

***E pluribus unum* & the National Materials Program**

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Welcome

It is great to join you here in Milwaukee. I look forward every year to participating in this annual meeting of the Organization of Agreement States. The topics that we discuss here are relevant and important in our mutual efforts to ensure the protection of the American people. I appreciate the invitation of Cheryl Rogers, the OAS Board, and the organizers of this meeting for the opportunity to participate once again and share my perspective as a senior staff leader at the Nuclear Regulatory Commission.

What a treat it would have been to hear Commissioner Apostolakis' presentation on the Risk Management Regulatory Framework. The Commissioner was not able to attend due to flight delays caused by adverse weather yesterday in the DC area. Mark will do an excellent job presenting the Commissioner's talk. The Commissioner clearly has passion for this topic and a vision for how we can move forward, together, to improve regulating radioactive materials and nuclear facilities in the United States. Now I know that some of you might be sitting there thinking that you have heard this before. Previous initiatives to enhance consideration of risk in materials regulation met with only limited success. What is different with this proposal? This initiative began with a very thoughtful and thorough consideration of the subject and is now engaging stakeholders, including you. More on that topic later.

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I titled my presentation this year "*E pluribus unum* and the National Materials Program." After all, this is what we are about as we explore, coordinate, collaborate, and plan our actions. We take these actions as 38 independent regulators – 37 Agreement States and 1 NRC. "Out of many, one." I plan to review this important concept and its linkage to the National Materials Program, discuss the program, and identify some opportunities to strengthen it.

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E pluribus unum

You undoubtedly recognize the Latin phrase *e pluribus unum* from its inclusion in the Great Seal of the United States and its extensive use on U.S. currency. *E pluribus unum* was considered for many years as the unofficial motto of the United States. Congress decided to designate a different phrase, "In God We Trust," as the official motto in 1956. *E pluribus unum* was initially proposed as the motto for the United States by a Frenchman (Pierre Eugene du Simitiere) in 1776 to a committee responsible for developing the seal of the United States. Imagine that, even before we had secured independence from England, we had already formed a committee to design the seal for the new nation. Now that is positive thinking. One can only wonder whether they followed the equivalent of Management Directive 5.3 to guide the operations of this committee. The phrase is similar to an excerpt from Heraclitus's poem "The one is made up of all things and all things issue from the one." Over the years, the national understanding of *e pluribus unum* evolved. In the 1700's, *e pluribus unum* meant that out of many colonies or states emerges a single nation. More recently, the concept has evolved into a single people and nation emerging out of many peoples, races, religions, cultures, and ancestries. Thus, *e pluribus unum* has played an important role in bringing us together as a people and nation.

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The National Materials Program

In a similar vein, the National Materials Program concept evolved over the years as the number of Agreement State programs grew from the first program, Kentucky, fifty years ago. By the end of 1970, there were 22 Agreement States regulating about half of the materials licensees. Today, the 37 Agreement States regulate more than 85% of the materials licensees. The National Materials Program is the broad collective framework within which both the NRC and the Agreement States work together to accomplish radiation safety. NRC's focus on the National Materials Program sharpened in the 1990s as we realized that NRC was regulating fewer and fewer materials licensees and the Agreement States were regulating more and more. The Agreement States possess the majority of knowledge and experience in people serving as license reviewers, inspectors, responders, and administrators. With the Congressional mandate that we recover about 90% of our budget through fees imposed on NRC licensees, we realized that the program was trending in the direction of NRC shouldering the bulk of the burden to maintain the regulatory infrastructure while imposing ever higher fees on a shrinking population of NRC materials licensees.

In response to these trends, the staff proposed to the Commission and the Agreement States in the late 1990s that we explore adjustments to our partnerships that we had forged over the decades. These adjustments entailed the Agreement States sharing a larger amount of the load for maintaining the regulatory infrastructure by shaping regulations and guidance documents. The cost of bearing this load would be supported by the growing population of Agreement State licensees. Of course, we recognized that these adjustments would have to align with the policies and fee structures of the 37 independent Agreement States. These

adjustments would also require a willingness of the Agreement State licensees to shoulder this new burden of fees. *E pluribus unum.*

With this background, the staff and the Agreement States formed a working group in 2000 to provide advice to the NRC on the National Materials Program. The working group completed its final report in May 2001 and recommended that the NRC adopt a cooperative process (the so-called "Alliance" option). Under the Alliance option, the NRC and Agreement States collectively identify, prioritize, and fulfill the regulatory needs of the materials program.

As a starting point, NRC, the Organization of Agreement States (OAS), and the Conference of Radiation Control Program Directors (CRCPD) collaborated on five pilot projects to assess the feasibility and viability of the Alliance option in 2002. These pilots included:

- Pilot 1 - Establishment of Priorities
- Pilot 2 – National Industrial Radiographer Safety Certification Program
- Pilot 3 – Operating Experience Evaluation
- Pilot 4 – Guidance for a New Use or Modality
- Pilot 5 – Revision to Inspection Manual 2800

By November 2004, the pilot project working groups had completed their final reports. Based on the collective experience with the pilot projects, the NRC, OAS, and CRCPD identified three options for Commission consideration on how to proceed with the National Materials Program. After careful and thorough consideration, the Commission approved the recommendation to continue with the National Materials Program under a blended option in January 2005. The Commission agreed that the pilots did not resolve the concerns previously identified with the alliance approach. They did demonstrate the ability of NRC and the Agreement States to collaborate effectively and resolve regulatory issues. The NRC and Agreement States identified other challenges associated with the National Materials Program implementation, including:

- Dealing with an environment that is constantly evolving, including changes in priorities for regulatory needs and resources
- Consistently devoting the resources to support shared program activities
- Sharing responsibility for development and maintenance of the regulatory infrastructure and applying these shared products without significant changes
- Establishing priorities for work early in the planning process

Recent initiatives continue to build upon the collaborative efforts of the Agreement States and NRC. These include the revision of the Policy Statements on Principle and Policy of the Agreement State Program and the Adequacy and Compatibility of the Agreement State Programs to integrate security as part of the underlying foundation of the National Materials Program and revise associated guidance documents. Another recent NRC initiative demonstrates the vitality of the National Materials Program – the development of Web Based Licensing using the existing platform used successfully by the State of Ohio and building from the License Tracking System. A number of States have expressed interest in using this

platform to support their licensing and inspection programs, particularly when the revised software becomes available. We are implementing in the NRC Web Based Licensing Version 2.0 this week. The early and substantive dialogue with the States has strengthened radiation protection and safety and security of radioactive materials through regulatory development and infrastructure improvements.

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State of the Program

So what is the state of our National Materials Program today – are we a cohesive and collaborative confederation focused on accomplishing a common objective of public protection? *E pluribus unum?*

There are approximately 23,000 specific licenses authorizing medical, academic, commercial, and research uses of Agreement material, with hundreds of thousands of users of the material and hundreds of thousands of generally licensed devices. Regulation of these licensees is accomplished by 38 regulators – 37 Agreement States and 1 NRC. NRC regulates about 3,000 specific licensees and the Agreement States regulate the remaining 20,000. The States with the largest numbers of licensees include California, Florida, Texas, and New York; most Agreement States have several hundred licensees.

To accomplish a high level of safety and fulfill the National, State, and local expectations, regulatory oversight of these materials and waste licensees annually costs about \$350M (NRC \$240M in FY2011) and requires about 700 people (NRC 300 in FY2011; Agreement States about 400).

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In 2011, we succeeded in accomplishing all of the safety and security measures identified in the NRC's Strategic Plan, except one due to the theft of a radiography source. The safety and security outcomes are by far our most important accomplishments. Other outcomes include the success of the Integrated Materials Performance Evaluation Program (IMPEP), which we use to evaluate the effectiveness and performance of our regulatory programs. In 2011, 28 programs were adequate to protect public health and safety and 10 programs were adequate, but needed improvement. 35 programs were compatible. These outcomes indicate that the programs are thriving, but most of them are feeling the strain of resource constraints imposed by a distressed economy and staffing challenges.

We can also portray the success of the National Materials Program by describing program outputs that contribute to positive outcomes. For 2011, these include successful completion of a large number of regulatory actions as depicted on this slide:

Activity	NRC	Agreement States	Estimated Total
Licensing actions	2000	15400	17400
Sealed source and device reviews	50	375	425
Inspections	1100	8500	9600
Enforcement actions	65	-	-
Rulemakings	5	111	116
IMPEP reviews	10		
Event notifications***	40	90	130
Allegations reviews	119	~70	~190
Investigations	30	-	

For enforcement and investigation actions, the Agreement State processes vary significantly and are not required for compatibility. IMPEP does review enforcement actions to ensure that appropriate measures are taken commensurate with the significance of inspection findings.

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We have also advanced safety through research to confirm or enhance the existing regulatory framework, including

- Risk-informing decision making for medical applications,
- Assessing the merits of revising radiation protection regulations,
- Evaluating the safety of gemstone enhancements,
- Evaluating the exposure of the public to patients,
- Reporting to Congress the Abnormal Occurrences, and
- Providing a Radiological Toolbox for inspectors and license reviewers.

Other accomplishments include enhanced outreach to key stakeholders, substantial improvements to security of sources, significant advancements in the Information Technology tools, and contributions to global security and safety through bilateral and multilateral accomplishments.

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We have accomplished these outcomes and outputs despite common challenges, including:

- Maintaining our focus on safety and security while accommodating emergent work
- Coping with budget and staffing constraints
- Striking a balance between operational effectiveness and efficiency and long-term program success
- Overcoming unforeseen technical challenges and complexities with new technologies
- Enhancing safety culture within and among diverse user communities with large variations in sophistication and capabilities

Opportunities to Strengthen the Program

As we look forward beyond our meeting this week and these walls, let us seize the opportunities to further strengthen our programs by working together. We can achieve a higher level of protection of the American public by using our collective resources more effectively and efficiently through *e pluribus unum* as envisioned by our public service predecessors in the late 1700s.

How will we get to this better place? By successfully executing five strategies.

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Through discernment of intermediate outcomes – being clear on what really matters in our work and aligning on these outcomes. The extent to which we accomplish these intermediate outcomes will give us clear and direct feedback on the success of our efforts. These outcomes are at a high enough level to be meaningful and effective indicators of how well our National Materials Program is doing in serving our citizens. What are we trying to accomplish and how will we know whether our National Materials Program is succeeding?

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Through collaboration to adopt strategies to accomplish outcomes – once we have established the intermediate outcomes, we'll need to work together to identify the approaches that offer the highest likelihood of achieving these outcomes using available resources – people, money, information, tools, and time. We'll need to try new ways, let go of some of the old practices, and use our collective wisdom to succeed more effectively and efficiently.

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Through assessment of the cumulative effects of regulation and more integrated planning – by clearly identifying and agreeing upon our objectives before launching an initiative and recognizing the lifecycle investment required to achieve these objectives. We need to objectively confirm these initiatives achieve a net improvement in safety and security, rather than diverting us away from what is most important. We also need to assess the landscape before us and seize opportunities to make strategic improvements aware of the broader environment and trends that we operate within.

Based on the forecast portrayed in this chart, it looks like 2015 and 2016 could be busy years for rulemakings in the Agreement States. To reduce the cumulative impact of multiple rulemakings, we may need to combine actions into a single rulemaking as we are currently doing for the medical rulemaking for Part 35. We will also consider adjusting effective or implementation dates for some rules. We will work together on adoption of Part 37 over the next several years. Additionally, we will cooperate on developing revisions to Part 35,

transportation requirements in Part 71, waste disposal requirements in Part 61, and potentially developing changes to the radiation protection requirements in Part 20. You will hear more about these rulemakings later in the week.

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Through application of a structured decision-making framework, such as the Risk Management Regulatory Framework, to guide our decisions considering risks that we seek to manage. Commissioner Apostolakis' Task Force evaluated how we should be regulating 10 to 15 years in the future. The Risk Management Regulatory Framework proposed by the Task Force offers many positive attributes, including enhancing the use of risk information in support of regulatory decisions and enhancing their consistency. The Task Force also recommended that the exploration and development of this framework for the materials program be closely coordinated with the Agreement States. Work with us next year to chart an optimal path forward on this important initiative.

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Through disciplined adherence to plans and strategies once we establish them with full knowledge of the associated benefits, costs, threats, and opportunities. We need to see initiatives through to completion to achieve the objectives and reap the benefits that originally enticed us to act. We also need to learn from our experiences and incorporate lessons learned through best business practices that foster continuous improvement.

Closing

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I know that this sounds like a tall order. Our experience demonstrates that we can work together to overcome serious challenges and barriers. We have leveraged our capabilities, communicated candidly, strengthened our relationships, and enhanced trust because we know that we share a common goal of protecting people and the environment. We are many focused on the one goal – protecting people and the environment. *E pluribus unum.*

Thank you and have a great annual meeting.

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