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# **NRC Commissioners Briefing: Implementation of Energy Policy Act of 2005**

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May 15, 2006

# Acronyms Used in Presentation

- PET: Positron Emission Tomography
- FDG: Fluorine-18 fludeoxyglucose
- NH<sub>3</sub>: N-13 ammonia
- Rb: Rubidium-82 Chloride
- IMV: Information Means Value—Research Marketing Analysis
- FLT: Fluorine-18 flurothymidine
- FMISO Fluorine-18 fluoromisonidazole
- Cu-ATSM: Copper-64 diacetyl-bis-methylthiosemicarbazone

# Acronyms Used in Presentation

- F-RGD: Fluorine-18 cyclo(-Arg-Gly-Asp-D-Phe-Lys-(sugar amino acid)-)
- FDOPA: Fluorine-18 fluorodopa
- PIB: Carbon-11 Pittsburgh compound B
- F-Amyloid: Fluorine-18 amyloid
- ACMUI: Advisory Committee Medical Use of Isotopes
- T&E: training and experience
- NARM: Naturally occurring or Accelerator produced Radioactive Material

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# Acronyms Used in Presentation

- CT/PET: Computed tomography/PET
- R&D: Research and development
- RAM: Radioactive Materials
- FDOPA: Fluorine-18 fluorodopa
- FDA: Food and Drug Administration
- IAEA: International Atomic Energy Agency

# Importance of PET

- PET is an integral part of clinical Nuclear Medicine—field rapidly advancing the diagnosis and treatment of the most prevalent diseases:
  - Cancer: >90% of all studies-FDG
  - Cardiovascular Disorders:
    - Perfusion;  $\text{NH}_3$ , Rb; Viability; FDG
  - Brain disorders (dementia, seizures)-  
FDG

# PET Statistics

- Number of Cyclotrons USA: 2005: 177;  
2006: 185
- Number of PET scanners USA: 2005: 1280
- Number of PET scans performed
  - 2000: 211,600
  - 2005: 1,180,625
  - 2010 (projected): 2,086,647

Data from IMV Research

# Current PET Advances

- Research and Development
  - Cancer diagnosis: proliferation: FLT; hypoxia: FMISO, Cu-ATSM; Monitoring anti-angiogenesis: F-RGD
  - Neurological Disorders, Alzheimer's (FDOPA, PIB, F-Amyloid)
  - Cardiovascular Perfusion/Viability (F-18 flow agent)
  - Monitoring Therapy
- CT/PET

# **Accelerator-produced Radioactive Material**

- ACMUI supports proposed categorization of accelerators
- ACMUI endorses Not regulating therapy accelerators
- ACMUI supports High compatibility across state lines for
  - Mobile PET licenses
  - Centralized nuclear pharmacies
  - Standardized T&E requirements



# ACMUI Concerns

- Maintaining availability of PET radiopharmaceuticals for research & clinical practice is essential
- Noncommercial distribution of PET radionuclides for R&D
- Impact of Decommissioning Financial Assurance
  - Creates special hardship for older facilities
  - Concerns regarding 16 MeV cyclotrons

# ACMUI Concerns (continued)

- Aggressive implementation schedule may be difficult for new NARM licensees and NRC
  - mobile PET, free standing PET facilities
- License guidance needed at publication date of the final rule, which has been vetted
  - ACMUI must review prior to publication to refine and clarify

# ACMUI Comments

- NRC moving all RAM under single umbrella, similar to State regulation for ~40 years
- Must allow sufficient time interval for all states to come into compliance
- FDA has been “in process” of establishing regulations for FDG since 1995
- Medicare: May 8, 2006 extended coverage to cover all cancers under the new PET registry

# Ra-226 Discrete Sources

- Obsolete for medical/clinical applications since ~1989
- No other discrete sources (similar to Ra-226) expected for medical or medical research use
- Number of Ra-226 sources remaining in inventory is unknown
  - But  $\ll$  IAEA Code of Conduct Category 2 sources



Organization of Agreement States



# **NRC Commission Briefing May 15, 2006**

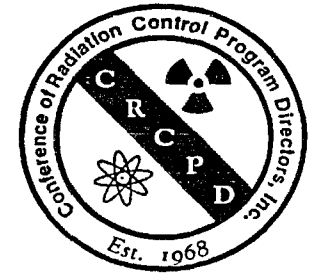
**Jared W. Thompson, Past-Chair  
Organization of Agreement  
States**

**Pearce O'Kelley, Chair  
Conference of Radiation Control  
Program Directors**



Organization of Agreement States

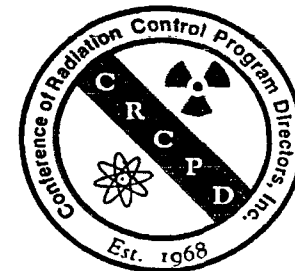
# NARM Rulemaking



- **Compatibility designation for definition of “byproduct material”**
  - **States have regulated NARM for over 40 years**
  - **Management Directive 5.9 specifically addresses the use of the term “radioactive material” in lieu of “byproduct material”**



Organization of Agreement States

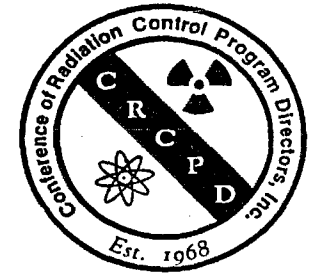


# NARM Rulemaking

- **33 of 34 Agreement States support a Compatibility Category “D” designation**
- **26 of 34 Agreement States are concerned they may have to seek legislative changes to amend the definition of “byproduct material”**
- **34 of 34 Agreement States already regulate NARM in a manner consistent and compatible with other byproduct material**



Organization of Agreement States



# NARM Rulemaking

- **Congress directed:**
  - **“The Commission...to the maximum extent practicable—  
(i) cooperate with the States;  
and (ii) use model State standards in existence on the date of enactment of this Act**





Organization of Agreement States

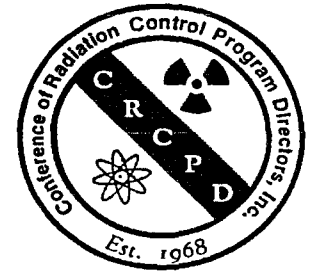


# NARM Rulemaking

- **To this end, the Compatibility Category for this and other definitions arising from the EPAct should be a “D”.**



# NARM Rulemaking



- **As an alternative, the Statements of Consideration should acknowledge that certification by the Governor that the State has an adequate NARM program which should preclude definitional changes**



Organization of Agreement States



# Sections 656 and 652

- **Support NRC staff recommendation –**
  - **Section 656 – Implement via Order to high-risk and high-priority licensees to meet deadline**
  - **Section 652 and 656 – Proceed in parallel to address imports, exports and domestic transfers/access comprehensively**

# **Comments on the Draft NARM Rulemaking & Secure Transfer**

Roy W. Brown  
Senior Director, Federal Affairs  
Council on Radionuclides and Radiopharmaceuticals



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# Acronyms Used in Presentation

NARM ≡ Naturally occurring or Accelerator produced  
Radioactive Material

CORAR ≡ Council on Radionuclides and  
Radiopharmaceuticals

AU ≡ Authorized User

ANP ≡ Authorized Nuclear Pharmacist

PET ≡ Positron Emission Tomography

DAC ≡ Derived Air Concentration (Part 20)

ALI ≡ Annual Level of Intake (Part 20)



# General Comments on NARM Rulemaking

- Staff has completed a tremendous amount of work in a short time frame.
- Staff has been very helpful and understanding to the medical community's needs.
- CORAR members are generally pleased with draft rulemaking.
- Rulemaking needs some minor fixes to assure smooth transition for medical community.

# Favorable Sections of Draft Rulemaking

- Delineation of three types of cyclotrons and their handling in rulemaking is appropriate.
- Grandfathering of Part 35 AUs & ANPs will be helpful to licensees.
- NRC's waiver will allow seamless operations until final rule is in place.
- CORAR is pleased another workshop will be held for regulated community.

# Concerns With Draft Rulemaking

- Although *Compatibility Level B* will provide some uniformity, CORAR fears some inconsistency among states will remain.
- Reciprocity between states needs to be improved.
- PET community needs specific DACs and ALIs for O-15 and N-13.



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# Concerns With Draft Rulemaking (Cont'd)

- Low energy ( $\leq 11$  MeV) PET cyclotrons which are self-shielded should not be required to have financial assurance for decommissioning.
- PET community needs cyclotron operators and engineers recognized as Part 30 AUs as is done in several states, and be grandfathered.

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# Concerns With Draft Rulemaking (Cont'd)

- The new fee structure in Part 170 will negatively impact facilities located in non-Agreement states, which will now be under NRC's jurisdiction.

# Comments on Secure Transfer Portion of EPA Act

- CORAR feels radiopharmaceutical and medical radionuclide shipments do not warrant inclusion in *secure transfer* rulemaking.
- Congressional intent (from '03 cmte report) was to exclude these materials: “The NRC should focus particular attention on identifying radiopharmaceuticals and other medical materials for appropriate exemption from the new regulations, to assure the uninterrupted availability of these materials to patients that need them”

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# **Comments on Secure Transfer Portion of EPA Act (Cont'd)**

- Although CORAR has not seen the draft rulemaking, we understand it is NRC staff's intent to exclude these materials from the rulemaking.

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# Summary

- Thank you for opportunity to present our comments directly to you.
- We will continue to work with NRC staff on the NARM rulemaking.
- We hope we have the opportunity to directly interact with the Commission in the future.



**Briefing on Status of  
Implementation of  
the Energy Policy Act  
of 2005**

**May 15, 2006**

# Acronym Slide

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **CORAR – Council on Radionuclides and Radiopharmaceuticals**
- **CRCPD – Conference of Radiation Control Program Directors**
- **DHS – U.S. Department of Homeland Security**
- **DOT – U.S. Department of Transportation**
- **EPAAct – Energy Policy Act of 2005**
- **H&S – “Health and Safety” (adequacy designation)**
- **NARM – Naturally Occurring and Accelerator-produced Radioactive Material**
- **NMSS – NRC’s Office of Nuclear Material Safety and Safeguards**
- **NORM – Naturally Occurring Radioactive Material**
- **OAS – Organization of Agreement States**
- **SECY – NRC’s Office of the Secretary of the Commission**
- **SIG – Safeguards Information**
- **TSA – Transportation Security Administration**

# **Overall Status of Implementation Activities**

- **Many Implementation Actions Completed**
- **Majority of Remaining Actions on Schedule**
- **Several of Remaining Actions will be Discussed in More Detail**
  - **Sections 651(e), 652 and 656**



# **Section 651(e)**

## **Accelerator-Produced and Other Radioactive Material**

**Amend definition of byproduct material  
to include:**

- Accelerator-produced radioactive material**
- Discrete sources of radium-226**
- Discrete sources of other NORM that pose  
a threat similar to discrete sources of  
radium-226**

# **Section 651(e) - Waivers**

- **EPAct allows the Commission to grant waivers to allow current programs to continue regulating**
- **NRC issued waiver on August 25, 2005**
- **Waiver was published in the Federal Register on August 31, 2005  
(70 FR 51581)**

# **Section 651(e) - Outreach**

## **Stakeholder Input**

- **To the maximum extent practicable, NRC will:**
  - **Consult and cooperate with States**
  - **Use model State standards**
- **Other stakeholders - Consultation**

# **Outreach (cont'd)**

## **Public Meeting**

- **Roundtable Discussion, 11/9/2005**

## **Interagency Meeting**

- **Discussion of definition of "discrete source," 11/17/2005**

# Outreach (cont'd)

## State Involvement

- FL, MI, OR, and TX on NARM Rulemaking Working Group
- AR (OAS) and CA (CRCPCD) representatives on Steering Committee
- OR (CRCPCD) and NC (OAS) participated on NMSS EPAct Task Force
- CA and IL served as resource members for NMSS EPAct Task Force

# Outreach (cont'd)

## Staff Presentations

- OAS Annual Meeting, 10/4/2005
- U.S. Food and Drug Administration Meeting, 11/17/2005
- CORAR Manufacturing, Quality, and Safety Committee Meeting, 12/7/2005
- Interagency Steering Committee On Radiation Standards Meeting, 1/26/2006
- High Country Nuclear Medicine Conference, 2/27/2006
- Advisory Committee on Nuclear Waste Presentation, 4/18/2006
- Advisory Committee on the Medical Uses of Isotopes Presentation, 4/25/2006
- U.S. Department of Veterans Affairs Master Materials License Meeting, 5/3/2006
- CRCPD Annual Conference, 5/9/2006

# **Section 651(e) - Status**

- **Proposed Rule developed (SECY-06-0069)**
- **Draft Proposed Rule and SECY Paper publicly available on NRC's RuleForum website (as of 4/7/2006)**
- **Final Rule due no later than 2/7/2007 (required by EPA Act)**

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# **Section 651(e) - Rulemaking**

## **Key Issues**

- **Definition of "discrete source"**
- **Exercise of authority over accelerator-produced radioactive material in accelerators**
- **Regulatory approach for certain discrete sources of radium-226**
- **Waiver termination strategy**



# **Section 651(e) - Compatibility**

- **Staff applied the process described in Management Directive 5.9**
- **Staff recommends a designation of "H&S" for the definition of byproduct material**
- **Program elements with a designation of "H&S" are required to be addressed as part of an Agreement program, as a matter of adequacy, and therefore are reviewed by NRC staff**

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# Compatibility (cont'd)

- **State members of the Steering Committee, and the Agreement States in general, did not agree with the “H&S” designation**
- **OAS and CRCPD letters on this issue are attached to the Commission Paper**
- **Program elements with Compatibility “D” are not a required part of an Agreement program, and therefore are not reviewed by NRC staff**

# Compatibility (cont'd)

- **"If the definition of the term byproduct material or another term (such as radioactive material) which encompasses all of the byproduct materials regulated by the State were not somewhere within the State program (i.e., in statute or in regulations) it is possible that some byproduct material could escape regulatory oversight with a result of exposure to an individual in excess of the Part 20 limits"**

# **Section 651(e) - Summary and Next Steps**

- **Staff developed a draft proposed rule, in a very short time period, that addresses a number of EPA Act issues**
- **The proposed rulemaking under Section 651(e) is a key expansion of NRC's authority**

# **Summary and Next Steps (cont'd)**

- **Once the proposed rule is published, staff will continue to reach out to Agreement States, non-Agreement States, the public, and affected industry stakeholders**
- **The staff will hold a public meeting during the public comment period**
- **Achieving the 2/7/2007 Final Rule date remains a challenge**

# **Section 656 - Secure Transfer of Nuclear Materials**

**For materials transferred or received in the U.S. by any party pursuant to an NRC import or export license, the Commission shall establish a system such that:**

- a. Materials are accompanied by a manifest describing type and amount of materials**
- b. Each individual receiving or accompanying the transfer shall be subject to a security background check conducted by appropriate Federal entities**

# **Secure Transfer of Nuclear Materials (cont'd)**

**Issue regulations not later than 1 year  
after date of EPA Act, identifying materials  
and classes of individuals that are  
appropriate exceptions**

# **Section 656 - Status**

- **Staff is drafting a proposed rule**
- **Staff is coordinating with Agreement States, DOT, DHS/TSA, and US Coast Guard**
- **Draft Proposed Rule is due to the Commission on 6/1/06**
- **Manifest requirements are already covered by existing DOT and NRC regulations**
- **System for security background checks has proven to be challenging in advance of the broader Section 652 rulemaking**



# **Section 656 - Recent Developments**

- **Agreement States and DOT have raised concerns about the proposed rule. Some States want the requirements to apply to importers and exporters only (exclusive NRC jurisdiction)**
- **Establishing exceptions now may set a precedent for the broader Sec 652 rule on fingerprinting and criminal history records check**

# Recent Developments (cont'd)

- In response, staff is considering an approach that initially focuses on the most significant quantities of material
- This approach would allow NRC to address fingerprinting through Orders until the broader Section 652 rulemaking could be completed
- Staff would clarify these issues in the Statement of Considerations on the Section 656 rule

# Section 656 - Next Steps

- **Complete Draft Proposed Rule and send to Commission**
- **Inform Congress about timing of Final Rule**
- **Continue outreach with Agreement States, DOT, DHS/TSA, and US Coast Guard**
- **Revise/supplement Orders to require fingerprinting and criminal history records check, where appropriate**
- **Address broader fingerprinting and criminal history records check issues through the Section 652 rulemaking**

# **Section 652 - Fingerprinting for Criminal History Records Check**

**The Commission shall require to be fingerprinted any individual who:**

- is permitted unescorted access to--
  - a utilization facility; or**
  - radioactive material or other property subject to regulation by the Commission that the Commission determines to be of such significance; or****
- is permitted access to safeguards information under section 147**

# **Fingerprinting for Criminal History Records Check (cont'd)**

**All fingerprints shall be submitted to the  
U.S. Attorney General for identification  
and a criminal history records check**

# **Section 652 - Status**

- **The statute requirements for fingerprinting for access to SGI are effective now, and staff is developing Orders**
- **Staff is proceeding to develop Orders to require fingerprinting for access to radioactive material**

# **Section 652 - Schedule**

- **Section 652 requirements are being incorporated through:**
  - **Current 73.21 rule package for access to safeguards information**
  - **Future rule to address access to material**

# **Schedule (cont'd)**

- **Schedule for Section 652 Orders and rulemakings to address fingerprinting and criminal history records check:**
  - **Order supplements/revisions:  
Under development**
  - **Final 73.21 rule to Commission:  
Approximately 10/06**
  - **Final Section 652 rule to  
Commission: 09/08**



# **EPAct of 2005 - Summary**

- **Beginning in August 2005, NRC immediately began activities to implement the Energy Policy Act of 2005**
- **NRC has made significant progress over the past eight months and continues to move rapidly**

# **EPAct of 2005 - Summary (cont'd)**

- **NRC reached out to stakeholders within the short time frames given in the statute, and involved States in the "NARM rulemaking" in an unprecedented manner**
- **While NRC has clear accomplishments, the Energy Policy Act requirements still present challenges for the staff**

# **Background Material**

## Energy Policy Act of 2005 Implementation Activities

EPAct Sec.	Title	Action	Schedule Milestone
601-609	Price-Anderson Act Renewal	Issue Final Rule amending regulations to implement revised P-A Act	Complete
622	NRC Scholarship and Fellowship Program	Provide Commission with draft program description	On Track
623	Cost Recovery from Government Agencies	- Issue proposed FY06 Fee Rule - Issue Final Rule	Complete On Track
624	Elimination of Pension Offset for Certain Rehired Federal Retirees	- Issue draft MD - Issue Final MD	Complete On Track
625	Antitrust Review	Issue Final Rule amending regulations to reflect elimination of antitrust reviews	Complete
629	Whistleblower Protection	- Complete Review of Management Directives - Incorporate contract clauses	On Track Ongoing
630	Medical Isotope Production	Issue Final Rule amending Part 110 to reflect revised export licensing criteria	Complete
632	Prohibition on Nuclear Exports to Countries that Sponsor Terrorism	Issue Final Rule amending Part 110 to prohibit export licenses to countries identified as engaged in State-Sponsored terrorism	TBD
637	NRC User Fees and Annual Charges	- Issue proposed fee rule for FY07 - Issue Final Rule	On Track On Track
638	Standby Support for Certain Nuclear Plant Delays	Provide first quarterly report to Commission on status of licensing actions associated with facilities covered by DOE program	TBD
639	Conflicts of Interest Relating to Contracts and Other Arrangements	- Submit proposed conflict of interest policy for Commission approval - Incorporate conflict of interest policy into MD 11.7	Complete On Track
644	Next Generation Nuclear Plant Project (NGNPP)	Joint NRC/DOE report to Congress on a licensing strategy for a prototype reactor.	On Track

## Energy Policy Act of 2005 Implementation Activities

EPAct Sec.	Title	Action	Schedule Milestone
645	Project Timelines and Authorization of Appropriations for NGNPP	<ul style="list-style-type: none"> <li>- Transfer of funds from DOE to NRC</li> <li>- Issuance of license</li> </ul>	TBD On Track
651(a)(1)	Security Evaluations	<ul style="list-style-type: none"> <li>- Provide proposed rule to Commission amending Part 73</li> <li>- Provide to Commission Congressional Annual Report on security force evaluation results</li> <li>- Provide to Commission Final Rule amending Part 73</li> </ul>	On Track On Track On Track
651(a)(1)	Design Basis Threat Rulemaking	<ul style="list-style-type: none"> <li>- Issue proposed rule amending DBT</li> <li>- Provide to Commission Final Rule</li> </ul>	Complete On Track
651(a)(3)	Federal Security Coordinators	Assign Federal Security Coordinator to each Region	Complete
651(b)	Backup Power for Certain Emergency Notification Systems	Issue Confirmatory Order to Indian Point to provide backup power for Emergency Notification System	Complete
651(c)(1)	Provision of Support to University Nuclear Safety, Security, and Environmental Programs	<ul style="list-style-type: none"> <li>- Issue draft program description</li> <li>- Issue Management Directive</li> </ul>	On Track On Track
651(c)(3)	Expenses Authorized to be Paid by the Commission	<ul style="list-style-type: none"> <li>- Issue draft program description</li> <li>- Amend Memorandum of Understanding with State Department</li> </ul>	Complete Complete
651(c)(4)	Partnership Program with Institutions of Higher Education	<ul style="list-style-type: none"> <li>- Develop policy and procedures</li> <li>- Award initial grants to qualified institutions</li> </ul>	On Track On Track
651(d)(1)	Radiation Source Protection, Import/Export Controls	Issue Final Rule to amend Part 110	Complete
651(d)(1)	Radiation Source Protection, Tracking System	<ul style="list-style-type: none"> <li>- Provide Final Rule to Commission for National Source Tracking System</li> <li>- Provide to Commission information paper on Category 3 sources</li> </ul>	Complete Complete
651(d)(1)	Radiation Source Protection, National Academy of Sciences Study	<ul style="list-style-type: none"> <li>- Award grant to NAS</li> <li>- Provide report to Congress on NAS study results</li> </ul>	Complete On Track

## Energy Policy Act of 2005 Implementation Activities

EPAct Sec.	Title	Action	Schedule Milestone
651(d)(1)	Radiation Source Protection, Task Force on Radiation Source Protection and Security	<ul style="list-style-type: none"> <li>- Finalize Task Force Charter</li> <li>- Provide first Task Force Report to Congress</li> </ul>	Complete On Track
651(e) (1)-(4)	Treatment of Accelerator-Produced and Other Radioactive Material as Byproduct Material	<ul style="list-style-type: none"> <li>- Provide proposed rule to Commission</li> <li>- Issue Final Rule</li> <li>- Issue transition plan for States concerning regulation of NARM and NORM</li> </ul>	Complete On Track On Track
652	Fingerprinting and Criminal History Record Checks	<ul style="list-style-type: none"> <li>- Provide proposed rule to Commission amending 73.21</li> <li>- Provide proposed rule to Commission amending 73.55</li> <li>- Provide proposed rule to Commission for other entities/individuals</li> </ul>	Complete On Track On Track
653	Use of Firearms by Security Personnel	<ul style="list-style-type: none"> <li>- Provide proposed rule to Commission amending</li> <li>- Provide Final Rule to Commission</li> </ul>	On Track On Track
654	Unauthorized Introduction of Dangerous Weapons	<ul style="list-style-type: none"> <li>- Issue proposed rule</li> <li>- Issue Final Rule</li> </ul>	On Track On Track
655	Sabotage of Nuclear Facilities, Fuel, or Designated Material	<ul style="list-style-type: none"> <li>- Issue proposed rule</li> <li>- Issue Final Rule</li> </ul>	On Track On Track
656	Secure Transfer of Nuclear Materials	<ul style="list-style-type: none"> <li>- Provide proposed rule to Commission</li> <li>- Issue Final Rule</li> </ul>	Pending Pending
657	Department of Homeland Security Consultation	Develop protocol with DHS on security consultation process and provide to Commission	On Track
953	Advanced Fuel Cycle Initiative	Provide to Commission information on policy and resource implications	Complete