

NRC BACKGROUND INFORMATION

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS ANNUAL MEETING

April 2010

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 April 2010 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

| | PAGE |
|--|------|
| PARTS 30, 31, 32, 40, AND 70 DISTRIBUTION OF BYPRODUCT MATERIAL..... | 4 |
| PART 31.6 GENERAL LICENSED DEVICES | 4 |
| PART 35 MEDICAL USE OF BYPRODUCT MATERIAL- MEDICAL EVENT DEFINITION RULEMAKING | 4 |
| PART 35 MEDICAL USE OF BYPRODUCT MATERIAL – DIRECT FINAL RULE TO CLARIFY WORK EXPERIENCE SUPERVISORS AND ATTESTORS..... | 5 |
| PART 35 REVISION TO MEDICAL USE REGULAITONS..... | 5 |
| PART 37 SECURITY RULEMAKING AND GUIDANCE DOCUMENTS | 5 |
| PART 40 SMALL QUANTITIES OF SOURCE MATERIAL | 6 |
| IMPACTS OF EPA’S IMPLEMENTATION OF A MAXIMUM CONTAMINANT LEVEL (MCL) FOR URANIUM IN DRINKING WATER | 6 |
| GROUNDWATER PROTECTION AT IN SITU LEACH URANIUM RECOVERY FACILITIES | 6 |
| URANIUM CONVERSION/DECONVERSION | 7 |
| DU GUIDANCE: UNIQUE WASTE STREAMS RULEMAKING | 8 |
| BLENDING..... | 8 |
| INTERAGENCY JURISDICTIONAL WORKING GROUP | 9 |
| CHAIRMAN’S TASK FORCE ON SOURCE SECURITY AND PROTECTION..... | 9 |
| IMPROVING SECURITY IN RADIOACTIVE MATERIALS PROGRAMS | 11 |
| SECURITY AND USE OF CS-137 CHLORIDE SOURCES | 11 |
| NRC/NNSA ACTIVITIES | 13 |
| NATIONAL SOURCE TRACKING SYSTEM | 13 |
| WEB-BASED LICENSING | 16 |
| TRITIUM EXIT SIGNS PATH FORWARD | 16 |
| EMERGENCY RESPONSE INITIATIVES | 16 |
| INTERNATIONAL NUCLEAR AND RADIOLOGICAL EVENTS SCALE (INES)..... | 16 |

| | PAGE |
|---|------|
| MULTIPLE MEDICAL EVENTS AT PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER..... | 17 |
| NIST AND VA LESSONS LEARNED..... | 17 |
| PATIENT RELEASE..... | 18 |
| MEDICAL ISOTOPES (Mo-99)..... | 18 |
| INSPECTION MANUAL CHAPTER (IMC) 2800..... | 18 |
| NUREG 1556 UPDATE PROJECT..... | 19 |
| NARM..... | 19 |
| AGREEMENT STATE TRAINING..... | 20 |
| NRC/OAS/CRCPD WORKING GROUP STATUS..... | 20 |
| WORKING GROUP PRIORITIZATION..... | 20 |
| STATUS OF AGREEMENT STATE NEGOTIATIONS..... | 21 |
| IMPEP SELF ASSESSMENT..... | 21 |
| SAFETY CULTURE POLICY STATEMENT..... | 22 |
| PANDEMIC AND COOP ACTIVITIES..... | 23 |
| INTERNATIONAL RADIATION STANDARDS..... | 24 |

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

A proposed rule was submitted to the Commission in SECY-09-0035 dated February 26, 2009, which will make requirements for distributors of byproduct material clearer, less prescriptive, more risk-informed, and up to date. It will also improve safety criteria for approving products through licensing actions, 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. This action is primarily intended to make licensing processes more efficient and effective. It is also intended to improve assurance that appropriate quantities of radionuclides are approved for use under the general license and under exemptions from license. This action 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 a Staff Requirements Memorandum (SRM) 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.

PART 31.6 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) to 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 is due to the Commission by April 30, 2010.

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

The proposed rule would modify 10 CFR 35.40 and 35.3045 to establish separate medical events criteria and written directive requirements for permanent implant brachytherapy. Criteria for defining permanent implant brachytherapy would change from dose-based to activity-based; a requirement to report, as a medical event, any administration requiring a written directive if a written directive was not prepared would be added as well as requirements for written directives for permanent implant brachytherapy would be clarified; and certain administrative and clarification changes would be made. The proposed rule was published on August 6, 2008 and the public comment period closed on November 7, 2008. Staff will be submitting a revised proposed rule to the Commission in June 2010. The revised rule will be published in the *Federal Register* for public comment.

PART 35 MEDICAL USE OF BYPRODUCT MATERIAL – DIRECT FINAL RULE TO CLARIFY WORK EXPERIENCE SUPERVISORS AND ATTESTORS

The direct final rule amended 10 CFR 35 in multiple places to clarify that all individuals grandfathered under 10 CFR 35.57 may serve as work experience supervisors and preceptors for individuals seeking recognition on an NRC license for the same uses. Additionally, several minor administrative changes were included. The final rule was effective on September 28, 2009 (74 FR 33901).

PART 35 REVISION TO MEDICAL USE REGULATIONS

NRC is preparing to undertake a major revision to the regulations governing the Medical Use of Byproduct Material in 10 CFR Part 35. In 2002, NRC revised the medical use regulations in their entirety. The regulations were revised to focus on those medical procedures that pose the highest risk to workers, patients, and the public, and to structure these regulations to be more risk-informed and performance based. Through implementation experience with the revised Part 35, the staff has identified 30 plus items that need to be considered in the rulemaking process. These include several issues of regulatory or technical complexity (e.g., amending preceptor attestation requirements, allowing multiple radiation safety officers on medical use licenses, and annualizing dose limits from released patients). The proposed rulemaking is due to the Commission in February 2012.

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 proposed 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. New requirements for background investigations and access control will be proposed to ensure that individuals that have access to these materials have gone through background investigations and are considered to be trustworthy and reliable. New requirements will also be proposed to establish physical protection systems to detect, assess, and respond to unauthorized access to Category 1 and Category 2 quantities of radioactive material. New requirements for 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 will be proposed for transportation of these radioactive materials.

The rulemaking will consider 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 staff provided the proposed rule to the Commission in SECY-09-0181 dated December 14, 2009. Once the Commission approves publication of the proposed rule for comment, and the proposed rule is published in the *Federal Register*, staff also plans to publish guidance documents for public comment during the comment period on the proposed rule.

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 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. Approval to publish the proposed rule for comment has not yet been given by the Commission.

IMPACT OF EPA'S IMPLEMENTATION OF A MAXIMUM CONTAMINANT LEVEL (MCL) FOR URANIUM IN DRINKING WATER

In December 2000, the Environmental Protection Agency (EPA) issued a MCL for uranium of 30 micrograms per liter. In 2004, NRC was notified that a significant number of drinking water facilities (500+) may be required to treat drinking water for uranium. In many cases, it is expected that treatment at these drinking water facilities will concentrate uranium above levels requiring specific licensing under the existing regulations in 10 CFR Part 40. Because of the significant burden on both water treatment facilities and regulatory agencies involved in specifically licensing each of these facilities, the staff evaluated alternative approaches, including rulemaking, which could limit the additional burden while maintaining public and worker health and safety and protection of the environment. On September 14, 2006, the staff issued a regulatory issues summary (RIS 2006-020) that allows enforcement discretion in non-Agreement States for Community Water Supplies. Currently, NRC is pursuing the possibility of removing its jurisdiction from these types of facilities through the action of the Part 40 Interagency Jurisdictional Working Group, which includes representatives of a wide variety of agencies including the OAS and CRCPD.

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. A draft proposed rule package is due to the Commission in April 2010.

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 kg or more of uranium hexafluoride (UF_6). 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 final rule is scheduled to be completed by the end of 2011.

International Isotopes, Inc., 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 licensing safety review and environmental impact statement are projected to be completed in late 2012. The proposed facility will process 7.2 million lbs/yr of depleted uranium hexafluoride (DUF_6) (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_6 (900 cylinders), approximately 25% of the projected DUF_6 produced in the US annually.

INIS is in contract discussions with the commercial enrichment facilities for obtaining DUF_6 . The negotiations are ongoing, and no contracts have been established. 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_6 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_6 to a uranium oxide. The Department of Energy is also constructing two depleted uranium deconversion facilities near the gaseous diffusion plants to disposition their 700,000 tons of DUF_6 .

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 14th, 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 acceptance review is scheduled for completion on February 26, 2010.

DU GUIDANCE: UNIQUE WASTE STREAMS RULEMAKING

In SRM-SECY-08-0147, dated March 18, 2009, the Commission directed the staff to pursue a limited rulemaking to specify a requirement for a site-specific analysis and associated technical requirements for unique waste streams including, but not limited to, the disposal of significant quantities of depleted uranium. In pursuing this limited rulemaking, the NRC is not proposing to alter the waste classification scheme. However, for unique waste streams including, but not limited to, significant quantities of depleted uranium, there may be a need to impose additional criteria on its disposal at a specific facility or deny such disposal based on unique site characteristics. Those restrictions would be determined through a site-specific analysis, which satisfies the requirements developed through the rulemaking process.

On June 24, 2009, the NRC published an announcement in the Federal Register , (74 FR 30175) to solicit early public input on major issues associated with potential rulemaking for land disposal of unique waste streams including, but not limited to, significant quantities of depleted uranium in near-surface, low-level radioactive waste facilities. Toward that end, the NRC staff hosted public workshops in Rockville, Maryland, on September 2–3, 2009, and in Salt Lake City, Utah on September 23–24, 2009, to discuss issues associated with rulemaking. Agendas for those public workshops were provided in advance through the NRC's Public Meeting Schedule. Following the workshops, the NRC received comments from the public and other interested stakeholders, regarding the issues discussed at the workshops; those comments were submitted through Regulations.gov, under Docket ID NRC-2009-0257.

The staff is in the process of developing a technical basis document to support the draft rulemaking. The draft rule is scheduled to be available for public comment in September 2011, with a final version issued in September 2012.

BLENDING

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, as defined here, refers to mixing of LLRW of different concentrations. It does not involve mixing radioactive waste with non-radioactive waste, (i.e., dilution) and concerns only waste disposal, not release of radioactivity to the general environment.

Blending is not prohibited nor explicitly addressed in NRC regulations. In addition, while NRC staff guidance discourages blending in some circumstances, it 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 thus there is increased interest in blending to reduce the radioactivity concentrations of wastes that might otherwise be classified as B or C waste. Class A waste can be disposed of and does not have to be stored on licensees' site. 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.

On October 8, 2009, NRC Chairman Gregory B. Jaczko directed the staff to prepare a vote paper for the Commission to consider issues related to blending of LLRW. Chairman Jaczko directed that the staff specifically consider:

- Issues related to intentional changes in waste classification due to blending, including safety, security, and policy considerations
- Protection of the public, the intruder, and the environment
- Mathematical concentration averaging and homogeneous physical mixing
- Practical considerations in operating a waste treatment facility, disposal facility, or other facilities, including the appropriate point at which waste should be classified
- Recommendations for revisions, if necessary, to existing regulations, requirements, guidance, or oversight related to blending of LLW

The staff held a number of public meetings to obtain additional information on these and other issues. Stakeholder views will be addressed in the vote paper the staff prepares for the Commission.

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/purposely concentrated for the use of the uranium or thorium. Although the Commission agreed with the recommendation, 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. The staff plans to submit recommendations to the Commission during the summer of 2010.

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 (EPAAct) of 2005 (Pub. L. 109-58), 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 Committee is chaired by NRC. An OAS/CRCPD representative is also participating in the Task Force meetings as a non-voting member.

EPAAct 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, EPAAct 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. The Task Force is required to submit its report to Congress and the President.

By letters dated August 15, 2006, NRC submitted the Radiation Source Protection and Security Task Force Report to the President and Congress. The first report 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 are the basis for many of the new recommendations, actions, or legislative changes that may be proposed in the next report that is due in August 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 and ban the export of CsCl sources. 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.

Currently, the Task Force is 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. Also, the Task Force will consider an evaluation of financial assurance required for radioactive sources 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, will be included in the 2010 Task Force report.

IMPROVING SECURITY IN RADIOACTIVE MATERIALS PROGRAMS

In 2007, the U.S. Government Accountability Office (GAO) “stung” NRC by obtaining an NRC license by using falsified information and subsequently altering the license using commercial computer software. GAO’s covert operation caused NRC to evaluate its materials licensing program. NRC tasked three groups with collectively performing a comprehensive review of its materials licensing program: the Pre-licensing Guidance Working Group, the Independent External Review Panel (a short-term advisory committee charged with identifying vulnerabilities in the NRC’s materials licensing program), and the Materials Program Working Group. All three groups had State representatives. The Pre-licensing Guidance Working Group issued revised guidance requiring pre-licensing site visits for “unknown” licensees on September 22, 2008. The guidance also required site visits for new and existing licensees requesting materials in quantities of concern. The Independent External Review Panel concluded its analysis on March 18, 2008, by issuing its report and briefing the Commission. The Panel made eight recommendations. The recommendations focused on changing the culture of NRC and Agreement State licensing programs to be more security minded. The Materials Program Working Group issued its comprehensive report on NRC’s radioactive materials program on October 23, 2008. The report offered a number of recommendations on the licensing process, inspection frequencies, security culture, and electronic tracking of sources and licenses. In February 2009, the Materials Program Working Group’s Steering Committee concluded its assessment of the working group’s recommendations. Those recommendations that will be implemented have been integrated with the Independent External Review Panel’s recommendations. Implementation is now under way. Major milestones that will address a number of the recommendations include revisions to the licensing guidance in NUREG-1556, the inspection guidance in Inspection Manual Chapter (IMC) 2800, and the training and qualification program for license reviewers and inspectors in IMC 1246. NRC staff estimates that it will take 3-5 years to complete all of the actions resulting from the recommendations.

SECURITY AND USE OF CS-137 CHLORIDE SOURCES

The safe and secure use cesium-137 chloride (CsCl) sources has been identified for attention 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 as used in these applications is highly soluble in water and easily dispersed in aerosol form, and consequently,

presents 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.

Several significant recent 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. Staff reviewed the results of the initial phase of inspections for compliance with the security orders, and, in conjunction with the Agreement States, conducted a review of the effectiveness of the implementation of the Increased Controls requirements and found good compliance with the requirements. The results are continually reviewed and provided to the working group developing the enhanced security measures proposed rule. The working group will consider this information and identify potential revisions to the requirements and guidance to address the identified issues.

Security could further be enhanced by the addition of simple cost-effective modification of blood irradiators. NRC is supporting DOE/NNSA in conducting a program to install physical protection measures on blood irradiators to enhance security of the sources.

To obtain input from stakeholders regarding the path-forward, the staff held a public workshop in September 2008, on five issues that were structured to initiate public comment. These five issues included (1) alternatives to the use of CsCl sources, (2) use of alternative technologies, (3) possible phase-out of CsCl sources, (4) additional requirements for enhanced security of CsCl sources, and (5) role of risk analysis in potential future CsCl requirements. The workshop was attended by 210 participants and the staff received 141 written comments. The stakeholder feedback received strongly indicated that near term replacement of devices or CsCl sources in existing blood, research and calibration irradiators is not practicable and would be disproportionately detrimental to patient health, longstanding research, and emergency response capabilities.

The staff also conducted a series of visits to the manufacturers of CsCl irradiators and sources between December 2007 and April 2008. A cohesive set of conclusions emerged from the manufacturers: for development of high activity sources using less soluble and dispersible forms of Cs-137, a significant research effort is needed; scaling up from current small activity levels may not be technologically successful; and if security is to be enhanced, the NRC should work with the industry to identify cost effective feasible enhancements.

The NRC staff compiled the relevant information into a Commission paper, "Strategy for the Security and Use of CsCl Sources" SECY-08-0184 dated November 24, 2008. In the paper, the staff has developed options for Commission consideration on a path forward based on information gathered from staff analysis, stakeholder inputs, a public workshop, site visits, and other sources. The Commission has approved the staff's recommendation for Option 1 of the paper, and issued requirements to the staff for follow-up actions in April 2009.

Currently, the staff is pursuing the following initiatives in response to Commission direction: (1) developing a policy statement on the protection of CsCl sources; (2) working with Federal partners to initiate research on (a) alternate chemical forms for large activity cesium-137 sources, (b) development of risk-based definitions for solubility and dispersibility, and (c) incentives for further voluntary enhancements of irradiator security; and (3) integrating these interagency efforts into the report of the Radiation Source Protection and Security Task Force which is due to the President and Congress in August 2010.

NRC/NNSA ACTIVITIES

Nuclear and radioactive materials are a critical and beneficial component of global medical, industrial, and academic efforts. The possibility that these materials could be used by terrorists is a national security concern. Domestically, the Department of Energy/National Nuclear Security Administration (NNSA) and the Nuclear Regulatory Commission (NRC) have partnered with state, local, and tribal governments, other federal agencies and the private sector with a common goal of preventing nuclear and radiological material from being used in an improvised nuclear device, a radiation exposure device, or a radioactive dispersal device – a so-called “dirty bomb”. Internationally, NNSA and NRC cooperate to identify countries and regions where the two organizations can work either together or independently to improve nuclear and radiological security.

The NRC and state regulatory agencies have worked together to create a strong and effective regulatory framework that includes licensing, inspection, and enforcement. This partnership ensures the security of 32 civilian nuclear research and test reactors and over 70,000 high-risk radioactive sources without adversely impacting their beneficial uses. This framework provides a common baseline level of security to ensure adequate protection of public health and safety and the common defense and security. Key elements include:

- Background checks, including fingerprinting, employment history, education and personal reference checks, to limit access to approved individuals;
- Enhanced physical barriers and intrusion detection systems, including guards and alarms, to monitor and immediately detect, assess and respond to unauthorized access;
- Coordination with local law enforcement to respond to an actual or attempted theft, sabotage, or diversion of nuclear or radioactive materials;
- Prompt notification of incidents to the appropriate government agency; and
- Closer monitoring of shipments to ensure the security of nuclear and radioactive material during transit.
- National Source Tracking System to track and account for, from cradle to grave, all the radioactive sources that warrant greatest control.

The ultimate responsibility for securing nuclear and radioactive materials in the United States rests with the licensees who possess these materials. To assist in that effort, NNSA works with the NRC, the materials licensees, state, local and tribal governments, and other federal agencies, to build on the existing regulatory requirements by providing voluntary security enhancements. Examples of these enhancements include:

- Remove disused radioactive sources, including packaging, transport, and secure disposition;
- Voluntary security upgrades based on best practices, including federally funded upgrades such as cesium-chloride irradiator hardening and facility specific security upgrades (e.g. deterrence, control, detection, delay, remote monitoring to ensure response, and sustainability);
- Specialized training for local law enforcement so they can better protect themselves and their communities when responding to alarms at facilities with nuclear and radioactive materials;
- No-fault table top exercises, co-sponsored with the Federal Bureau of Investigation, to promote cross communication, cooperation, and training in response to terrorist acts involving nuclear and radioactive materials; and
- Transportation Security, including a test bed and voluntary pilot demonstration of cargo hardening, alarm assessment, and shipment tracking.

These voluntary security enhancements are complementary to and do not replace the licensee's obligation to meet NRC and Agreement State regulatory requirements. The voluntary security enhancements are sound, cost-effective, and prudent best practices which further improve security above regulatory requirements.

NNSA is also working on alternative technologies research and development (R&D), focusing on non-radioactive replacements (e.g. x-rays) for the highest risk radioactive sources.

These efforts are an excellent example of Federal, State, Tribal, and local agencies working in cooperation with the private sector to further reduce the risks of terrorism involving nuclear and radioactive materials in the United States.

NRC and NNSA have complementary and coordinated programs aimed at assisting our international counterparts improve the security of nuclear and radioactive materials. International efforts include working bilaterally with the host country, regionally with the host and other donor countries, and/or in partnership with the International Atomic Energy Agency (IAEA).

NNSA's program includes a variety of security efforts including:

- Searching for, securing, and/or recovering orphaned and abandoned radioactive sources;
- Designing and installing physical protection upgrades for sites with nuclear and radioactive materials;
- Assessing security of the transportation of nuclear and radioactive materials and providing training and transportation security upgrades;
- Conducting response force training; and
- Assisting countries in sustaining and properly operating these nuclear and radiological security upgrades by working with each country to establish national-level regulations and inspection mechanisms.

NRC works internationally with select international regulatory counterparts to implement key provisions of the IAEA-sponsored Code of Conduct on the Safety and Security of Radioactive Sources including:

- Development and maintenance of a national registry of radioactive sources;
- Development, implementation and maintenance of legal, technical and licensing bases for safety and security regulatory oversight; and
- Conducting workshops that describe NRC's physical protection requirements for radioactive materials and provide an overview of U.S. legal and regulatory framework, source security requirements, increased controls, security inspections and enforcement.

These efforts, in total, improve long-term nuclear and radiological security by ensuring that nuclear and radioactive materials are subject to continuous, effective nuclear regulatory safety and security oversight.

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.

Approximately 1,400 licensees are reporting information on over 70,000 sources to the NSTS. Over 140 transactions are reported to NSTS daily. The majority of the sources found in NSTS are Cobalt-60 (93%), Iridium-192 (3.5%), and Cesium-137 (3%). The majority of transactions for manufacture, transfer, and receipt, are with Iridium-192.

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 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
 - Lost and Stolen Sources
- 2) Reporting Capabilities
- 3) Automated Alerts for Significant Events
 - Pending/Overdue Transfers
 - Pending Licensing Agency Verifications (Make/Model, Licensees, 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. Some of the pertinent Version 2 requirements were removed from the Version 2 of NSTS and put into a maintenance release. These include the annual inventory verification functionality, and the decay calculation.

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 bi-monthly conference calls with the Agreement States to discuss NSTS issues and plan for upcoming events.

With one year of operations and one Annual Inventory reconciliation underway, we are working through identified improvements for better functionality and more timely entry of data.

WEB-BASED LICENSING

NRC staff evaluated additional alternatives for completing the development of the Web-Based Licensing (WBL) System, and recently selected an existing Government-Off-the-Shelf (GOTS) materials licensing solution as the base product for WBL implementation. WBL is intended to modernize existing legacy licensing systems to provide an integrated, comprehensive license information system for the byproduct materials arena accessible by NRC staff, licensees, Agreement States, other Government agencies and the public. The GOTS product is currently being adopted for internal NRC use by migrating License Tracking System (LTS) data to the new system environment (LTS 2.0) and configuring the system to initially serve as a replacement for LTS. LTS 2.0 is presently in the final user acceptance test and system verification phase and is expected to be released in April, 2010. 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. To support this capability, NRC will expand WBL to include Agreement State license data and serve as a nationwide repository of license information. A joint NRC/Agreement State working group was established in June 2008 to develop a plan for including Agreement State license information in WBL. The working group recently completed a review of information provided by 22 Agreement States on the status and availability of State licensing information, and is currently evaluating potential challenges to obtaining the State data and incorporating it in WBL. NRC staff submitted a report with the recommendations and findings based on the provided information (Task 1) to NRC management. The WBL working group members will continue to work on the remaining tasks and submit their findings and recommendations to management when completed.

TRITIUM EXIT SIGNS PATH FORWARD

The staff is presently engaging manufacturers and distributors to ensure they provide complete information and adequate notification of licensees who purchase tritium exit signs (TES), per the regulatory requirements in 10 CFR Part 32.51a. To improve the inventory of tritium exit signs in the NRC's General License Tracking System (GLTS), the staff will engage manufacturers and licensees to obtain information to update GLTS. The staff will use Petition for Rulemaking 32-6 to comprehensively consider TES control long-term

EMERGENCY RESPONSE INITIATIVES

The NRC's State outreach and reactor/materials exercise programs are intended to help state and local emergency response personnel understand the capabilities of the federal Government, and the NRC in particular, in the event of a radiological emergency. A benefit of federal, state and local participation in reactor exercises is a better understanding and coordination among these various agencies during real-world events.

The current CY 2010 exercise participation schedule, including regional participation, is located at: <http://www.nrc.gov/about-nrc/emerg-preparedness/exercise-schedules/nrc-ex-schedule.html>.

INTERNATIONAL NUCLEAR AND RADIOLOGICAL EVENT SCALE (INES)

On July 13, 2009 and March 15, 2010, FSME sent out All Agreement State letters FSME-09-052 and FSME-10-027, on the current status of INES and the publication of a new User's Manual

(ML091880272). By way of background, All Agreement States Letters (STP-02-018 and STP-04-064) provided information related to NRC's participation in the International Atomic Energy Agency's (IAEA) INES. INES is used for promptly and consistently communicating to the public the safety significance of incidents and events associated with sources of radiation. It covers a wide spectrum of practices, including industrial use such as radiography, use of radiation sources in hospitals, activities at nuclear facilities, and the transport of radioactive material.

Initially, the scale was applied to classify events at nuclear power plants, and then was extended and adapted to enable it to be applied to all installations associated with the civil nuclear industry. The STP-04-064 letter described a pilot program that was initiated worldwide in 2004 to expand the use of INES to include the rating of transport and radiation source events. The pilot's successful use of the draft guidance from 2004-2007 allowed the IAEA and its INES Advisory Committee to obtain feedback on the rating of such events and to provide insights for a full revision of the 2002 INES User's Manual. As a result of these efforts, a new revised INES User's Manual was later developed and approved by the 63 member countries that use INES in July 2008. This new User's Manual incorporates the radiation source pilot initiatives and allows for the communication of the safety significance of all events associated with the transport, storage and use of radioactive material and radiation sources.

NRC continues to work with the Agreement States to submit information on certain new events (those events that exceed a Level 2 on the INES Scale, such as overexposures) to the IAEA as a *provisional rating* within 48 hours of notification of the event. The following link: <http://www.iaea.org/Publications/Factsheets/English/ines.pdf> provides more concise information about the INES scale and its application for nuclear and radiological materials.

MULTIPLE MEDICAL EVENTS AT PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER

Ninety seven medical events that involved iodine-125 permanent seed implants to treat prostate cancer occurred between February 2002 and May 2008 at the Philadelphia Veterans Affairs Medical Center (PVAMC). These events were not identified nor reported to the NRC until after May 2008. Inspections by the NRC identified that a substantial programmatic breakdown occurred in the brachytherapy program at the PVAMC. It was determined that the staff involved in the treatments failed to take action when the dose delivered to the prostate was less than the prescribed dose. It was also determined that the PVAMC had inadequate policies, procedures, and training, inadequate program oversight at multiple levels of responsibility, and was lacking in safety culture. The prostate brachytherapy program at the PVAMC has been suspended with no plans to re-start. The NRC issued a substantial civil penalty (\$227,500.00) to the Department of Veterans Affairs for violations of NRC requirements identified at PVAMC.

NIST AND VA LESSONS LEARNED

As a result of the events at the Veterans Administration (VA) Philadelphia Medical Center (improper prostate brachytherapy treatment for approximately 90 patients) and National Institute of Standards and Technology (NIST) - Boulder Colorado (improper handling of a source containing powered Plutonium), the NRC staff chartered two internal lessons learned teams which will provide reports in the late spring. The team reviewing the VA event will look at a number of issues including the adequacy of NRC oversight of Master Materials Licensees. The team reviewing the NIST event will look at a number of issues including, the adequacy of licensing guidance on what constitutes a sealed source.

PATIENT RELEASE

Congressman Edward Markey has sent the NRC two letters asking question about the patient release criteria of 10 CFR Part 35.75. Some of the issues raised in the letters and accompanying questions touch on the whether or not release of patients to hotels should be restricted, the adequacy of NRC inspection and documentation of the review of licensee records for patients released under 35.75, and the NRC's lack of any reporting requirements for cases where members of the public may be overexposed by released patients. As a result of earlier questions raised by regional inspectors, the NRC staff is presently reviewing the adequacy of guidance relating to release of patients to hotels.

MEDICAL ISOTOPES (Mo-99)

As of April 5, 2010, the NRC has received four letters of intent (B&W, GE, MURR, Coqui) for domestic Mo-99 production facilities, but no applications. Additionally, the NRC is reviewing a regulatory issues request from another potential producer (AMIC). The Department of Energy (DOE) is focusing on the development of four distinct technologies: low enriched uranium (LEU) solution reactor (Aqueous Homogeneous Reactor, AHR), neutron capture (natural molybdenum targets), LEU conventional targets (RTR), and accelerator driven fission in uranium solution. They have signed cost sharing Cooperative Agreements (CA) with B&W and GE Hitachi which requires 3,000 6-day Curies of Mo-99 production using LEU by the end of 2013. The agency's initial point of contact is an internal Mo-99 Working Group (WG) composed of staff from most NRC 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 March 10, 2010, the WG meet with members of the medical isotope community including Lantheus and Covidien. The American Medical Isotopes Production Act of 2009, (HR 3276) passed the House (11/5/2009) and the Senate Committee on Energy and Natural Resources, with amendments (12/16/2009). Sen. Bond has placed a "hold" on the bill related to the cutoff date for highly enriched uranium (HEU) of US origin for medical isotope production. NNSA and industry representatives have met with him. The bill provides the Energy secretary \$163 million to support Mo-99 domestic production projects. NRU in Canada has completed 65% of repairs as of March 31, 2010 and has revised the return-to-service date to the end of July 2010. Petten in the Netherlands shut down for repairs on February 19, 2010 until mid-August. Covidien reached an agreement with POLATOM on February 16, 2010 to irradiate targets at Poland's Maria Reactor to produce Mo-99. On March 10, 2010 FDA approved its domestic use so U.S. patients could begin benefiting later that month. Covidien provides a daily projection calendar for Tc-99m generators in order to maintain the community informed of expected availability levels. There are no NRC licensed facilities being considered for U.S. short term production.

INSPECTION MANUAL CHAPTER (IMC) 2800

The last revision to IMC 2800, which established the general policies for the materials inspection program, occurred in September 2005. Since that time, the NRC and Agreement States have implemented new security requirements. As a 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, coordination with Agreement States, and inspections for all locations possessing quantities of concern. The latest draft revision of IMC 2800 was issued to the Agreement States for comment in FSME-10-013 on February 18, 2010.

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 were identified following a GAO sting in 2007 during which time vulnerabilities in the materials licensing process were exposed. 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 over 3 years. (The tentative start and finish dates are April 2010 and June 2013, respectively). The charter will be refreshed periodically at which time the working group assignments and volume ranking for revision may be re-issued. The first few volumes to undergo review and update include the following: Vol 1, Portable Gauges; Vol 2, Industrial Radiography; Vol 4, Fixed Gauges; and Vol 16, Generally License Distribution/Devices.

NARM

Section 651(e) of the EPA Act of 2005 expanded the definition of byproduct material in Section 11e. of the Atomic Energy Act of 1954, as amended (AEA) to include discrete sources of radium-226, accelerator-produced radioactive materials, and other discrete sources of naturally-occurring radioactive material (hereafter referred to as NARM). The EPA Act required the Commission to provide a regulatory framework for licensing and regulating the additional byproduct material. A NARM Working Group and a Steering Committee were established with active participation from representatives of OAS and CRCPD as a voting member.

The final rule on the Expanded Definition of Byproduct Material was published in the *Federal Register* on October 1, 2007, and became effective on November 30, 2007 (72 FR 55864, 73 FR 42671). Although, the legislation made NRC's authority over NARM effective immediately when the bill was enacted in August 2005, NRC published a time-limited waiver of the requirements in the *Federal Register* (70 FR 51581) on August 31, 2005. The waiver allows persons owning, using, and otherwise engaging in activities involving NARM to continue with their activities and States to continue to regulate such material during the waiver period. NRC planned to terminate the waiver in phases, starting from the effective date of the rule and ending on August 7, 2009. The approach used to determine in which phase the waiver would terminate for States and U.S. Territories considered: (1) the scope of the current State's regulatory program, (2) the estimated total number of licensees impacted, and (3) the State's level of interest in becoming an Agreement State.

NRC published a "Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material" (transition plan), in the *Federal Register* (72 FR 59157), for assuming the new authority over NARM on October 19, 2007. The Agreement States which regulate radioactive materials under agreements with the NRC retained regulatory authority over NARM under their existing agreements with the agency.

NRC has finalized the NUREG-1556 guidance for Volume 9, Revision 2, "Program-Specific Guidance about Medical Use Licenses," Volume 13, Revision 1, "Program-Specific Guidance about Commercial Radiopharmacy Licenses," and the new Volume 21 "Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator." NRC provided stakeholders with an opportunity to comment on these NUREGs in the Spring/Summer of 2007. NRC is also planning to make minor revisions, which reflect the regulation of NARM, to other NUREG-1556 licensing guidance documents and related inspection procedures. Furthermore, the NRC announced the availability of a set of "Frequently Asked Questions" on radium-226 in FSME letter 08-082 dated November 7, 2008

Information on NARM-related activities is available in the "NARM Toolbox" on the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Web site at: <http://nrc-stp.ornl.gov/narmtoolbox.html>.

AGREEMENT STATE TRAINING

To assist the Agreement States in maintaining adequate and compatible programs, the Commission approved the restoration of NRC funding the training and associated travel for Agreement State staff. The funding went into effect on January 1, 2008. The NRC staff revised the FSME Procedure for Agreement State training (SA-600) to reflect this change in policy. The procedure provides a prioritization process for selecting attendees at the NRC sponsored courses to provide for an equitable distribution among the States of the spaces in the courses. The funding level provided was for the currently scheduled training classes.

During the period of October 1, 2008-September 30, 2009 (FY 2009), NRC sponsored 39 training courses, during which 414 training slots were filled by Agreement State personnel. 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 are mobile (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.

NRC/OAS/CRCPD WORKING GROUP STATUS

NRC and the Agreement States continue to address policy and rulemaking issues using NRC/State Working Groups. Management Directive 5.3, Agreement State Participation in Working Groups, was revised in December, 2009. A list of currently active working groups is located on the NRC website at: http://nrc-stp.ornl.gov/special/nrc-as_working_grps.pdf.

WORKING GROUP PRIORITIZATION

In SRM-M080814 dated August 26, 2008, the Commission suggested that staff work with OAS and CRCPD to develop specific plans to prioritize materials security related activities and establish a well defined path that represents the most effective sharing of responsibilities and resources. Subsequently, staff has been working with OAS and CRCPD to establish priorities and improve integration of the work from various materials related working groups on a semi-annual basis.

After the most recent meeting with OAS and CRCPD on October 27, 2009, it was determined that, in 2010, the top priorities will be the Part 37 rulemaking, blending of low level waste and

launching the revision of the NUREG-1556 series for materials licensing. An additional priority will be given to better communicate to the States the intent and benefits of NSTS, WBL and LVS (ISPM system), and to have a clear understanding on feedback expectations of working group members and their significance in the NRC rulemaking process. It is expected that, in 2011, even more attention will be given to reinvent the Inspection/License Reviewer Qualification Program, end-of-life management for sources, and updates to Part 20. A continuous priority is to monitor activities of established working groups through work products to ensure timely completion of working group tasks that will serve to enhance the materials safety and security.

STATUS OF AGREEMENT STATE NEGOTIATIONS

Currently only one State is negotiating an Agreement; Michigan.

Michigan

NRC received a letter of intent from Michigan's Governor on July 31, 2007, indicating the State's intent to pursue an Agreement. In November 2008, the State indicated that they were working on entering into an Agreement with the NRC by 2013. Since that time, the State's progress towards an Agreement has been slowed due to State budget shortfalls and the need to consolidate the radiation control program into one Department. Some key radiation program staff may retire later this year due to an incentive package being proposed with the goal of reducing the State workforce.

New Jersey

On September 2, 2009, the NRC approved an Agreement with the State of New Jersey under Section 274b. of the Atomic Energy Act of 1954, as amended. The Agreement was signed by Chairman Jaczko on September 8, 2009, and by Governor Corzine on September 23, 2009. The Agreement became effective on September 30, 2009. New Jersey becomes the 37th state to sign such an Agreement with the NRC.

Under the Agreement, New Jersey has regulatory authority for byproduct materials as defined in Sections 11e.(1), 11e.(3), and 11e.(4) of the Act; source materials; special nuclear materials not sufficient to form a critical mass, and regulation of land disposal of byproduct material, source material, or special nuclear material waste received from other persons. New Jersey did not seek authority for the following: (1) conduct safety evaluations of sealed sources and devices manufactured in New Jersey and distributed in interstate commerce, or (2) the regulation of Section 11e.(2) byproduct material resulting from the extraction or concentration of source material from ore processed primarily for its source material content, and its management and disposal.

IMPEP SELF ASSESSMENT

On March 16, 2009, NRC's Office of the Inspector General (OIG) issued an audit report titled, "Audit of NRC's Agreement State Program." The objective of the audit was to assess NRC's oversight of the adequacy and compatibility of Agreement State programs. The OIG focused its review on IMPEP as well as other elements of the Agreement State program. The OIG made the following findings in its report:

- 1) Management does not effectively monitor IMPEP operational issues.
- 2) NRC could be challenged to re-exert authority over an Agreement State program in the event of an emergency.

- 3) NRC lacks standardization in communications with, and collection from, the Agreement States.
- 4) Weaknesses exist in NRC's review of Agreement State event reporting.

The OIG made several recommendations, including the following: "Develop a mechanism for conducting self-assessments and capturing lessons learned for IMPEP on a regular basis." In response to this recommendation, an NRC-Agreement State team has been formed to prepare a self-assessment of IMPEP. The team will meet on March 31-April 1 to finalize a charter and project plan. The team will be led by a retired NRC executive and will complete its work by July 31, 2010. The scope of work will include the IMPEP process as it has been documented and conducted since the 2002 WG report and will make appropriate findings and recommendations to improve program effectiveness. The scope also includes preparation of a procedure which will result in periodic conduct of self-assessments in the future.

SAFETY CULTURE POLICY STATEMENT

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. The draft policy statement is intended to expand the Commission's policy on safety culture to address the unique aspects of security and to ensure the resulting policy is applicable to all licensees and certificate holders. 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. 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>. The results from this public workshop and public comments on the draft policy statement will be used to develop a final policy statement. The NRC staff is planning on providing the Commission with its recommendations for the final policy statement in March 2011.

PANDEMIC AND COOP ACTIVITIES

Since 2007, NRC has engaged in activities regarding Agency readiness in the event of a Pandemic and Continuity of Operations situation, including establishing agency Pandemic and COOP Working Groups to evaluate issues, developing Pandemic and COOP Plans and support rosters, conducting staff awareness and training, engaging in outreach to staff and licensees, and coordinating with other regulators.

To test the robustness of the Plans, NRC has conducted both Pandemic and COOP exercises. NRC has conducted internal Pandemic exercises since 2008. NRC participates in federal-wide COOP exercises every other year, starting in 2008, supplemented by internal exercises in interim years.

Some of the major issues addressed by the working groups have included:

- Flu Control in the Workplace
- Development and testing of an Agency-Wide Personnel Availability System
- Review of Essential Staff and Contract Support
- Development of a Staff Emergency Notification System
- Further refinement of Agency and Office Specific Pandemic Plans
- Monitoring the Status of Regulated Activities During a Pandemic or COOP Situation

Major issues that emerged from the Pandemic Tabletop Exercises included:

- The need for identification of priorities, identification of contingent resources and technical expertise in order to supplement staff during high absenteeism.
- The importance of considering and developing plans for recovering activities that have been deferred (held-off until later in the pandemic) or shed (stopped altogether until the office is back to normal or near-normal staffing).
- The importance of putting Telework contingency plans in place now – not waiting until absenteeism increases.
- The need to have clearly defined orders of succession so that decision-making will not be interrupted during periods of high absenteeism, and the need to ensure reliable communications for those decision-makers, especially at the onset of a COOP situation.
- The ability to address work-place safety, including cleanliness in the event of a pandemic (e.g., cleaning of secretarial stations/SLES kiosks, and the availability of hand sanitizers), and safety of the building and area in the event of a COOP.

INTERNATIONAL RADIATION STANDARDS

NRC staff and management participate in a number of international radiation standards forums, including the International Atomic Energy Agency (IAEA), the Nuclear Energy Agency (NEA), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the International Commission on Radiological Protection (ICRP). These international agencies have been developing revised recommendations and standards for both the protection of humans and protection of the environment.

Protection of Humans

The previous set of ICRP recommendations were published in 1990 as ICRP Publication 60. Revised ICRP recommendations were published in December, 2007 as ICRP Publication 103. The basis of these recommendations continues to be the justification of exposures which are introduced, the protection of an individual from exposure, and the optimization of protection. Protection of the individual will be emphasized, with optimization constrained by the individual dose for a variety of exposure situations.

The IAEA has begun the process of considering revisions to the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. A first complete draft was reviewed during the summer of 2008, and comments from the CRCPD were included in the U.S. comments used in the Radiation Safety Standards Committee (RASSC) meeting in November, 2008. The IAEA has revised the draft, and posted it to its web site for IAEA member state review. CRCPD has been invited to provide comments as part of the development of the U.S. comments that are to be submitted by May 31, 2010. A public meeting, hosted by the Interagency Steering Committee on Radiation Standards (ISCORS), was held on February 26, 2010. NRC is coordinating closely with other Federal Agencies via ISCORS on the continuing review of this document, and will continue to engage the CRCPD.

The publication of the ICRP recommendations, and participation in IAEA revision of international standards is in parallel with NRC staff consideration of appropriate changes for NRC Standards for Protection Against Ionizing Radiation (10 CFR Part 20) and other regulations and guidance. At present, there are three generations of ICRP recommendations and dosimetric systems in use within the United States. The NRC staff provided options to the Commission in December, 2008 (SECY-08-0197) for moving the NRC regulatory framework towards greater alignment with the revised ICRP recommendations. In the SRM dated April 2, 2009, the Commission approved the staff's recommendation to begin engagement of stakeholders and the development of the necessary technical basis development for possible revision of the NRC's radiation protection regulations, as appropriate and where scientifically justified. Following an extensive set of presentations to various professional organizations, including CRCPD and the OAS, the NRC staff is now preparing for structured, facilitated round table stakeholder meetings to be held starting in June 2010. NRC staff will be inviting state representatives to participate in each of the three meetings.

Opportunities are increasing State participation in international activities, particularly in IAEA missions to provide review and assistance to developing countries. The CRCPD Chairperson elect participated in the December 2010 technical meeting of the IAEA to discuss specific provisions on radon for the Basic Safety Standards.

Protection of the Environment

ICRP has continued to pursue development of a framework for protection of the environment through a standing committee of the Commission. ICRP Committee 5 released a draft of the report on reference animals and plants in January, 2008, and the U.S. contributed a number of comments. The final document was published in 2009 as ICRP Publication 108.

IAEA has developed a Plan of Activities to guide international activities related to protection of the environment, based upon the work being done by ICRP, and other organizations. The Plan of Activities was approved by the IAEA Board of Governors in September, 2005. Coordination meetings were held in January, 2006, February, 2007, and June 2008.