



**Fuel Facilities and  
Nuclear Materials Users  
Business Lines  
Commission Briefing  
April 26, 2018**



# **Opening Remarks**

**Victor M. McCree**  
**Executive Director**  
**for Operations**

# **Fuel Facilities Business Line Meeting Agenda:**

- **Business Line Overview –  
Marc Dapas**
- **Current Program Environment –  
Craig Erlanger**
- **Inspection Program Activities –  
Eric Michel**
- **Fee Billing Project Update –  
Brian Smith**



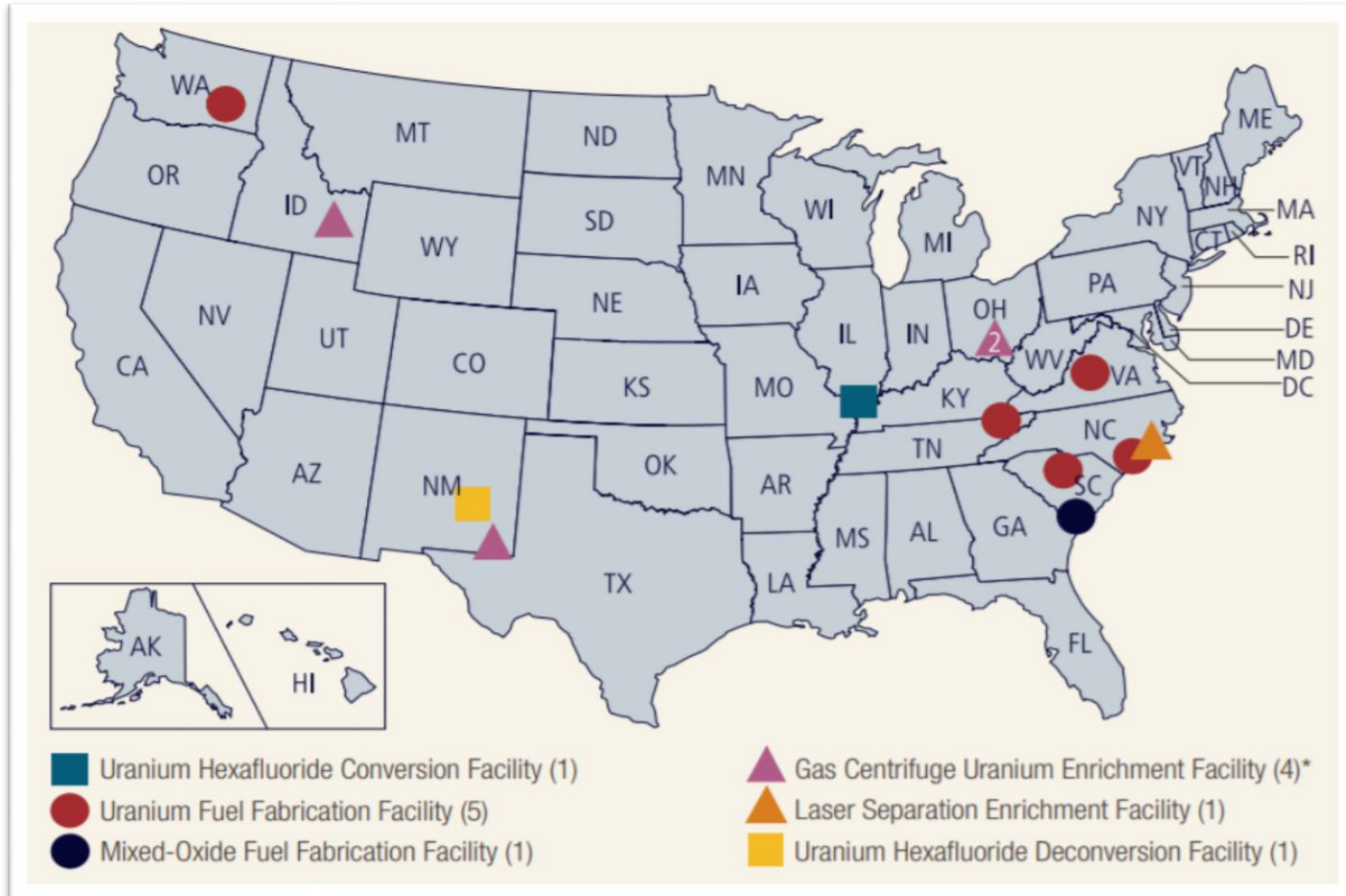
# **Overview of the Fuel Facilities Business Line**

**Marc Dapas, Director  
Office of Nuclear Material  
Safety and Safeguards**

# **Focusing on Our Priorities**

- **Ensuring safety and security through licensing, oversight, and environmental reviews**
- **Supporting U.S. non-proliferation activities**
- **Maintaining effective communications with stakeholders on regulatory activities**

# Location of Fuel Cycle Facilities



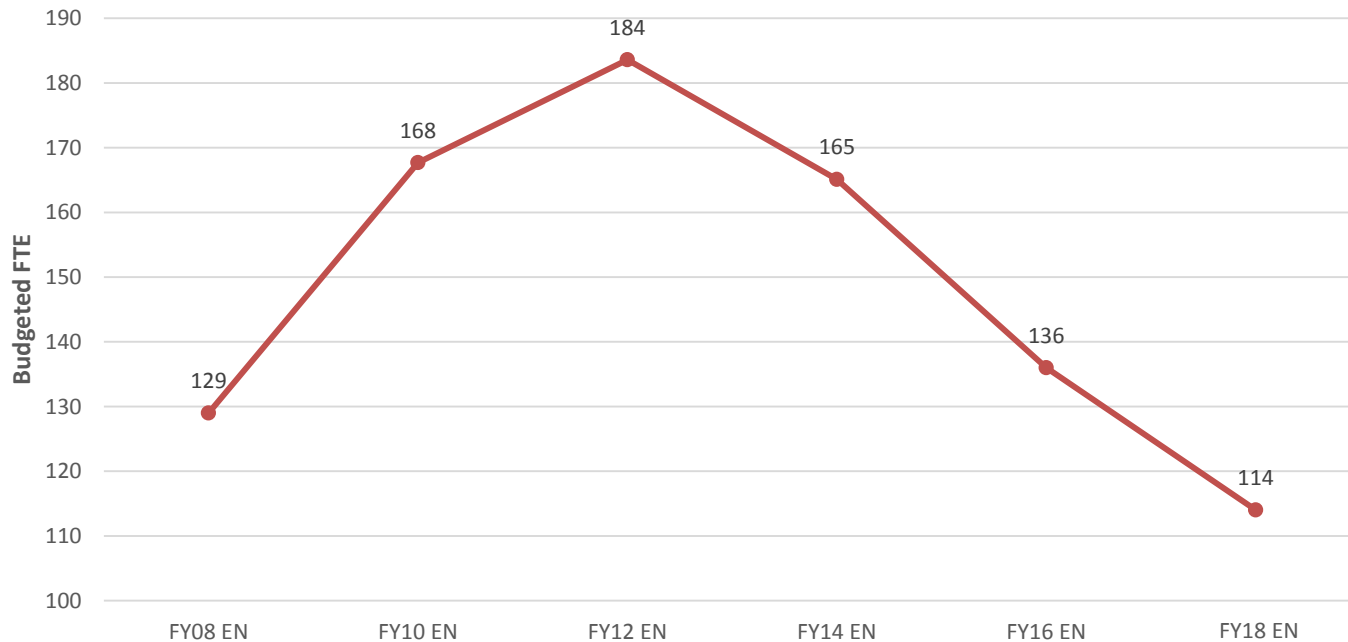
\* Lead Cascade facility used for testing, is currently transitioning to decommissioning.

# **Proactively Addressing Fee-Related Challenges**

- **Performed an evaluation of the Nuclear Materials and Waste Safety program and fee classes**
- **Initiated stakeholder outreach on potential improvements to the Fuel Facilities fee class annual fee calculation methodology**

# Addressing the Changing Workload

Fuel Facilities Business Line - FTE Levels FY2008-FY2018





# **Successfully Completed Post-Fukushima Activities**

- **Completed all activities involving Generic Letter 2015-01, “Treatment of Natural Phenomena Hazards at Fuel Cycle Facilities”**
- **Confirmed that licensees are in compliance with existing regulatory requirements**
- **Achieved safety and regulatory improvements**

# **Providing Outreach and Education Opportunities on Safety Culture**

- **Outreach:**
  - **Presented at 2017 FCIX**
- **Educational Tools:**
  - **NRC's Safety Culture Webpage and Educational Resource Workbook**
- **Addressing safety culture through our Alternative Dispute Resolution Program**



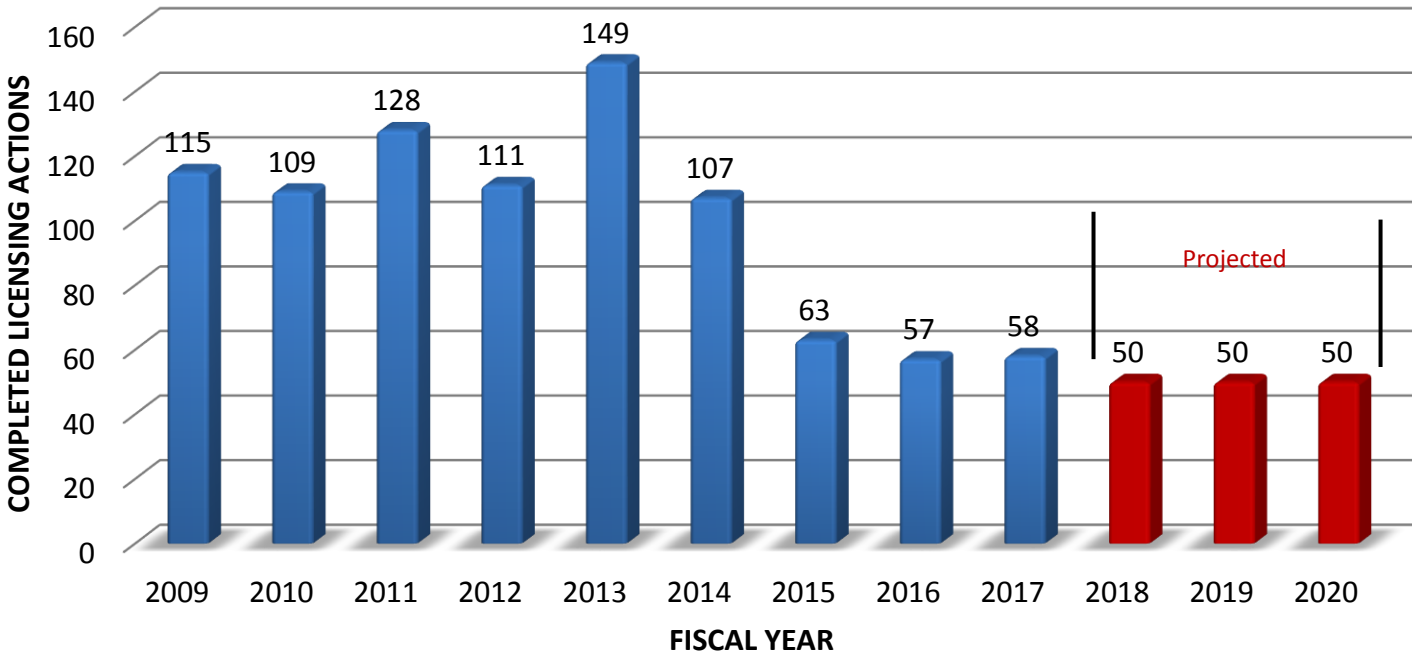
# **Current Fuel Cycle Program Environment**

**Craig Erlanger, Director  
Division of Fuel Cycle Safety,  
Safeguards, and Environmental Review,  
NMSS**

# **Making Significant Progress on Several Regulatory Initiatives**

- **Rulemakings:**
  - **Cyber Security for Fuel Cycle Facilities**
  - **Modified Small Quantities Protocol**
- **Westinghouse Lessons-Learned initiative**

# Focusing on the Anticipated Licensing Workload



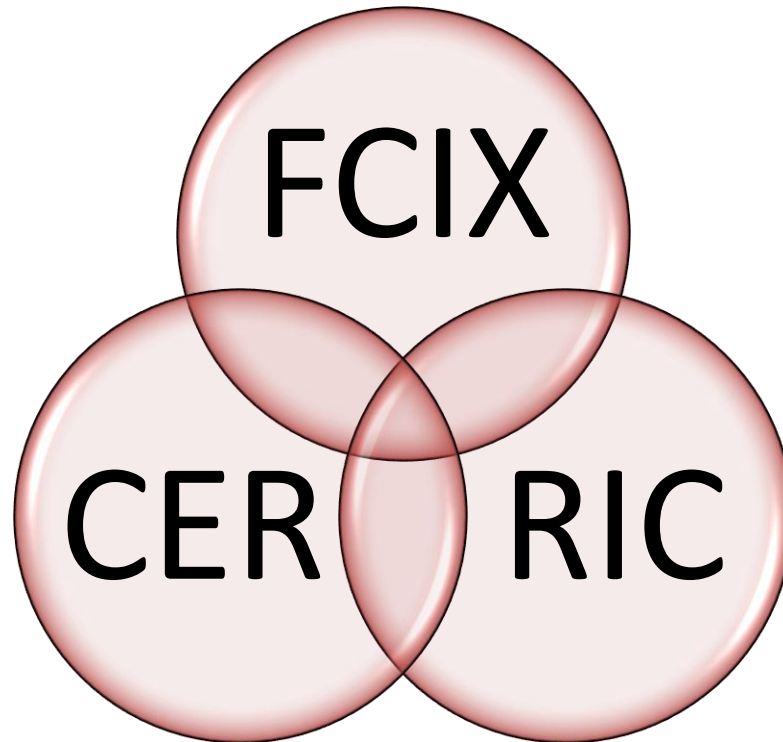
# **Successfully Implementing the Licensing and Oversight Programs**

- **Performed internal licensing process reviews**
- **Implemented enhancements to the licensing program**
- **Continued to leverage operating experience to improve the oversight program**

# **Successfully Implementing the Licensing and Oversight Programs**

- **Revised 3 Inspection Manual Chapters and 6 inspection procedures**
- **Completed enhancements to the Security Core Inspection Program**
- **Continued to lead the NRC material control and accounting program**

# **Positively Impacting Regulatory Activities through Stakeholder Outreach**





# **Successfully Implementing the International Safeguards Program**

- **Ensuring that the U.S. Government can meet its obligations under international agreements and treaties**
- **Supporting efficient and accurate reporting for nuclear materials and export-import licensing**
- **Effectively engaging with Federal partners and interagency groups**

# **Focusing on Future Opportunities**

- **Improving the accuracy of fee billing**
- **Continuing stakeholder engagement on the Fuel Facilities Effort Factors Matrix**
- **Ensuring effective reorganization of FCSE**
- **Continuing to support our partner offices**
- **Ensuring effective implementation of the current licensing and oversight programs**



# **Fuel Cycle Inspection Program**

**Eric Michel, Chief Projects Branch 2  
Division of Fuel Facility Inspection,  
Region II**

# **Effectively Implementing the Oversight Program**

- **Completed Core Inspection Program**
- **Performed a reactive special inspection at the BWXT Nuclear Operations Group**
- **Conducted plant specific follow up inspections**
- **Completed two alternative dispute resolution sessions**

# **Enhancing the Oversight Program**

- **Proposed shifting some regional inspection activities to the senior resident inspectors at Category 1 fuel cycle facilities**
- **Conducted an inspection program gap analysis following recent events resulting in escalated enforcement actions**

# **Effectively Overseeing the Mixed Oxide Fuel Fabrication Facility**

- **Completed 1768 hours of inspection activities**
- **Completed 2 of 53 principal systems, structures, and components verifications**
- **Return of licensee to Column 1 of the Construction Action Matrix**

# **Continued Oversight of the Westinghouse Columbia Scrubber Condition**

- **Closed the Confirmatory Action Letter**
- **Identified an Area Needing Improvement and issued a Confirmatory Order**
- **Conducted additional inspection activities**

# **Focusing on the Future of the Oversight Program**

- **Ensuring strong collaboration with headquarters offices**
- **Continuing to leverage Communities of Practice to enhance knowledge management**
- **Encouraging cross-qualification and support of other divisions within Region II**





# **NMSS/OCFO Fee Billing Project Update**

**Brian Smith, Deputy Director  
Division of Fuel Cycle Safety,  
Safeguards, and Environmental Review,  
NMSS**

# **Improving the Accuracy of Fee Billing**

- **Identified fee billing errors across all NMWS business lines**
- **Established a joint NMSS/OCFO team**
- **Developed a project plan and identified areas for improvement**
- **Prioritized tasks into phases**
- **On schedule to complete all tasks this fiscal year**

# **Significant Accomplishments Achieved**

- **Completed WBL data review of high priority licenses**
- **Consolidated licenses in WBL**
- **Enhanced FAIMIS and WBL interfaces to integrate with the Master Data Management System**

# **Significant Accomplishments Achieved**

- **Established roles and responsibilities related to fee billing**
- **Established a decommissioning status change process**
- **Performed internal and external stakeholder outreach**

# **Future Actions**

- **Complete the review of the remaining license data in WBL and system interface improvements**
- **Complete the tax identification number and billing address collection process for new licensees**
- **Conduct training across NMSS and regional offices**

# Questions



# **Nuclear Materials Users Business Line**

**April 26, 2018**



# **Opening Remarks**

**Victor M. McCree**  
**Executive Director**  
**for Operations**



# **Nuclear Materials Users Business Line Meeting Agenda:**

- **Overview of Nuclear Materials Users Business Line**
- **Current National Materials Program Environment**
- **Regional Materials Licensing and Inspection Program Activities**
- **Emerging Medical Technologies**



# **Overview of Nuclear Materials Users Business Line**

**Marc Dapas, Director  
Office of Nuclear Material  
Safety and Safeguards**

# **Ensuring Safety Over a Broad Range of Activities**

- **Communicating and coordinating with stakeholders to ensure external factors are identified and considered**
- **The Nuclear Materials Users business line consists of 223 FTE and \$22.7 million in contract support and travel**

# **Focusing on Several High Priority Items**

- **Supporting the Government Accountability Office's Engagement on Effectiveness of 10 CFR Part 37**
- **Participating in the Office of Inspector General's Audit of the National Materials Program**
- **Reviewing the Wyoming and Vermont Agreement State draft applications**

# **Focusing on Several High Priority Items**

- **Engaging Native American Tribes**
- **Organizing several State Liaison Officers Program Activities**

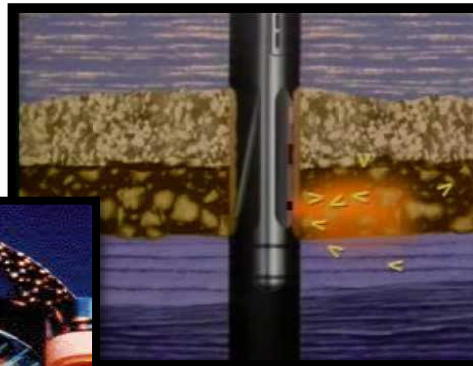
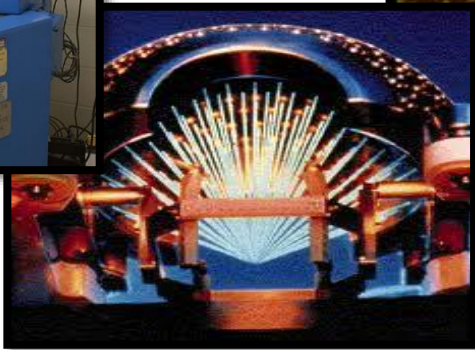


# **Current National Materials Program Environment**

**Kevin Williams, Acting Director  
Division of Materials Safety, Security,  
State, and Tribal Programs,  
NMSS**

# Ensuring Safety and Security under the National Materials Program

- **Over 19,300 specific licensees**
- **Agreement States regulate about 86%**
- **Number of materials licensees remains relatively stable**



# **Effectively Engaging the Agreement States as Our Regulatory Partners**

- **Participating in working groups for guidance development and agency evaluation of regulatory approaches**
- **Organizing periodic meetings and calls to cover a wide range of regulatory topics**
- **Collaborating on non-military, radium-related activities**



# **Engaging with Wyoming on Its Agreement State Application**

- **Letter of Intent submitted to become an Agreement State in 2015, followed by a Draft Application in 2016**
- **Wyoming Proposed a Limited Agreement for uranium recovery programs**
- **Staff will request Commission approval to publish the results of the staff assessment and the proposed Agreement for public comment next month**

# **Successfully Outreaching to Native American Tribes**

- **Established cooperative relationship with the Catawba Indian Nation**
- **Supporting uranium contamination clean-up in the Navajo Nation**
- **Providing in person health physics training to the Tribes and making training material available online**

# **Working Collaboratively on the Radiation Protection and Security Task Force**

- **The Task Force was established to provide recommendations relating to the security of radioactive sources in the US**
- **Coordinating with the Task Force member agencies on the status of existing recommendations and developing new recommendations**
- **NRC will submit to the President and Congress the 4th Task Force Report in August 2018**

# **Completed the Cyber Security Evaluation for Byproduct Materials Licensees**

- **Determined that the current cyber security threat environment does not warrant new regulations**
- **Developing an Information Notice to communicate effective practices for cyber security for risk-significant radioactive materials licensees**
- **The evaluation results were posted on the NRC Public website**

# **Addressing the Source Security Program Review Recommendations**

**Issued Regulatory Issue Summary  
(RIS) 2018-01, “Common Violations  
cited during First 2 Years of 10 CFR  
Part 37, ‘Physical Protection of  
Category 1 and Category 2 Quantities  
of Radioactive Material,’  
Implementation and Guidance  
Development Available to Support  
Rule Implementation”**

# **Addressing the Source Security Program Review Recommendations**

- **Drafted a revision to NUREG-2155, “Implementation Guidance for 10 CFR Part 37, ‘Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material’”**
- **Preparing a rulemaking plan to address recommendations**



# **Regional Materials Licensing and Inspection Program Activities**

**Aaron T. McCraw, Chief,  
Materials Inspection Branch,  
Division of Nuclear Material Safety,  
Region III**

# **Creating Efficiencies Through the Agency's Rebaselining Initiative**

- 1) Limited scope revision to IMC 2800**
  - Changed routine inspection eligibility period to +/-50% of assigned frequency**
  - Extended the initial inspection period for licensees that have not taken possession of any materials**
  - Allowed inspection interval extensions for good performance on a case-by-case basis**
- 2) Extended renewals from 10 to 15 years**
- 3) Centralized bankruptcy reviews in NMSS**



# **Looking on the Horizon for Additional Efficiencies**

- **Further risk-inform inspection frequencies**
- **Evaluate requirements for inspections at locations of use**
- **Review reciprocity inspection metrics**
- **Enhance inspection documentation**

# Regional Materials Staff in Action



# Regional Materials Staff in Action



# **Tracking Trends in Allegations and Enforcement**

- **Workload continues to be stable**
- **No notable trends in allegations**
- **Escalated enforcement cases continue to involve gauge security and Part 37**

# Transforming Enforcement of Portable Gauge Security Violations

- **Opportunity to further risk-inform the enforcement process and consider:**
  - **Location of use**
  - **Duration of the lapse in surveillance**
  - **Whether damage occurred**



# **Adapting to Advancements in Security Technology**

- **Regional materials inspectors are uniquely positioned to observe new advancements in security technology**
- **New technologies do not necessarily guarantee compliance with Part 37**
- **Working to evaluate regulations that may inadvertently discourage new technologies**



# **Emerging Medical Technologies**

**Linda Howell, Acting Deputy Director  
Division of Materials Safety,  
Security, State, and Tribal Programs,  
NMSS**

# **NRC's Outreach and Process for Evaluating Emerging Medical Technology**

- **NRC staff engages numerous stakeholders to maintain awareness of any emerging medical technology**
- **While developing the standard license conditions for emerging technologies, the staff continues to engage internal and external stakeholders**



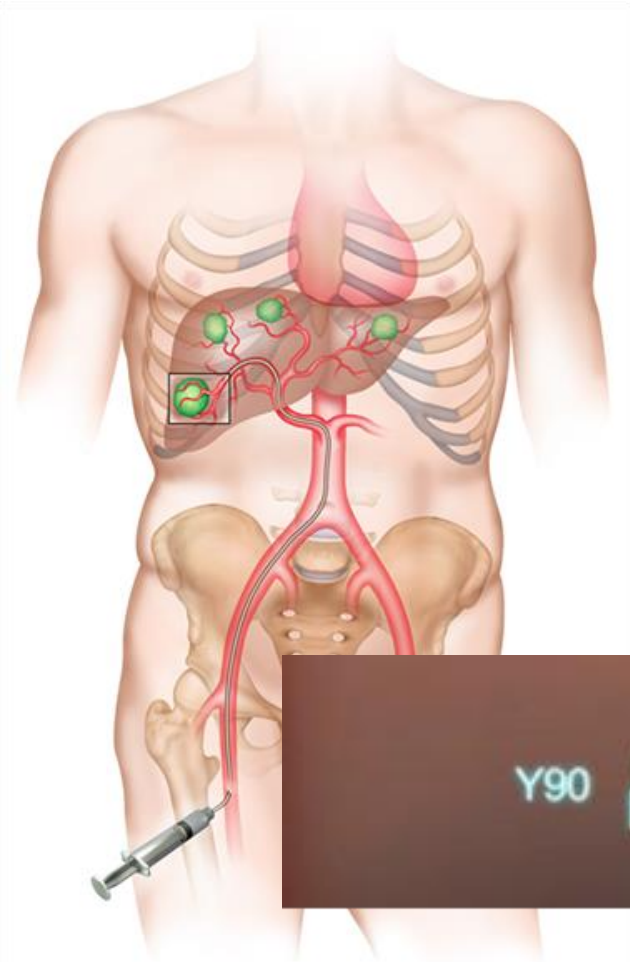
# **Continuing Efforts to Evaluate Emerging Medical Technologies**

- **NRC staff submitted a SECY paper on emerging technologies, providing an estimate of the staff resources needed to develop licensing guidance**
- **NRC staff will continue to engage its stakeholders in determining the regulatory needs for emerging medical technology**

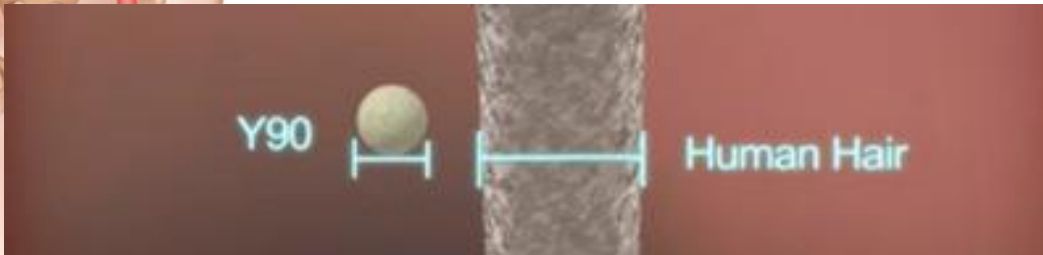
# **Anticipating Future Staff Reviews For Emerging Medical Technologies**

- **Phosphorus-32 Oncosil microparticles**
- **MASEP Infini cobalt-60 stereotactic radiosurgery**
- **GammaPod cobalt-60 stereotactic radiotherapy**
- **Iodine -131 radiolabeled monoclonal antibody**
- **Thorium processed into lead-212**

# Yttrium-90 Microsphere Brachytherapy Events



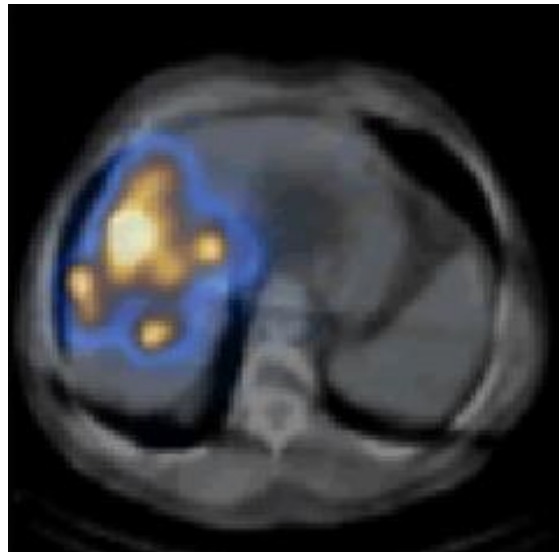
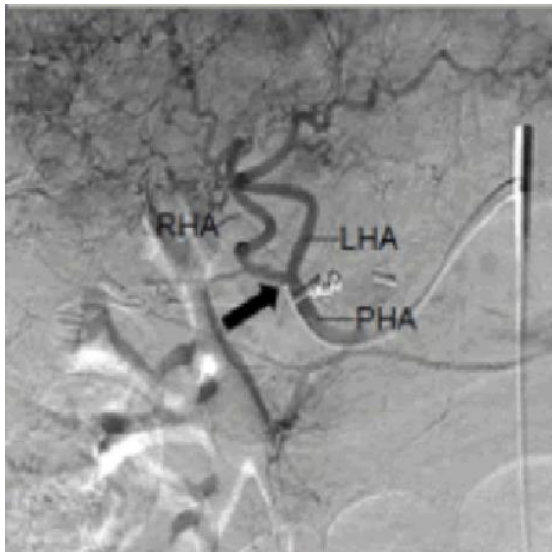
**SIRSpheres®**



**TheraSphere®**

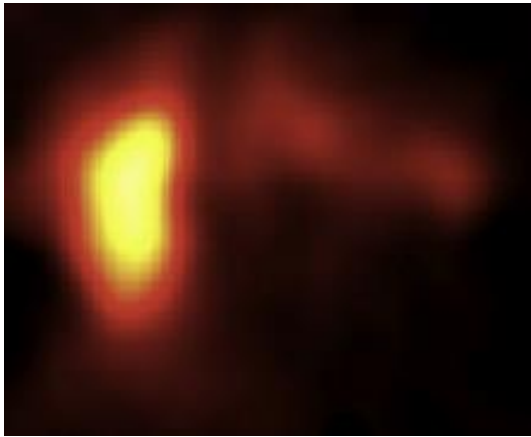
# Catheter Placement

## Pre-treatment Image



# Post-Treatment Imaging

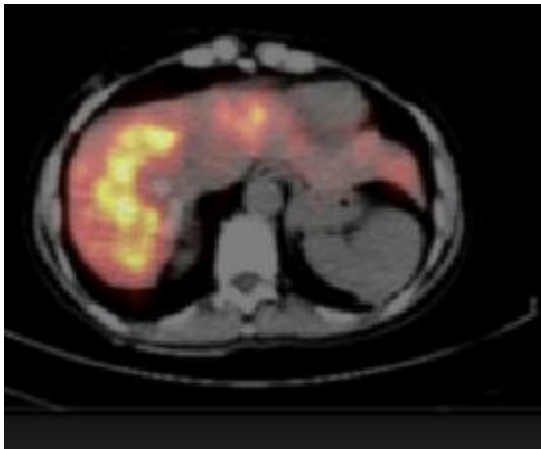
**Yttrium-90 SPECT**



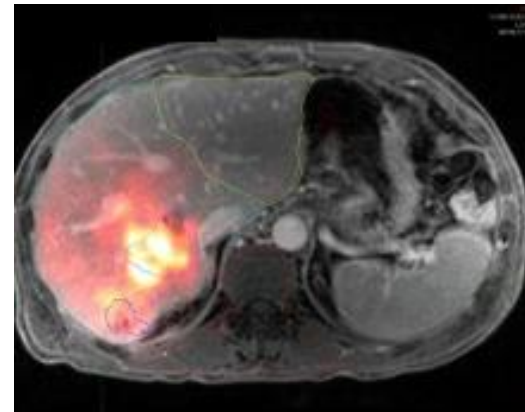
**Yttrium-90 SPECT / CT**



**Yttrium-90 PET/CT**



**Yttrium-90 PET/MRI**



# **Evaluating Reported Yttrium-90 Medical Events**

- **Staff asked INL to perform a case study on Yttrium-90 microsphere events over the past 10 years**
- **Since Yttrium-90 treatments began (15 years ago), the numbers of medical events have increased**
- **The increase in reported medical events is commensurate with the increase in use of Yttrium-90 microspheres**

# **The Staff Did Not Identify a Negative Performance Trend**

- **Based on the INL report and analysis of the trending data, the staff did not find a negative performance trend or gaps in NRC regulations**
- **Though no negative trends were identified at this time, it is beneficial to question our regulations to determine what is adequate when it comes to evolving medical technologies**

# Questions



# List of Acronyms

- **ACMUI – Advisory Committee on Medical Uses of Isotopes**
- **CER – Cumulative Effects of Regulation**
- **CFR – Code of Federal Regulations**
- **CRCPD – Conference of Radiation Control Program Directors**
- **FAIMIS – Financial Accounting and Integrated Management Information System**
- **FCIX – Fuel Cycle Information Exchange**
- **FCSE – Division of Fuel Cycle Safety, Safeguards and Environmental Review**
- **FDA – Food and Drug Administration**
- **FTE – Full Time Equivalent**

# List of Acronyms

- **GAO – Government Accountability Office**
- **IMC – Inspection Manual Chapter**
- **INL – Idaho National Laboratory**
- **MDMS – Master Data Management System**
- **NMSS – Office of Nuclear Material Safety and Safeguards**
- **NMU – Nuclear Materials Users**
- **NMWS – Nuclear Materials and Waste Safety**
- **NORM – Naturally Occurring Radioactive Material**

# List of Acronyms

- **NRC – Nuclear Regulatory Commission**
- **OAS – Organization of Agreement States**
- **OCFO – Office of the Chief Financial Officer**
- **OIG – Office of Inspector General**
- **SLO – State Liaison Officer**
- **RIC – Regulatory Information Conference**
- **OCFO – Office of the Chief Financial Officer**
- **WBL – Web-Based Licensing**