draft policy statement sets forth the Commission's expectation that all licensees and certificate holders establish and maintain a work environment where management and employees are dedicated to putting safety first. The comment period for the revised draft policy statement closed on October 18, 2010.

The draft policy statement expands the Commission's current policy on safety culture and provides the Commission's expectations for individuals and organizations that perform or manage regulated activities. The NRC is seeking to develop safety-culture-related terminology that could be used by the NRC, Agreement States, licensees, certificate holders, and others involved with the use of byproduct material.

On February 2, 2010, the NRC held a 2-day public workshop to develop the safety culture terminology. At the workshop, a panel consisting of a wide range of materials users, nuclear power reactor licensees, and non-licensees—with contributions

from other meeting attendees—developed a definition of safety culture and a set of safety culture traits (high-level descriptions of areas important to safety culture). The revised draft policy statement published for comment in September 2010 included a definition of safety culture (i.e., **Nuclear safety culture** is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment) and a set of safety culture traits—Leadership Safety Values and Actions, Problem Identification and Resolution, Personal Accountability, Work Processes, Continuous Learning, Environment for Raising Concerns, Effective Safety Communication, and Respectful Work Environment. The descriptions of the traits were modified from the wording developed during the February workshop; however, the modifications made were minor and not substantive in nature.

The revised draft policy statement, safety culture terminology, and next steps were discussed at a public meeting on September 28, 2010. During the public meeting, the attendees had some discussion regarding whether complacency and a questioning attitude should be added to the set of safety culture traits. Information on safety culture, NRC activities relating to safety culture, and workshops can be found at the NRC's safety culture Web site: <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

(Contact: James Firth, FSME, 301-415-6628 or e-mail: James.Firth@nrc.gov)

EXPORTS TO CUBA, IRAN, IRAQ, NORTH KOREA, SYRIA AND SUDAN

NRC permits the export of NRC-controlled commodities through either a "general license" or a "specific license". The NRC regulations authorizing general licenses are found at 10 CFR §§110.21 through 110.26. An NRC general license cannot be used to export NRC-controlled commodities to an embargoed destination (Cuba, Iran, Iraq, North Korea, Syria or Sudan) which are found at NRC regulation 10 CFR §110.28. Shipments to a distributor or to a "middle man" in a non-embargoed destination do not relieve the exporter of the requirement to obtain a specific license for NRC-controlled commodities being exported to end users in embargoed destinations. Exporters must determine who the consignee or end user is for exports of any NRC-controlled commodities. If the consignee or end user is in an embargoed destination, then the NRC regulations require the exporter to apply for and obtain a specific NRC license authorizing the export of a specific commodity to a named ultimate consignee for a particular end use in the embargoed destination.

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FROM THE DESK OF THE FSME DIRECTOR



Since FSME was formed in October 2006, I have had the distinct honor of serving as its only Director. This position and newsletter column give me a forum to announce important office developments. I hope you have found them informative. In this issue, I would like to highlight some of our major achievements from fiscal year 2010.

Starting with nuclear byproduct materials, I am especially proud of our office leadership on the NRC's submission of the 2010 Radiation Source Protection and Security Task Force report. This effort, which is discussed in more detail in a separate article in this newsletter, resulted in several important security and control enhancements for radioactive sources. The report required extensive internal and external Federal and State coordination.

We spent much of 2010 working with States to roll out a new generation of our License Tracking System (LTS). This laid the foundation for a new Web-Based Licensing System (WBL). A new contract, which we call the Integrated Source Management Portfolio, will allow us to integrate LTS Version 2, WBL, and the License Verification System.

With State and regional assistance, FSME completed an assessment of the Integrated Materials Performance Evaluation Program (IMPEP). IMPEP is a 15 year old program which evaluates the technical adequacy and consistency of NRC and Agreement State materials programs. Soon you should see some IMPEP enhancements and expansions based on that assessment.

Our Waste Management and Environmental Protection Division issued a license to Uranium One Americas, Inc. to construct and operate its Moore Ranch in situ recovery facility in Wyoming- the first such new license issued to a uranium recovery applicant in many years. Meanwhile, the Division continued to review other uranium recovery submissions. By engaging successfully with other State and Federal agencies, the Division also concurred on the West Valley New York Environmental Impact Statement and its Phase I Decommissioning Plan.

Our Rulemaking Division spent the year engaging with stakeholders and participating in collaborative working groups. Numerous important rulemakings were proposed or finalized that will lead to regulatory changes affecting medical users, general licenses, distributors of source material, and spent fuel licensees and vendors. Additionally, I was able to meet with many of you who are State regulators and licensees in a Part 37 (materials security) workshop in Austin, TX. This workshop, and a second one held in Rockville, MD, was well-attended. Both workshops' participants provided us with excellent feedback that will allow us to formulate a more informed proposed rule to the Commission in 2011. That same division also published a brochure highlighting the importance of NRC interactions with Native American stakeholders, and hosted a program, to draw more attention to the tribal liaison program.

In 2010, as part of the President's Open Government initiative, all Federal agencies opened more portals to the public. In FSME, we published several new data sets that will allow interested individuals to be better informed about our materials licensing, uranium recovery, and decommissioning activities. These data sets will be routinely updated.

Now, we transition into 2011. As always, FSME remains committed to seek and maintain strong partnerships with program stakeholders under a common goal of ensuring safety, security, and protection of the environment.

Charles L. Miller

Charles L. Miller, Director



SIGNIFICANT ENFORCEMENT ACTIONS

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

National Institute of Standards and Technology

(EA-09-142)

On March 1, 2010, the NRC issued an Immediately Effective Confirmatory Order to the U.S. Department of Commerce's National Institute of Standards and Technology (NIST or licensee) to confirm commitments made as a result of an Alternate Dispute Resolution mediation session held on January 5, 2010. This enforcement action is based on 10 apparent violations of NRC requirements at NIST's facility in Boulder, Colorado, which were identified during NRC inspection and investigation activities conducted in response to a June 9, 2008, plutonium spill. The apparent violations involved the licensee's failure to conduct the radiation safety program at NIST-Boulder in accordance with NRC requirements and the conditions of the NIST-Boulder license. The licensee agreed to take the following actions: (1) complete an independent assessment of the radiation safety program at NIST-Boulder; (2) submit copies of the required annual radiation safety audit to the NRC; (3) develop and implement a procedure for training new employees on radiation safety policies and procedures; (4) upgrade initial and refresher training for employees

who work with radioactive materials, including a review of lessons learned from the plutonium spill and the associated apparent violations; (5) submit a license amendment request for deletion of the radionuclides on the NIST-Boulder license that NIST no longer plans to use; (6) develop a formal radiation hazards analysis process; (7) revise the NIST Ionizing Radiation Safety Committee charter to require additional review of NRC submittals; (8) revise the NIST radiation safety program policy to indicate that all individuals interacting with the NRC are required to provide complete and accurate information; (9) develop a clearly defined process for acquiring radioactive materials; and (10) pay a civil penalty of \$10,000. In consideration of these commitments, and other actions already completed by NIST, the NRC agreed not to pursue any additional enforcement actions for the apparent violations or count this matter as previous enforcement for the purposes of assessing potential future enforcement actions in accordance with Section VI.C. of the Enforcement Policy.

Gamma Knife Center of the Pacific

(EA-09-289)

On February 23, 2010, the NRC issued a Notice of Violation for a Severity Level III violation to Gamma Knife Center of the Pacific for a failure to implement 10 CFR 35.41(b). Specifically, as of July 2, 2009, the licensee failed to develop, implement, and

maintain written procedures to provide high confidence that each medical administration is in accordance with the written directive. The procedures did not require explicit verification that the administration was in accordance with the treatment plan and written directive. Consequently, the treatment plan and written directive were not followed to ensure that the collimator was used in the treatment of a patient.

Kanawha Scales & Systems, Inc.

(EA-09-312)

On February 18, 2010, the NRC



issued a Notice of Violation to Kanawha Scales & Systems, Inc.,

a licensee of the State of Ohio, for a Severity Level III violation involving 10 CFR 150.20. Specifically, on November 2, 2009, Kanawha Scales & Systems, Inc. used sealed sources in a non-agreement state without filing an NRC Form 241 at least 3 days prior to engaging in licensed activities in areas of exclusive Federal jurisdiction.

Beta Gamma Nuclear Radiology, Inc.

(EA-09-147)

On January 21, 2010, the NRC issued a Notice of Violation (NOV) and Immediately Effective Confirmatory Order to Beta Gamma Nuclear Radiology, Inc. (BGNR) to confirm commitments made as a result of an Alternative Dispute Resolution (ADR) mediation session held on October 27, 2009. This enforcement action is based on a violation of 10 CFR 30.9 which requires, in part, that information

provided to the Commission by a licensee, or information required by the Commission's regulations to be maintained by the licensee shall be complete and accurate in all material respects. Contrary to this requirement, in a May 5, 2008 response contesting a Severity Level IV Notice of Violation, BGNR maintained, and provided to the NRC, information that was not complete and accurate in all material respects. Specifically, the BGNR response stated that three written directives, administered on September 14, 2005, and February 19 and 26, 2008, were written prior to the administrations, when in fact, the written directives were signed and dated after the administrations. The written directives were required to be maintained by 10 CFR 35.40(a), and were therefore, material to the NRC. BGNR agreed to: (1) perform quarterly comprehensive radiation safety audits and (2) authorize a new radiation safety officer for a 2 year period. In recognition of these commitments, the NRC agreed to issue to BGNR a civil penalty in the amount of \$5,000 and also issue an NOV for a Severity Level III violation of 10 CFR 30.9.



Nanticoke Memorial Hospital
(EA-09-335)

On February 2, 2010, the NRC issued a Notice of Violation to Nanticoke Memorial Hospital for a Severity Level III violation involving

the failure to notify the NRC Operations Center by telephone no later than the next calendar day after discovery of the medical event as required by 10 CFR 35.3045(c). Specifically, Nanticoke Memorial Hospital became aware that a medical event had occurred on June 26, 2009, but the NRC was not notified until July 15, 2009.

Great Falls Clinic
(EA-09-290)

On January 21, 2010, the NRC issued a Notice of Violation to Great Falls Clinic for Severity Level III violations associated with the failure to: (1) secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas, in violation of 10 CFR 20.1801 and (2) secure the unit, console, console keys and the treatment room when not in use or unattended, in violation of 10 CFR 35.610 (a)(1). Specifically, the licensee stored a high dose-rate remote afterloader unit in a designated controlled area and did not secure the radioactive material from unauthorized removal or access. The console and unit were found in the unattended, and unsecured, designated controlled area. The console was found with its key inserted.

CJW Medical Center - Johnston-Willis Campus
(EA-09-040)

On January 21, 2010, the NRC issued a Notice of Violation to CJW Medical Center - Johnston-Willis Campus for a Severity Level III violation of 10 CFR 35.41(a)(2) involving the failure

to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with written directives. Specifically, as of December 16, 2008, the licensee's procedures did not require verification of the treatment site nor resolution of any inconsistencies in the written directive prior to administration of the dose. This resulted in a patient receiving treatment to the left trigeminal nerve instead of to the originally-intended site (right trigeminal nerve).

Allegiance Health
(EA-09-266)

On January 6, 2010, the NRC issued a Notice of Violation to Allegiance Health for a Severity Level III violation involving the failure to develop written procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41. Specifically, on April 16, 2009, the licensee's procedures did not contain any steps to ensure that no changes had occurred in the patient's prostate volume between the time the treatment plan was prepared and the administration of the treatment. No other method was provided to ensure that the administration was in accordance with the written directive.





INDIVIDUAL ACTION

Dr. Juan E. Perez Monté

(IA-09-041)

On January 21, 2010, the NRC issued a Notice of Violation (NOV) and Immediately Effective Confirmatory Order to Dr. Perez Monté, former Radiation Safety Officer for Beta Gamma Nuclear Radiology, Inc., (BGNR) to confirm commitments made as a result of an Alternative Dispute Resolution (ADR) mediation session held on October 27, 2009. This enforcement action is based on an apparent deliberate violation of 10 CFR 30.10, which requires, in part, that an employee of a licensee may not deliberately submit to the NRC information that the employee knows to be incomplete or inaccurate in some respect material to the NRC. Contrary to this requirement, Dr. Perez Monté submitted information known to be inaccurate in some respect material to the NRC, in violation of 10 CFR 30.10(a)(2); and as a result, caused BGNR to maintain inaccurate information contrary to 10 CFR 30.9, in violation of 10 CFR 30.10(a)(1). Dr. Perez Monté agreed to: (1) not serve as radiation safety officer (RSO) at BGNR or other licensed facilities for at least two years and (2) provide outreach to the nuclear medicine community to help deter others from violating NRC regulations. In recognition of these commitments, the NRC agreed to not issue Dr. Perez-Monté an Order prohibiting involvement in NRC-licensed

activities other than the 2 year restriction on serving as RSO, and also issued him an NOV containing a Severity Level III violation of 10 CFR 30.10.

The NRC's enforcement program can be accessed at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html> under Recently Issued Significant Enforcement Actions. Documents related to cases can be accessed through the NRC's Agency wide Document Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209 or by sending an e-mail to PDR.Resource@nrc.gov.

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GENERIC COMMUNICATIONS ISSUED

The following are summaries of NRC generic communications issued by FSME. If any of these documents appears relevant to your needs and you have not received it, please call one of the technical contacts listed below. The Internet address for the NRC library of generic communications is <http://www.nrc.gov/reading-rm/doc-collections/gen-comm>.



Regulatory Issue Summary

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

The NRC issued RIS 2010-09, "Radiation Safety Officers for Medical Use Licenses under 10 CFR PART 35" on September 9, 2010. The NRC issued this RIS to all NRC medical-use licensees, NRC master material licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers.

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





SELECTED FEDERAL REGISTER NOTICES

Governor's Designees Receiving Advance Notification of Transportation of Nuclear Waste, 75 FR 38151, July 1, 2010

(Contact: Dr. Stephen N. Salomon, FSME, 301-415-2368 or e-mail: Stephen.Salomon@nrc.gov)

Implementation Guidance for Physical Protection of Byproduct Material; Category 1 and 2 Quantities of Radioactive Material, 75 FR 40756, July 14, 2010 (Draft Guidance of Comments)

(Contact: Paul Goldberg, FSME, 301-415-7842 or e-mail: Paul.Goldberg@nrc.gov)

Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions 75 FR 43425, July 26, 2010 (Proposed Rule for Comments)

(Contacts: Gary Comfort, FSME, 301-415-8106 or e-mail: Gary.Comfort@nrc.gov) or Catherine Mattsen, FSME, 301-415-6264 or e-mail: Catherine.Mattsen@nrc.gov)

Licenses, Certifications, and Approvals for Material Licensees, 75 FR 43865, July 27, 2010

(Contact: Ms. Tracey Stokes, OGC, 301-415-1064 or e-mail: Tracey.Stokes@nrc.gov)

Implementation Guidance for Physical Protection of Byproduct Material; Category 1 and Category 2 Quantities of Radioactive Material; Meeting, 75 FR 47494 August 6, 2010 (Notice of Meeting)

(Contacts: Merri Horn, FSME, 301-415-8126 or e-mail: Merri.Horn@nrc.gov) or Paul Goldberg, FSME, 301-415-7842 or e-mail: Paul.Goldberg@nrc.gov)

Notice of Issuance and Availability of Draft Regulatory Guide, DG-1228, "Standard Format and Content of License Termination Plans for Nuclear Power Reactors," 75 FR 48382, August 10, 2010 (Draft Regulatory Guide)

(Contacts: James C. Shepherd, FSME, 301-415-6712 or e-mail: James.Shepherd@nrc.gov)

Revised Draft Safety Culture Policy Statement: Request for Comments 75 FR 57081, September 17, 2010

(Contacts: Maria E. Schwartz, OE, 301-415-1888 or e-mail: Maria.Schwartz@nrc.gov) or Catherine Thompson, OE, 301-415-3409 or e-mail: Catherine.Thompson@nrc.gov)

Radiation Protection Regulations and Guidance; Public Meetings and Request for Comments, 75 FR 59160, September 27, 2010

(Contacts: Kimyata Morgan Butler, FSME, 301-415-0733 or e-mail: Kimyata.MorganButler@nrc.gov) or Dr. Donald Cool, FSME, 301-415-6347 or e-mail: Donald.Cool@nrc.gov)

Notice of Public Meeting to Solicit Comments on the Draft Policy Statement on the Protection of

Cesium-137 Chloride Sources, 75 FR 60149, September 29, 2010

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

Licenses, Certifications, and Approvals for Material Licensees; Reopening of Comment Period, 75 FR 60341, September 30, 2010 (Proposed Rule)

(Contact: Ms. Tracey Stokes, OGC, 301-415-1064 or e-mail: Tracey.Stokes@nrc.gov)

Physical Protection of Byproduct Material; Extension of Comment Period, 75 FR 62330, October 8, 2010 (Proposed Rule)

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

Implementation Guidance for Physical Protection of Byproduct Material Category 1 and Category 2 Quantities of Radioactive Material; Draft Guidance Document for Comment; Extension of comment period, 75 FR 62694, October 13, 2010 (Proposed Rule)

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

Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions; Extension of Comment Period, 75 FR 70618, November 18, 2010 (Proposed Rule)

(Contact: Gary Comfort, FSME, 301-415-8106 or e-mail: Gary.Comfort@nrc.gov)

TO OUR READERS



In our attempt to keep the FSME Licensee Newsletter relevant, we welcome useful and informative feedback on the contents of the newsletter. If you would like to suggest topics, please contact Vanessa Cox or Gwendolyn Davis, from FSME Rulemaking Branch A. Ms. Cox may be contacted at 301-415-8342 or Vanessa.Cox@nrc.gov. Ms. Davis may be contacted at 301-415-8165 or Gwendolyn.Davis@nrc.gov. In addition, to ensure proper delivery of the FSME Licensee Newsletter, please report any address changes to Ms. Cox to prevent any interruption of service at FSME_Newsletter@nrc.gov.

Please send written correspondence to the following address:



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