



## **NRC BACKGROUND INFORMATION**

### **CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS ANNUAL MEETING**

**May 2011**

Background: This “Background Information Document” has been prepared for the NRC Federal Liaison Report to the Executive Board of the Conference of Radiation Control Program Directors, Inc., during the May 2011 Annual Meeting. It is not intended to be inclusive, but is intended to provide status and background information on a number of key areas of possible interest.

## Table of Contents

NRC ACTIONS IN RESPONSE TO JAPAN NUCLEAR EVENT .....	4
PART 37 SECURITY RULEMAKING .....	4
PART 35 MEDICAL USE OF BYPRODUCT MATERIAL- MEDICAL EVENT DEFINITION RULEMAKING .....	5
CHAIRMAN'S TASK FORCE ON SOURCE SECURITY AND PROTECTION .....	5
URANIUM CONVERSION/DECONVERSION.....	7
INTERNATIONAL ISOTOPES, INC. APPLICATION FOR A DEPLETED URANIUM DECONVERSION FACILITY .....	8
AGREEMENT STATE TRAINING.....	8
INSPECTION MANUAL CHAPTER (IMC) 1246.....	9
NUREG-1556 UPDATE PROJECT.....	9
PART 40 SMALL QUANTITIES OF SOURCE MATERIAL.....	10
GROUNDWATER PROTECTION AT IN SITU LEACH URANIUM RECOVERY FACILITIES .	10
INTERAGENCY JURISDICTIONAL WORKING GROUP .....	11
INSPECTION MANUAL CHAPTER (IMC) 2800.....	11
SECURITY AND USE OF CS-137 CHLORIDE SOURCES .....	11
NATIONAL SOURCE TRACKING SYSTEM.....	12
MEDICAL ISOTOPE PRODUCTION .....	14
SAFETY CULTURE POLICY STATEMENT.....	15
INTEGRATED SOURCE MANAGEMENT PORTFOLIO (ISMP).....	16
WEB-BASED LICENSING .....	17
PATIENT RELEASE .....	18
PARTS 30, 31, 32, 40, AND 70 DISTRIBUTION OF BYPRODUCT MATERIAL .....	19

PART 31.5 GENERAL LICENSED DEVICES .....	19
REVISION OF NRC POLICY STATEMENT OF PRINCIPLES AND POLICY FOR AGREEMENT STATE PROGRAM AND POLICY STATEMENT ON ADEQUACY AND COMPATIBILITY OF AGREEMENT STATES PROGRAMS .....	19
BLENDING OF LOW-LEVEL RADIOACTIVE WASTE .....	20
REVISIONS TO 10 CFR PART 61 .....	22

## **NRC ACTIONS IN RESPONSE TO JAPAN NUCLEAR EVENT**

The NRC is launching a two-pronged review of U.S. nuclear power plant safety in the aftermath of the March 11, 2011, earthquake and tsunami in Japan and the resulting crisis at the Japanese Fukushima Dai-Ichi nuclear power plant. This review may involve other Federal departments and agencies. NRC is creating an agency task force, made up of current senior managers and former NRC experts with relevant experience, to conduct both short- and long-term analysis of the lessons that can be learned from the situation in Japan, and the results of their work will be made public. The NRC will examine all available information from Japan, to see if there are changes that should be made to programs and regulations to ensure continued protection of public health and safety.

The task force's short-term effort will be supported by NRC resident inspectors at each U.S. nuclear power plant and agency's regional and headquarters offices, as necessary. This effort will help determine if any additional NRC responses, such as Orders requiring immediate action by U.S. plants, are called for, prior to completing an in-depth investigation of the information from events in Japan.

The task force's longer-term review will inform any permanent NRC regulation changes determined to be necessary. A report with recommended actions will be provided to the Commission within six months of the start of that effort. The Commission plans to hold monthly public meetings on the status of the NRC response to the Japan earthquake and will post the meeting schedule in the NRC's public webpage.

## **PART 37 SECURITY RULEMAKING**

The staff is working on a rulemaking to create a new Part 37 that will contain the security requirements for Category 1 and Category 2 quantities of radioactive material. The objective of the rulemaking is to ensure that effective security measures are in place for the protection of Category 1 and Category 2 quantities of radioactive material against the possibility of the dispersion of radioactive material for malevolent purposes. The proposed rule contained requirements for background investigations and access control to ensure that individuals that have access to these materials have gone through background investigations and are considered to be trustworthy and reliable. The proposed rule contained new requirements to establish physical protection systems to detect, assess, and respond to unauthorized access to Category 1 and Category 2 quantities of radioactive material. The proposed rule also contained new requirements related to transportation security that included recipient license verification; coordination of shipment information; advance notification of shipments; notification of shipment delays, schedule changes and suspected loss; continuous and active shipment position monitoring; two-way and redundant telecommunication; secondary drivers for certain shipments; contingency procedures; and safeguarding shipment information.

The rulemaking considered the requirements contained in the various orders, lessons-learned during implementation, petition for rulemaking 71-13 filed by the State of Washington, as well as other factors. The proposed rule was noticed in the *Federal Register* on June 15, 2010. The public comment period closed on January 18, 2011. The NRC received 110 comment letters on the proposed rule. Major areas of concern were the fingerprinting and approval of the reviewing official, background investigation elements, and local law enforcement notification for work at temporary jobsites. Commenter's also raised the issue of too much burden and a preference to

only include the requirements from the orders. The staff is analyzing and preparing responses to the comments. The final rule is due to the Commission in December 2011. Guidance associated with this rulemaking was noticed for public comment on July 14, 2010. The public comment period ended on January 18, 2011.

CRCPD submitted comments on the Part 37 proposed rule on November 23, 2010. The Agencywide Document Access and Management System (ADAMS) accession number for the comment letter is ML103280512. The Organization of Agreement States (OAS) provided comments on July 8, 2010. The ADAMS accession number for the OAS comments is ML102150291.

### **PART 35 MEDICAL USE OF BYPRODUCT MATERIAL- MEDICAL EVENT DEFINITION RULEMAKING**

This rulemaking would modify 10 CFR 35.40 and 35.3045 to establish separate medical events criteria and written directive requirements for permanent implant brachytherapy. The proposed rule was published on August 6, 2008, and the public comment period closed on November 7, 2008. Staff submitted a revised proposed rule to the Commission in June 2010, with significant changes. In July 2010, the Commission voted not to publish the re-proposed rule and directed the staff to hold a series of stakeholder workshops to discuss issues associated with the medical event definition.

NRC plans to hold a series of public workshops to obtain stakeholder comments on issues associated with the Medical Event (ME) definition, including sections involving reporting and notifications of MEs for permanent implant brachytherapy and other medical issues that are currently being considered for rulemaking. The first workshop will be held on June 20-21, 2011, in New York, NY. The NRC also plans to hold a second public workshop in August 2011 in Houston, TX.

### **CHAIRMAN'S TASK FORCE ON SOURCE SECURITY AND PROTECTION**

Section 170H.f. of the Atomic Energy Act, added by section 651(d) by the Energy Policy Act (EPA) of 2005 (Pub. L. 109B58), requires the establishment of an inter-agency task force on radiation source protection and security. The Task Force was established to evaluate and provide recommendations relating to the security of radiation sources in the United States from potential criminal or terrorist threats, including acts of sabotage, theft, or use of a radiation source in a radiological dispersal device. The Task Force is comprised of representatives of the NRC, Department of Homeland Security, Department of Defense, Department of Energy, Department of Transportation, Department of Justice, Department of State, Director of National Intelligence, Central Intelligence Agency, Federal Emergency Management Agency (FEMA), Federal Bureau of Investigation, Environmental Protection Agency, Office of Science and Technology Policy, and Health and Human Services/Food and Drug Administration. The Task Force is chaired by NRC. An OAS/CRCPD representative is also participating in the Task Force meetings as a non-voting member.

EPA requires the Task Force to evaluate and make recommendations for possible regulatory and legislative changes on several specific topics related to the protection and security of sources. For the purposes of the Task Force, EPA defines a radiation source as a Category 1 Source or a Category 2 Source as defined in the International Atomic Energy Agency (IAEA)

Code of Conduct on the Safety and Security of Radioactive Sources (Code) and any other material that the Commission, by regulation, defines as a radiation source for the purposes of Section 170H. Spent nuclear fuel and special nuclear materials (plutonium and uranium isotopes) are excluded from this definition. The Task Force is required to submit its report to Congress and the President.

By letters dated August 15, 2006, NRC submitted the first Radiation Source Protection and Security Task Force Report to the President and Congress, which contains 10 recommendations and 18 actions that address security and control of radioactive sources.

Following the issuance of the first report and in an effort to continue the cooperation and coordination between Federal and State partners, the Task Force continued to meet periodically to discuss topics of interest, receive updates on activities being conducted by the various agencies, and obtain status reports on the implementation of the recommendations and the actions provided in the first report. In addition, the Task Force conducted a number of assessments to address recommendations and actions outlined in the first report, including five studies in the areas of public education, alternative technologies, financial assurance for disused sources, evaluating the feasibility of phasing out cesium chloride (CsCl), and reevaluating the radionuclides and threshold levels warranting enhanced protection. These analyses and results from various applicable initiatives are the basis for 11 new recommendations-proposed in the quadrennial report submitted to the President and Congress on August 11, 2010.

The public education analysis was completed with the creation of an action plan for a coordinated public education campaign to reduce fears of radioactivity, diminish the impact of a radiological attack if one were to occur, and provide a deterrent to attackers considering the use of radiological materials. Ten recommendations were formulated and seven projects were identified to carry out the public education program. Beyond the established seven projects, the Task Force recognized that since the 2007 timeframe, Federal and State agencies have made progress on other initiatives that support public education outreach, but are not directly related to the plan. As an outcome of coordination efforts between the Task Force and the FEMA National Preparedness Directorate, it was agreed that the public education outreach initiatives be transferred from the Task Force to FEMA since it has been identified as the lead for the U.S. Government in public communication issues related to radiation and other hazards.

The study to assess the feasibility of phasing out the use of CsCl in a highly dispersible form was completed. This study was to consider the availability of alternative technologies for the scope of current uses, safe and secure disposal of existing material, and international safety and security implications. The assessment identifies that a step-wise phase-out could be feasible, but certain challenges would have to be overcome. Sufficient time would be necessary for replacement technologies to be established, including the implementation of incentives for the replacement with alternatives, and issues related to disposal pathways would need to be resolved. Also, the assessment addresses that a rulemaking or other regulatory process should be initiated at the appropriate time to include stakeholder input to eliminate further licensing of CsCl sources and ban its export. Lastly, the assessment supports the short-term and long-term research and development for alternative technologies.

An evaluation was also conducted to reevaluate the list of radioactive sources that warrant enhanced security and protection to assess their adequacy in light of the evolving threat environment. In the evaluation process, definitions for a significant Radiological Dispersal Device (RDD) and Radiation Exposure Device (RED) were agreed upon by the inter-agency

task force. Also, 16 radionuclides from the IAEA Code are identified as remaining as the radionuclides that warrant enhanced security and protection. Additionally, a limited number of other radionuclides are identified that should be considered for enhanced control in limited situations when aggregated or in bulk quantities. There are a very small number of major radionuclide producers and distributors worldwide that may possess such sources/quantities. The IAEA Category 2 and above radionuclides and associated quantities are validated based on economic, physical, psychological, and social disruption consequences, as well as radiological health effects.

An evaluation was also performed considering the financial incentives, research needs for both alternative technologies and alternative designs, and cost-benefit of potential alternatives for certain Category 1 and 2 radioactive sources. Lastly, an evaluation of financial assurance required for radioactive sources was conducted to ensure that enough funding is available for the disposition of the sources. This evaluation includes assessing the storage of risk-significant sources for longer than 24 months and establishing a maximum time limit for long term storage. The final conclusions from these assessments, as well as the conclusions drawn from the assessments discussed above, were included in the 2010 Task Force report and provided the basis for many of the new recommendations.

Currently, the Task Force is discussing the implementation plans for the open and new recommendations and actions from both the 2006 and 2010 Task Force reports.

## **URANIUM CONVERSION/DECONVERSION**

In SRM-M070308B dated March 22, 2007, pertaining to the Nuclear Materials Safety and Safeguards program briefing to the Commission on February 22, 2007, the Commission provided direction to the staff that NRC will regulate future major fuel cycle facilities licensed under 10 CFR Part 40, e.g., uranium conversion and deconversion facilities. The Commission also directed NRC staff to propose options for rulemaking that would require these facilities to complete an Integrated Safety Analysis (ISA) similar to the current Part 70 Subpart H requirements for special nuclear material.

The draft Part 40 rulemaking incorporates ISA requirements, similar to Part 70 Subpart H, for source material licensees who possess 2000 kilograms (kg) or more of uranium hexafluoride (UF<sub>6</sub>). In addition to the ISA requirements, the draft rule would require facilities to be licensed by the NRC and to submit an emergency plan if there is a potential for offsite hazardous chemical exposures. The draft rule package was submitted to SECY on February 12, 2010. The Commission sent the paper back to the staff for revision before they consider approving the proposed rule. The staff sent a letter to the Agreement States (FSME-10-049) dated June 21, 2010, requesting source material licenses that could authorize the possession of UF<sub>6</sub> in quantities greater than 2,000 kg. The additional information was included in a revised paper sent to the Commission. The Commission has approved publication of the draft rule and it should be published this summer. The final rule is scheduled to be completed by the end of 2012.

## **INTERNATIONAL ISOTOPES, INC. APPLICATION FOR A DEPLETED URANIUM DECONVERSION FACILITY**

On December 30, 2009, International Isotopes Inc., (INIS) submitted its application for a depleted uranium deconversion facility near Hobbs, NM. The proposed facility will process 7.2 million pounds per year (lbs/yr) of depleted uranium hexafluoride (DUF<sub>6</sub>) (300 cylinders) from commercial enrichment facilities and deconvert the material into commercially resellable fluorine products and chemically stable depleted uranium oxides for disposal. The applicant has indicated they plan to submit a second phase of construction for licensing in the 2016 timeframe. The combined operations would eventually be capable of processing 21.7 million lbs/yr of DUF<sub>6</sub> (900 cylinders), approximately 25% of the projected DUF<sub>6</sub> produced in the US annually.

INIS is in contract discussions with the commercial enrichment facilities for obtaining DUF<sub>6</sub>. In addition, INIS has indicated they will dispose of the depleted uranium oxides at a commercial disposal facility. Two facilities are under consideration to receive the waste, Energy Solutions in Clive, Utah or Waste Control Specialists (WCS) in Andrews, Texas. There are currently no contracts in place for disposal of INIS waste at either facility.

The INIS deconversion facility will be licensed under Part 40. Although Part 40 does not contain ISA requirements, the Commission directed the staff in SRM SECY-07-0146 to require new conversion/deconversion facilities which have significant quantities of UF<sub>6</sub> to comply with 10 CFR 70, Subpart H, ISA requirements. INIS has submitted an ISA Summary consistent with the Commission's direction.

The INIS deconversion facility will be the first major commercial deconversion facility licensed by the NRC to convert DUF<sub>6</sub> to a uranium oxide. The Department of Energy is also developing two depleted uranium deconversion facilities near the gaseous diffusion plants to disposition their 700,000 tons of DUF<sub>6</sub>.

The NRC conducted a pre-licensing public outreach meeting in Hobbs, NM to inform the public of the receipt of the application and describe NRC's licensing process. The meeting was held on January 14, 2010. Although there were several questions regarding the disposal of depleted uranium oxide, no negative opposition was raised to the INIS facility during the public meeting. The NRC held an environmental scoping meeting on July 29, 2010, to gather public input on issues to be addressed in the Environmental Impact Statement (EIS) for the INIS proposed facility. The safety evaluation report is scheduled to be completed by December 2011. The draft environmental impact statement (EIS) is scheduled for publication in September 2011, followed within 30 days by a public meeting in Hobbs, NM to discuss the draft. The final EIS is scheduled for completion by March 2012. There is no hearing associated with this Part 40 license application, but the staff plans to provide an information briefing to a sub-committee of the Advisory Committee on Reactor Safeguards. If the application is approved, the license will be issued following completion of the EIS.

## **AGREEMENT STATE TRAINING**

NRC continues to fund Agreement State training. The procedure for Agreement State Training is documented in FSME procedure SA-600. The procedure and additional information is available on the FSME website at Training and Travel, <http://nrc-stp.ornl.gov/training.html>.

During the period of October 1, 2009 to September 30, 2010 (FY 2010), NRC sponsored 43 training courses, during which 480 training slots were filled by Agreement State personnel. For FY 2011 to date, NRC has sponsored 16 courses with 148 Agreement State staff attending. As needs have been identified and as funding has allowed, additional course sessions have been added to the NRC-sponsored training schedule to accommodate the backlog of requesting Agreement State individuals. Several Agreement States have volunteered to host NRC-sponsored courses that can be taught at a remote location. This has helped the hosting States gain additional training slots for their personnel for the particular course and reduced travel cost for NRC.

The staff expects that the OAS will continue to pursue NRC to re-establish the contract for the 5-week Applied Health Physics course at Oak Ridge National Laboratory to assist the States in training their own health physicists. The NRC through the Inspection Manual Chapter (IMC) 1246 Working Group is considering whether the 5-week Health Physics course is needed to meet the minimum training requirements. If needed, the estimated cost for sponsoring the 5-week course (24 students) is about \$400,000. The staff is aware that the OAS/CRCPD has been exploring other options such as an online course(s) that could provide the same technical information. Also, the Health Physics Society training committee was considering this option. Training for State staff beyond the minimum requirements specified in IMC 1246 is the responsibility of the States. The next section provides the status of IMC 1246.

### **INSPECTION MANUAL CHAPTER (IMC) 1246**

An NRC/Agreement State working group has been chartered to revise and update NRC's the qualification journals for materials license reviewers and health physics inspectors. The qualification journals are currently located in Inspectional Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

The revisions and updates will: (1) provide licensing and inspection personnel with the tools and training necessary to make risk-informed decisions that address security aspects, as well as health and safety and foster a security culture, (2) update IMC 1246 to include new formal materials training and new licensing and inspection guidance and procedures (i.e. security inspection training, pre-licensing visits, naturally occurring or accelerator-produced radioactive material (NARM)), (3) change the format and content of IMC 1246 and qualification journals to more closely follow the apprentice style approach developed by the Office of Nuclear Reactor Regulation (NRR) for IMC 1245, and (4) determine if new classroom training should be developed or required for qualification as a license reviewer or inspector and address the need for the 5-week health physics course.

The revised qualification journals will come under a new IMC, IMC 1248. It is expected that the revised/new qualification journals will be completed in the summer 2011.

### **NUREG-1556 UPDATE PROJECT**

The NUREG-1556 Series is a 21 volume document set that provides consolidated guidance to materials license applicants and reviewers. The documents were first published between 1997 and 2000. Most volumes have never been updated. The need for specific improvements to licensing guidance was identified following a Government Accountability Office (GAO) investigation in 2007. Subsequently, recommendations from two review groups identified the

need for the materials program to address vulnerabilities in the materials licensing process. The recommendations concerned the good faith presumption in the licensing process and lack of security in licensing guidance. To address these recommendations, there are three core objectives for the NUREG-1556 update project: incorporation of security requirements, removal of exploitable information, and general update for regulatory and policy changes enacted since the initial publication(s).

An NRC/Agreement State working group has been chartered to update the NUREG-1556 Series. All 21 volumes are planned to be reviewed and updated as appropriate in a period of 3 years. The project began in July 2010, and is scheduled to be completed by October 2013. The volumes currently undergoing review and update include the following: Vol. 1, Portable Gauges; Vol. 2, Industrial Radiography; Vol. 8, Exempt Distribution Licensing; Vol. 15, Bankruptcy; Vol. 16, Generally License Distribution/Devices; Vol. 19, Reciprocity; and Vol. 20, Administrative Licensing Procedures.

### **PART 40 SMALL QUANTITIES OF SOURCE MATERIAL**

On May 10, 1999, a petition for rulemaking was received by the NRC from the State of Colorado and the OAS regarding 10 CFR Part 40. The request was for the NRC to amend its regulations governing small quantities of source material to eliminate the exemption for source material licensees from the requirements that specify standards of protection against radiation and notification and instruction of individuals who participate in licensed activities. The comment period for this petition ended on September 20, 1999. In 2001, NRC staff provided recommendations for rulemaking for a major revision of general license and distribution requirements which would include resolution of the petition through rulemaking. An SRM issued in 2003, directed the staff to collect additional information to support any such rulemaking. NRC staff has collected additional information and forwarded recommendations to the Commission in SECY-07-0196 dated November 6, 2007. The staff provided the proposed rule to the Commission in SECY-09-0179 dated December 10, 2009. The proposed rule was published for public comment on July 26, 2010. The public comment period closed on February 15, 2011. Staff is evaluating comments and preparing a proposed final version of the rule due to the Commission ??.

### **GROUNDWATER PROTECTION AT IN SITU LEACH URANIUM RECOVERY FACILITIES**

In an SRM to COMJSM-06-0001, dated March 24, 2006, the Commission directed the staff to initiate a rulemaking effort specifically tailored to groundwater protection programs at *in situ* leach uranium recovery facilities with a specific focus on eliminating dual regulation by the NRC and EPA of groundwater protection. After coordinating with EPA, the staff determined that the initial proposed approach, through deferral of active regulation of groundwater protection programs to the EPA or the EPA-authorized state through EPA's underground injection-control permit program, as directed in the SRM, was not feasible. In April 2007, the staff provided this information to the Commission, along with recommendations for a path forward. The staff expanded the working group to include representatives from EPA and CRCPD (it already had an OAS member). In August 2008, EPA informed NRC of concerns regarding the latest draft of the proposed rule. NRC staff continues to work with EPA staff to resolve these concerns. In April 2009, EPA staff notified the NRC staff that EPA was considering rulemaking changes to 40 CFR 192. By statute, NRC would have to conform its byproduct regulations to any standards changed or newly implemented in 40 CFR 192. The NRC is deferring its rulemaking until the

EPA completes their rulemaking or decides to not move forward in order to avoid the potential for confusion by industry and other stakeholders.

### **INTERAGENCY JURISDICTIONAL WORKING GROUP**

In 2003, the staff recommended to the Commission, in SECY-03-0068, that NRC's regulatory authority for source material be limited to only uranium and thorium that was extracted or purposely concentrated for the use of the uranium or thorium. Although the Commission agreed with the recommendation at that time, the Commission did not wish to expend resources on drafting legislation because the probability of success was considered to be very low. In August 2006, in the SRM to SECY-06-0117, the Commission directed the staff to accelerate the activities of the Interagency Jurisdictional Working Group (IJWG). The staff reassembled representatives of the original IJWG, including representatives from OAS and CRCPD, and held its first meeting in December 2007. At that meeting the IJWG members reconfirmed the original recommendation. The staff determined that a regulatory alternative would not be feasible and has drafted sample legislation for new source material definitions for review by the IJWG.

### **INSPECTION MANUAL CHAPTER (IMC) 2800**

IMC 2800 established the general policies for the materials inspection program. As part of NRC's routine review of its materials inspection program, in addition to recommended changes from the Materials Program Working Group, IMC 2800 is being revised to address new materials security requirements, as well as programmatic changes. Specific major changes include the addition of a security inspection frequency that is equal to the health and safety frequency, a requirement for initial security inspections, pre-licensing visits, and the process for coordination with Agreement States. IMC 2800 was issued on July 27, 2010, containing major revisions and was subsequently reissued with minor changes on November 15, 2010, following comments from the Standing Committee on Compatibility. The effective date for the revised IMC 2800 is November 15, 2010, for NRC and May 15, 2011, for Agreement States.

### **SECURITY AND USE OF CS-137 CHLORIDE SOURCES**

The safe and secure use of cesium-137 chloride (CsCl) sources has been identified for attention by the Radiation Source Protection and Security Task Force (Task Force) in its 2006 report and as a result of a February 2008 study by the National Academies because (a) these sources are widely used in self-shielded irradiators in three major modes of application (blood sterilization, bio-medical research, and calibration), and (b) the physical form of CsCl is highly soluble in water and easily dispersed in aerosol form consequently presenting security concerns. The staff conducted a number of initiatives to assess the solubility/dispersibility issue, the adequacy of current security requirements, less soluble and dispersible chemical and physical forms for Cs-137, and the feasibility of utilizing alternate nuclides and alternate technologies without radioactive materials.

#### **Significant previous activities:**

Security of the sources has been greatly improved by the current security requirements, and the risk of malicious use of the material has been reduced significantly. Strong measures and regulatory requirements are currently in place for ensuring security and control of radioactive sources. The NRC and the Agreement States conduct inspections of the licensees'

implementation of the security requirements. Security is being enhanced further by the addition of simple cost-effective modification of blood irradiators. NRC is supporting Department of Energy/National Nuclear Security Administration (DOE/NNSA) in conducting a program to install physical protection measures on blood irradiators to enhance security of the sources.

#### Significant recent activities:

NRC initiated activities to develop and adopt a statement of policy on the protection of cesium-137 chloride (CsCl) sources. This statement would provide the Commission's policy regarding secure uses of these sources and express the Commission's potential actions for the future. The draft of the policy statement was published in the *Federal Register* (Ref. No. 2010-15734) on June 29, 2010, for public comment. The draft policy statement, as published, contains a declaration of the issues that the Commission finds important, followed by a detailed discussion of the points of considerations for these issues.

The NRC also conducted a public meeting in November 2010, to solicit public input on major issues associated with the draft policy statement regarding the current use of certain forms of Cs-137 sources used by NRC- and Agreement State-licensees. Information on the public meeting is available at the dedicated website <http://www.nrc.gov/materials/miau/licensing.html>. The staff received a large number of written comments in response to the *Federal Register* notice as well as oral comments from the panelists and the audience in the public meeting. The overwhelming majority of the comments supported the Draft Policy Statement. None of the comments affected the basic principles of policy listed in the Draft Policy Statement.

In August 2010, the Task Force completed its quadrennial report to the President and Congress (ML102230141). The Task Force Report addressed the security of all radioactive sources, but singled out the issue of CsCl sources in several of the recommendations. As a follow-up to the Task Force Report, the NRC staff provided to the Commission in December 2010, the NRC implementation plan for the Task Force Report (ML103050432) which defined the recommendations as tasks to be completed by the Task Force within the framework of their upcoming activities including the issue of CsCl sources. The proposed Policy Statement is in conformance with the conclusions and the recommendations of the Task Force report.

Disposal of CsCl sources was a significant issue of consideration in the earlier initiatives discussed above, such as the Draft Policy Statement, the Task Force Report and its implementation plan. Significant progress was achieved for disposal of such sources by DOE by the publication of the "Draft Environmental Impact Statement for the Disposal of Greater-Than-Class C (GTCC) Low-Level Radioactive Waste and GTCC-Like Waste" (EIS) on February 18, 2011, for public comment (accessible at <http://nepa.energy.gov/1653.htm>). The EIS includes proposals for resolution of disposal issues for sealed sources, including CsCl sources. The proposed Policy Statement recognizes DOE's issuance of the EIS and expresses the Commission's active support for the DOE initiative to resolve the issue of waste disposal.

The staff compiled a summary of the comments and prepared a final Policy Statement. The final Policy Statement was submitted to the Commission in April 2011.

#### **NATIONAL SOURCE TRACKING SYSTEM**

The National Source Tracking System (NSTS) was deployed in December of 2008, and was available for use by licensees and regulators in January of 2009. As of January 2009, licensees

began reporting their initial source inventories and source transactions for Category 1 and 2 radioactive sources to the National Source Tracking System (NSTS). As previously established, the licensee can report this information online through the web interface, through fax, by email, or by phone. In January 2010, licensees reconciled their inventories for the first time. Licensees reconciled their inventories again in January 2011.

Approximately 1,430 licensees are reporting information on over 76,000 sources to the NSTS. On average, 200 transactions are reported to NSTS daily. The majority of the sources found in NSTS are cobalt-60 (92%), iridium-192 (3.7%), and cesium-137 (3.4%). The majority of transactions for manufacture, transfer, and receipt, are with iridium-192.

The NRC has been working closely with the Agreement States and licensees to encourage online reporting, as it is the most accurate and timely way to report source transactions. In addition to online reporting, some licensees are submitting their source transactions to the NSTS Help Desk in an electronic format, which can be quickly loaded into the system on the licensee's behalf. In the month of February, 78% of the transactions for NSTS were electronically reported (either reported online or submitted electronically to the NSTS Help Desk), up from 74% in January. Transactions submitted by faxing Form 748 are at 22% for the month of February, down from 26% in January.

<b>January Transactions</b>	<b>Number of Transactions</b>	<b>Percentage of Transactions</b>
Online Transactions	2,208	35%
Other Transactions (excluding QSA)	1,675	26%
QSA Global Transactions	2,457	39%
<b>Total NSTS Transactions</b>	<b>6,340</b>	<b>100%</b>

**ELECTRONIC REPORTING = 74%**

<b>February Transactions</b>	<b>Number of Transactions</b>	<b>Percentage of Transactions</b>
Online Transactions	927	24%
Other Transactions (excluding QSA)	860	22%
QSA Global Transactions	2,108	54%
<b>Total NSTS Transactions</b>	<b>3,895</b>	<b>100%</b>

**ELECTRONIC REPORTING = 78%**

Due to the large volume of system requirements, the development of NSTS was broken down into two software versions. NSTS Version 1, which is currently in production, has the basic functionality for licensees to report source manufacturing, import, export, transfer and receipt. In addition, licensees can update information on the source, including changing the location of use. Regulators can verify pending records, such as locations of use, license information, and make and model information. Reporting capability is limited; regulators have the ability to view an inventory report for their licensees.

NSTS Version 2, which is currently in development and planned for deployment later in 2011, will include import/export consents and notifications, event-triggered alerts, extended licensee functions, automated system interfaces, full reporting and query capabilities, and the ability to download data for other federal agencies. In more detail, Version 2 includes: (1) query support, allowing review of pending/overdue transfers, import/export notifications, alert history, inventory verifications, source history, licensee transfer history, and lost and stolen sources; (2) reporting capabilities; and (3) automated alerts for significant events, such as pending or overdue transfers and pending licensing agency verifications (make/model, licensees, and locations).

In addition to Version 1 and Version 2 of NSTS, there are three maintenance releases each year. These maintenance releases are comprised of change requests identified by system users and stakeholders. The content for each maintenance release is determined by a Change Control Board, which includes both Agreement State and Industry representation.

The NRC has been working with the Agreement States and licensees to overcome some of the challenges with the implementation of the NSTS. These challenges include credentialing for online access to NSTS, encouraging online usage of NSTS, proper fax reporting, and accuracy of data. The NRC has a contract with a marketing firm to help with outreach for NSTS, which included interviews with the Agreement States. The NRC has bi-monthly conference calls with the Agreement States to discuss NSTS issues and plan for upcoming events. The support of the Agreement States for this national system is integral to the success of the program.

## **MEDICAL ISOTOPE PRODUCTION**

NRC has received five letters of intent (B&W, GE, MURR, Coqui, SHINE) for domestic Molybdenum-99 (Mo-99) production facilities, but no applications. NRC responded to a regulatory issues request from another potential producer (AMIC). The Department of Energy (DOE) is focusing on the development of four distinct technologies. DOE signed cost sharing Cooperative Agreements (CA) with B&W for its low enriched uranium Aqueous Homogeneous Reactor approach, GE Hitachi for its neutron capture (natural molybdenum targets) approach, and both NorthStar and Morgridge for their accelerator based technologies. Although NorthStar signed a CA for an accelerator technology, it also signed an agreement with the University of Missouri Research Reactor to have the reactor irradiate the non-radioactive isotope of molybdenum-98 to produce NorthStar's initial Mo-99. At this time there is no cooperative agreement for the fourth technology, i.e., using Low-Enriched Uranium (LEU) conventional targets in a reactor. The cooperative agreements require 3,000 6-day Curies of Mo-99 production without using High-Enriched Uranium (HEU) by the end of 2013.

The initial point of contact for NRC is the internal Mo-99 Working Group (WG) composed of staff from several NRC Program Offices. The WG is preparing to address applications that may fall under Part 50, Part 70, Part 30, etc., by discussing the characterization of the anticipated applications along with the details of the proposed designs and technologies to determine the proper regulatory path.

The NRC also participates in an Interagency WG organized by the White House's Office of Science and Technology Policy (OSTP) and includes DOE/NNSA, FDA, HHS, DOS, and DOT. On January 25, 2011, Senators Bingaman and Murkowski introduced the "American Medical Isotopes Production Act of 2011," to the Senate Committee on Energy and Natural Resources. A public hearing was held February 1, 2011, on the bill by the committee. The bill is similar to

the American Medical Isotopes Production Act of 2009, which had wide congressional support but was put on hold during the last Congress.

With regards of current suppliers of Mo-99, major repairs were made to both the Canadian National Research Universal (NRU) and the Netherlands' Petten reactors in 2010 and they have remained in operation since their repairs, except when undergoing planned maintenance. Two additional European reactors (in Poland and the Czech Republic) have been approved to provide Mo-99 to American and European generator producers. The South African Reactor has been approved to produce Mo-99 from LEU targets for an U.S. generator manufacturer, and one shipment of this Mo-99 was received in the U.S. Covidien continues to provide a daily projection calendars for Tc-99m generators, and Lantheus provides supply initiative updates to keep the community informed of expected availability levels. At the current time, there are no Mo-99 shortages, and there is potential excess Mo-99 production capacity. Also, demand is below the pre-shortage level due to efficiencies in patient management and switching to alternative procedures.

### **SAFETY CULTURE POLICY STATEMENT**

In SRM-COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture" dated February 25, 2008, the Commission approved the need to expand the Commission's policy of safety culture to address the unique aspects of security and to ensure the resulting policy statement is applicable to all licensees and certificate holders. In SECY-09-0075, "Safety Culture Policy Statement" dated May 18, 2009, the NRC staff provided the Commission with a draft policy statement on safety culture and addressed the issues in SRM-COMGBJ-08-0001, "A Commission Policy on Safety Culture." These issues included: (1) how to increase attention to safety culture in the materials area; (2) 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; and (3) 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.

In SRM-SECY-09-0075, dated October 16, 2009, the Commission approved the publication of the draft policy statement and directed the staff to: (1) consider incorporating suppliers and vendors of safety-related components into the policy statement, (2) seek opportunities to comport NRC terminology with that of the existing standards and references maintained by those that NRC regulates, and (3) continue to engage a broad range of stakeholders, including the Agreement States and other organizations with an interest in nuclear safety to ensure the final policy statement benefits from a consideration of a spectrum of views and provides the necessary foundation for safety culture to the entire nuclear industry.

On November 6, 2009, the NRC published a draft policy statement on safety culture (74 FR 57525) for public comment with the comment period closing March 1, 2010. FSME-09-095 dated November 25, 2009 informed State contacts about: (1) an opportunity for States and their licensees to comment on a draft Commission policy statement on safety culture and (2) upcoming workshops relating to the draft policy statement and safety culture terminology. The letter also requested that Agreement States share the draft policy statement with their licensees and to inform their licensees about upcoming workshops related to developing a definition of

safety culture and safety culture terminology. The letter included, as attachments, a copy of the draft policy statement and a safety culture summary, which included information on safety culture, the draft policy statement, and the NRC workshops.

On February 2-4, 2010, the NRC held a public workshop to reach alignment on a high-level safety culture definition and descriptions/traits and to develop common terminology for safety culture that can be used across all industries regulated by the NRC. Following additional outreach activities, the NRC published a revised draft safety culture policy statement for a 30-day comment period on September 17, 2010, and held a public meeting on September 28, 2010. A proposed final policy statement (SECY-11-0005) was provided to the Commission on January 5, 2011. On March 7, 2011, the Commission approved a final policy statement (SRM-SECY-11-0005) and the final safety culture policy statement will be published after clearing a Congressional Review Act review. The policy statement describes the Commission's expectation that individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This includes all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. The policy statement indicates that the Commission encourages the Agreement States, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture. The Commission directed the staff: (1) to continue to engage all stakeholders on the content of the policy statement, educate stakeholders, and ensure that they have the necessary support to effectively employ the policy statement as they deem appropriate; and (2) not to pursue activities beyond communication and education without specific Commission approval. The staff is also required to seek Commission policy review before implementing any new initiatives.

Information related to safety culture can be found at the NRC Safety Culture web site, <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

### **INTEGRATED SOURCE MANAGEMENT PORTFOLIO (ISMP)**

The Integrated Source Management Portfolio (ISMP) is a set of information technology tools that will provide a web-based solution to (1) enable an up to date accounting of the possession of the most risk-significant radioactive sources in the nation; (2) authenticate the validity of radioactive materials licenses; (3) and modernize materials licensing.

The ISMP contract was awarded in May 2010. The portfolio consists of the National Source Tracking System (NSTS), the Web-Based Licensing System (WBL), and the License Verification System (LVS). The purpose of the ISMP contract is to provide contractor support for the planning, acquisition, system certification, development, deployment, hosting, and maintenance of the NRC ISMP project. The contract has duration of ten years, and consists of eleven tasks.

What ISMP will be able to achieve:

- Provide a method to validate both possession limits and current inventory for Category 1 and Category 2 sources.

- Provide a method to view or know possession limits for all other Categories of material.
- Provide protection against the ability to counterfeit licenses for all licensee categories if used.
- Provide a platform via WBL for NRC licensees to perform license operation activities.
- Provide a platform for Agreement States to adopt as their online licensing system.
- Support compliance with Part 30 requirements for transfer.
- Support compliance with proposed Part 37 requirements for Category 1 and 2 materials.

The current NRC License Tracking System (LTS) will be enhanced and ultimately made external facing and web-based so NRC licensees may use it to apply for licenses, check license status, request amendments, etc. NRC would work toward ensuring that if Agreement States wanted to use WBL for licensing they would be able to do so. There will be a National License Warehouse (NLW) that would receive license images from all the States and from WBL for NRC licenses. The key fields identified for use in license verification for Category 1 and 2 licenses would be extracted from WBL for NRC and from the NLW for States. The LVS would be used by licensees (e.g. suppliers) and regulators to check the official license image to ensure it is authentic (i.e. address counterfeiting), and will query the inventory in NSTS and compare it against the possession limits extracted from these licenses to address shopping around. Licensees and regulators will also be able to use LVS to ensure a license is authentic for all licenses and system alerts will be built in to look for suspicious activity within the system (e.g. querying the same license repeatedly in a short period of time).

### **WEB-BASED LICENSING**

The NRC awarded the Integrated Source Management Portfolio contract in May 2010. The development of the Web-Based Licensing System is a component of the ISMP. In October 2010, the NRC held a requirements workshop with WBL stakeholders to validate the requirements. The workshop was well attended by the NRC Regions, Agreement State representatives, and industry stakeholders. In January 2011, the WBL requirements were signed off by the NRC Regions. We received comments on the requirements document from the NRC Regions and the Organization of Agreement States. Some of the comments received resulted in minor changes to the requirements, which were updated in the System Requirements Specification document.

The development effort for WBL is on track; the infrastructure components task began in May 2010, and the development of the software began in March 2011. The NRC License Tracking System (LTS) is the foundation for the WBL, and this system is planned to be ready in August 2012.

The WBL Working Group is working on Task Two of their project charter, which is to develop a recommended protocol for Agreement States to include or make available their license image files for including in WBL.

The NRC is offering the Agreement States a “Distributed Version” of the License Tracking System. The development for this system is underway, and the beta version is planned to be ready in April 2011. North Carolina will be piloting the system, and many additional states have expressed interest in using it. The States may opt to use this “Distributed Version,” which they will install and host in their internal infrastructure. Alternatively, States will have the option to use the WBL as their licensing system. They will access the WBL through the internet, and will not need to purchase any servers or infrastructure components to use it.

Consistent with Recommendation S-3 in SECY-07-0147, “Response to U.S. Government Accountability Office Recommendations and Other Recommendations to Address Security Issues in the U.S. Nuclear Regulatory Commission Materials Program,” NRC has also begun work on a License Verification System that will utilize information from WBL and NSTS to provide a secure national license verification capability.

In February 2011, several webinars were conducted with the Agreement States to discuss the License Verification Process. Due to challenges identified by the WBL Working Group, a two phased approach to license verification is planned. In the short-term, a platform is in development to provide access to the electronic image files of licenses, supplied by the regulators, to regulators, licensees, and other authorities to authenticate the validity of radioactive materials licensees and to verify against possession limits of Category 1 and Category 2 sources. The long-term approach is to develop a platform to provide an effective electronic license verification capability to regulators, licensees, and other authorities based mainly on key information listed on licenses (no image files) and to verify against possession limits of Category 1 and Category 2 sources.

A requirements validation session was held for the License Verification System on March 30, 2011. Stakeholders who participated include Agreement States, NRC staff, and Industry representatives, including manufactures and distributors.

## **PATIENT RELEASE**

Over the last couple of years Congressman Edward Markey has sent NRC various letters concerned with the patient release criteria of 10 CFR 35.75. According to his letters and other statements attributed to him, he believes that NRC should change the rules in 10 CFR 35.75 back to the pre-1997 requirements. Those requirements were based upon activity limits rather than dose limits, and therefore less risk informed. At this time NRC does not have plans to undergo rulemaking activities related to this issue. However, in response to questions from the regions, a regulatory issue summary (RIS-2011-01) entitled “NRC Policy on Release of Iodine-131 Therapy Patients under 10 CFR 35.75 to Locations other than Private Residences” (ML1036201531) was published on January 25, 2011, to inform licensees of NRC’s policy on the release of Iodine-131 therapy patients under 10 CFR 35.75. The RIS recognizes that 10 CFR 35.75 does not expressly prohibit the release from the hospital of a patient who has been administered radioactive iodine to a location other than a private residence, but strongly discourages this practice. NRC posted potential Qs & As related to the RIS on the NRC website at (<http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html#p10>). NRC guidance will be updated to address the release of I-131 therapy patients to alternative locations.

## **PARTS 30, 31, 32, 40, AND 70 DISTRIBUTION OF BYPRODUCT MATERIAL**

In SECY-09-0035 dated February 26, 2009, staff described the amended requirements for distributors of byproduct material that would be clearer, less prescriptive, more risk-informed, and up to date. It would redefine categories of devices to be used under exemptions, add explicit provisions regarding the sealed source and device registration process, and add flexibility to the licensing of users of sealed sources and devices. It also would have improved safety criteria for approving products through licensing actions. This action is primarily intended to make licensing processes more efficient and effective. It is primarily an outgrowth of the systematic assessment of exemptions, the results of which were reported to the Commission in SECY-02-0196 dated November 1, 2002, and a follow-on to another rulemaking completed in 2007 (72 FR 58473). In SRM-SECY-09-0035 dated February 3, 2010, the Commission approved the publication of the proposed rule for public comment, but disapproved revising the safety criteria at this time. The proposed rule was published in the *Federal Register* on June 24, 2010 (75 FR 36211). The public comment period ended on September 7, 2010. Currently, staff is drafting a final rule package due to the Commission in August 2011.

### **PART 31.5 GENERAL LICENSED DEVICES**

In June 2005, the Nuclear Regulatory Commission (NRC) received a petition for rulemaking from the Organization of Agreement States (OAS) requesting that the NRC amend its regulations to: (1) require specific licensing for devices that are currently regulated by a combination of general licensing and registration, and (2) revise the compatibility category of 10 CFR 31.6 from "B" to "C." This action also addresses a request filed by the Bureau of Radiation Control of the Florida Department of Health for the NRC to change the compatibility category of 10 CFR 31.5(c)(13)(I) from category "B" to "C." The comment period for this petition and the Florida request ended on March 6, 2006. Four comments were received.

NRC staff considered the petition and its supporting rationale, and determined that issues and concerns raised in the petition merited further NRC consideration. The staff incorporated the issues into the General License Restrictions rulemaking and submitted a draft proposed rule to the Commission in September 2008. In a Staff Requirements Memorandum (SRM) dated May 1, 2009, the Commission approved publication of the proposed rule for public comment. The proposed rule was published on August 3, 2009, for a 75 day comment period, which ended on October 19, 2009. The final rule was sent to the Commission by August 13, 2010.

On December 2, 2010, the Commission acted on the final rule that would amend Title 10 of the Code of Federal Regulations (CFR) Part 31, in the Federal Register (SRM-SECY-10-0105). After review, the Commission has decided to disapprove the publication of the final rule, but approved revising the compatibility categories of 10 CFR 31.5 and 31.6 from B to C. Currently, a Federal Register Notice (FRN) is being prepared to provide information on the Commission's actions.

### **REVISION OF NRC POLICY STATEMENT OF PRINCIPLES AND POLICY FOR AGREEMENT STATE PROGRAM AND POLICY STATEMENT ON ADEQUACY AND COMPATIBILITY OF AGREEMENT STATES PROGRAMS**

The Commission directed the staff in the SRM dated December 2, 2010, "SECY-10-0105, Final Rule: Limiting the Quantity of Byproduct Material in a Generally Licensed Device," to update the

Commission Policy Statement on Adequacy and Compatibility of Agreement State Programs and associated guidance documents to include both safety and source security considerations in the determination process. Agreement State compatibility is a key component of the Integrated Materials Performance Evaluation Program (IMPEP) process. NRC developed the IMPEP process to evaluate the adequacy and compatibility of Agreement State Programs and the adequacy of NRC's nuclear materials program activities. Therefore, the Commission Policy Statement on the Statement of Principles and Policy for the Agreement State Programs will be revised concurrently. This revision will be conducted by a working group operating in accordance with NRC Management Directive 5.3, "Agreement State Participation Working Groups," dated August 22, 2007. The working group will be co-chaired by an NRC staff member and a representative from the Organization of Agreement States (OAS). The draft Policy Statement will be submitted to the Commission requesting approval for publication for comments from the Agreement State and the public by December 2011.

### **BLENDING OF LOW-LEVEL RADIOACTIVE WASTE**

Since the closure of the LLRW disposal facility at Barnwell, South Carolina on June 30, 2008, the issue of blending of LLRW has received increased attention from stakeholders, industry, and Agreement States, especially blending that results in a change in the classification of the waste, as defined by the radionuclide concentrations in 10 CFR Part 61.55. Blending is not prohibited nor is it explicitly addressed in current NRC regulations.

Existing NRC staff guidance discourages blending in some circumstance, but also recognizes that some blending, including blending that lowers the classification of a waste, may be appropriate in others. However, the closure of the Barnwell facility to LLRW generators in 36 States means that they have no disposal option for their Class B or C LLRW and must therefore store it, typically at their licensed facility. Any waste with Class B or C concentrations that could be blended down to Class A could potentially be disposed of at an existing Class A facility, and not have to be stored by licensees at their facilities. While some blending of LLRW resulting in reduced waste classification has occurred in the past, the scale of blending being considered since the closure of Barnwell has expanded.

NRC's existing guidance on blending of LLRW is contained in the 1995 Concentration Averaging Branch Technical Position (BTP). Although this document addresses many issues associated with concentration averaging of LLRW (i.e. the mathematical averaging of radioactivity concentrations in solid, non-mixable, materials, such as reactor components), it also addresses blending of homogeneous wastes. The BTP discourages blending by recommending a limit on the range of concentrations of batches that can be mixed. At the same time, these recommendations do not apply when there are operational efficiencies or worker dose reductions that can be achieved.

On October 8, 2009, the Chairman directed the staff to prepare a Commission vote paper on blending, noting that there were policy issues associated with blending that the Commission needed to consider. The staff completed the paper, SECY-10-0043, "Blending of Low-Level Radioactive Waste," on April 7, 2010. The paper identified and analyzed regulatory, safety, and policy issues and provided four different options on a blending position for Commission consideration. The staff-recommended option was for NRC to adopt a risk-informed, performance-based blending position, consistent with the Agency's overall policy for regulating its licensees. Other options included maintaining the status quo (i.e., relying on existing

blending guidance), prohibiting large-scale blending (i.e., blending of multiple generators' waste at an offsite processing facility), and adopting a regulation similar to Texas's which allows blending, but requires that waste be classified based on its highest concentration before blending, thus eliminating one of its primary advantages, the lowering of the waste class.

The Commission directed the staff to proceed with its recommended option in an October 13, 2010, Staff Requirements Memorandum. Implementation of this option, which will occur over the next two years, will improve and strengthen the agency's standards for blending of LLRW. The goal is to make NRC's regulation of LLRW blending more risk-informed, performance-based, and in general more consistent with the agency's overall policy for regulating the nuclear industry. NRC's previous position discouraged blending under some conditions, without a health and safety basis, but did not discourage blending if a nuclear facility's operational efficiency could be improved. This position was not fully risk-informed or performance-based. The new agency position is risk-informed – it is tied to how LLRW blending might affect the protection of public health and safety. The new position is performance-based - NRC's decision making involving blending will above all be based on performance and results. Performance means that the blended waste must meet the limits on radiation exposures at the disposal facility and limits on how much the radioactivity concentration may vary (i.e., how well-mixed it must be).

The first part of the new position is to include blended LLW into NRC's ongoing rulemaking that will require a site-specific analysis for wastes such as depleted uranium and large scale blended waste. This new regulation, to be completed in late 2012 or early 2013, will ensure that the safety of large-scale blended waste be evaluated before its disposal. Large-scale blending means mixing of waste from multiple generators at a third party location (i.e., a waste processing facility) prior to its disposal. Agreement States will have to adopt NRC's new regulation requiring a safety analysis of the disposal of large-scale blended waste. The Commission directed that the staff work closely with the Agreement States to ensure maximum State flexibility in drafting the rule language

In addition to a new regulation that will address disposal of blended waste, NRC is taking or has taken three other regulatory actions:

- NRC will publish regulatory guidance that addresses the characteristics of large-scale blended waste needed to ensure its safe disposal, including how uniform, or well mixed, the waste must be.
- NRC will update its "Policy Statement on Low-Level Waste Volume Reduction." Since its publication in 1981, nuclear facility operators have made significant progress in reducing LLRW volumes. The revised Policy Statement will recognize this progress and acknowledge that other factors may be used in determining how nuclear facilities manage their LLRW.
- NRC issued, on March 17, 2011, guidance to Agreement States on how to evaluate proposals to blend large quantities of waste until the staff guidance is updated. Agreement States should conduct case-by-case evaluations in the meantime. The guidance indicates to States that entities wishing to pursue large-scale blending should be advised that NRC guidance on blending is undergoing revisions and it may be advisable for them to wait until it is published in a final form.

NRC will solicit public and stakeholder input on the proposed rulemaking and guidance. Several public meetings will be conducted and the draft rule language and guidance will be published for

comment. Schedules for development of the rule and guidance, including meetings and public comment periods, will be posted on the NRC web site.

## **REVISIONS TO 10 CFR PART 61**

10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste" was originally published in 1982. Over the last several years there have been a number of developments that have called into question some of the key assumptions made in connection with the earlier Part 61 draft Environmental Impact Statement (EIS), including:

- The emergence of potential low-level radioactive waste (LLRW) streams that were not considered in the original Part 61 rulemaking, including large quantities of depleted uranium, blended LLRW, and possibly incidental wastes associated with the commercial reprocessing of spent nuclear fuel;
- DOE's increasing use of commercial facilities for the disposal of defense-related LLRW streams; and
- Extensive international operational experience in the management of LLRW and intermediate-level radioactive wastes that did not exist at the time Part 61 was promulgated.

In Staff Requirements Memorandum (SRM) M100617B, the Commission directed the staff to outline its approach to initiate activities in connection with a possible revision to Part 61 that is risk-informed and performance-based (RI/PB). SECY-10-0165, "Staff's Approach to Comprehensive Revision to 10 CFR Part 61" was published in December 2010, and recommended the staff initially engage stakeholders and solicit their views on whether there should be amendments to the current Part 61 and if so, what the nature of those amendments be. The purpose of these public meetings would be: (1) to gather information from a broad spectrum of stakeholders concerning their continued support for the existing Part 61; (2) to obtain recommendations for specific changes to the existing rule; and (3) to obtain suggestions for possible new approaches to commercial LLRW management.

The staff plans to conduct a series of public workshops to obtain stakeholder input on the possible RI/PB options presented by the staff or to suggest alternative regulatory strategies for the management of commercial LLRW. The first of the proposed stakeholder meetings was conducted on March 4, 2011, in Phoenix, Arizona, as a joint NRC-DOE workshop on LLW management. DOE had already scheduled a public meeting to discuss the revisions to Order 435.1-1. The meeting was held after the 2011 Waste Management Conference, which allowed the staff to take advantage of the large stakeholder presence expected at the conference.

After completing the public workshops and reviewing the information provided by stakeholders, the staff will submit a notation-vote paper to the Commission summarizing suggestions for revising Part 61, and recommending an option for Commission consideration. This notation-vote paper will be submitted in 2012.