Agenda

• NRC Rulemaking Process
• Regulatory Activities of Interest
  - NRC-OAS Working Group on the OAS Early Involvement in Rulemaking
  - OAS Involvement in NRC’s Common Prioritization of Rulemaking
• Rulemaking in New Jersey
• Discussion on OAS Involvement in the Rulemaking Process
  - Current Rulemakings
  - Petitions for Rulemaking
  - Rulemaking Plans
  - Review of Administrative Requirements
Federal Rulemaking Process

The Reg Map
Informal Rulemaking

Using The Reg Map

Specific Analysis for Steps Three and Seven

Drafting Requirements

Agenda for Rules Under Development or Review

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment
Federal Rulemaking Process

NRC Does Not Conduct Steps 4 and 8

Process Differences at NRC
NRC’s Rulemaking Process

A Typical Rulemaking Process

As of June 2017
NRC’s Petition for Rulemaking Process
The working group convened on July 16, 2018
OAS involvement in Commission - directed rulemaking activities:
   - Rulemaking Plan
   - Regulatory Basis
OAS Involvement in the NRC Petition for Rulemaking Process
Drafting of SA-801A is expected through September 2018 and will supplement SA-800 and SA-801
OAS Involvement in NRC Common Prioritization of Rulemaking Process

- NRC’s Common Prioritization of Rulemaking (CPR) process is used to determine the priority of rulemaking actions from an agency perspective.

- CPR considers how the rulemaking changes relate to the NRC’s goals and strategies or government and public interest.

- The CPR working group meets twice per year to determine the priority for planned rulemakings.

- OAS will serve as an ad hoc member on the CPR working group to participate in prioritizing planned NRC rulemakings.
Review of Administrative Requirements

-November 2017 – Staff submitted a plan to conduct a retrospective review
  Identify outdated or duplicative administrative requirements that may be eliminated without an adverse effect on mission
    - Enhance management and administration of regulatory activities
    - Ensure that the agency's regulations remain current and effective
    - Expect to conduct administrative regulatory changes that will make information submittal, record keeping, and reporting processes more efficient for the staff, applicants, and licensees

-May 3, 2018 – Action plan and draft selection criteria were noticed in the Federal Register (83 FR 19464);

-Staff is in the process of developing a SECY paper providing criteria recommendation to the Commission.
Current Rulemakings

Final Rule
“Medical Event Definitions, Training and Experience, and Clarifying Amendments”
10 CFR Part 35

Supplemental Proposed Rule
“Low-Level Radioactive Waste Disposal”
10 CFR Part 61

Draft Final Rule
“Material Control and Accounting for Special Nuclear Material”
10 CFR Part 74
Rulemaking in the Garden State

AND OAS FEED-BACK ON THE RULEMAKING PROCESS
The Players

- Rule Manager
- Program Director
- Assistant Commissioner
- Legal Specialist
- Office of Communications and Constituent Services
- Office of Economic Analysis
- Office of Information Resources Management
- Deputy Attorney General (DAG)
- Office of Administrative Law
The Process

- Of course, we have a CHECKLIST!
- The Checklist is 40 pages.
- We also have a Rulemaking Manual, affectionately known as:
Step 1: Get Prioritization for Rulemaking

- Compete with the Air program, the Water program, the Solid Waste program, the Hazardous Waste program, the Site Remediation program...
  - This may take up to 2 years.
- Once the rule is prioritized, the Checklist begins
The Proposal Process

Rule Manager assembles rule team
- Qualified
- Approved to participate
- All affected programs

Request a Legal Specialist from Office of Legal Affairs with target dates for:
- Stakeholder outreach
- Launch Meeting
- Proposal filing deadline date
- NJR publication date deadline
- Drop-dead deadline for the rulemaking

Rule Manager emails Director of the Office of Economic Analysis
- Prospective Analysis of the likely economic impacts including
  - Present the baseline or status quo
  - Identify groups affected
  - Identify and quantify the costs and benefits for each affected group
  - Monetize costs and benefits of each option
  - Adjust monetized values for inflation
  - Discount costs and benefits to present value
  - Calculate net benefits or cost-effectiveness ratios for each option
  - Report results and conclusions
Next Steps

First stakeholder outreach

At least 14 months before the anticipated proposal filing date
Second stakeholder outreach after proposal drafted, could be on website

Schedule and hold proposal Launch Meeting

Includes all players
The more players, harder to schedule
Could take a month to just schedule

Agenda of Launch Meeting is Proposal Launch Memo

Description of rulemaking
Advance notice/stakeholder process
Tie-in to DEP Vision and Transformation Initiative
Commonsense principles discussion
Waiver(s) of strict compliance
Cost-benefit, Other jurisdictions
Federal standards analysis
Performance-based outcomes
Science-based, Conflicts and impacts, Alternatives analysis, Permitting process improvements, Unfunded mandates, sources of controversy, enforcement issues, etc.
1 week after Launch Meeting
Finalize the Proposal
Launch Memo
Email to all players

Rule briefing meeting with the Commissioner
Could be waived

Commission on Radiation Protection (CORP)
Our Radiation Protection Act gives CORP the power to promulgate rules. Therefore, need approval of CORP members. Put on agenda of CORP meeting and brief the Commissioners. Use Launch Memo for briefing
Start Writing Proposal!!
- Rule Summary including Impact Statements:
  - Social
  - Economic
  - Environmental
  - Federal Standards Analysis
  - Jobs Impact
  - Agricultural Impact
  - Regulatory Flexibility Analysis
  - Housing Affordability impact
  - Smart Growth Impact

Reviews
- Legal Specialist (back and forth)
- DAG Managers
- CORP Members

Finalize Proposal for Filing
- Prepare the Proposal Briefing Memo
- Legal Specialist sends to Governor’s Office with the Governor’s Proposal Review Notice. Also send to the Smart Growth Ombudsman
- Prepare Commissioner’s Signature Package
- Prepare CORP Signature page
- Sends to Office of Administrative Law to publish

But Wait, we’re not finished
Next Steps

**OAL**
- Provides comments to Legal Specialist
- Rule Manager must respond to comments in 2 days with DAG approval

**Distribute Additional Notice of Proposal**
- Posted on Web Page
- Faxed to the news media
- Distributed through the Department’s rulemaking listserv
- Sent to persons listed

**Proofs**
- Send all proofs of publication of additional notice to the Legal Specialist
  - Copies of fax cover sheets
  - Print out of website the day it is posted
  - Copy of the email notice from listserv
- Proofread once published in Register and send Legal Specialist any errors
- 30 day comment period
- Start all over again for the Adoption, only this time address comments.
Who do you think the Rule Manager is?

- In New Jersey, the rule manager is a qualified inspector and license reviewer.
  - Every time there is a rulemaking required, we are down an FTE to do regular Agreement State work.
  - So far we have managed to get all our rules promulgated on time because
    - We incorporate by reference.
    - We say we don’t need a stakeholder meeting because the NRC has already gone through that process.
    - We shorten our comment period to 30 days for the same reason.
WE NEED MORE TIME!!!

- Reasonable time frame?

Unpredictability and rolling enactment dates make it difficult to manage.

- How do we fix this?
  - OAS representation on Prioritization committee
  - Convening a Working Group on OAS participation in rulemaking plan and regulatory basis

We don’t want to waste time on rulemaking that isn’t necessary

- Common Sense and Radiation Safety
- Precious resources. Our inspectors/license reviewers/emergency responders are the rule writers.
Medical Use of Byproduct Material

Purpose: Amended requirements related to –

- Medical events for permanent implant brachytherapy (reporting and notifications)
- Training & experience for preceptor attestations
- Testing and reporting for failed tests in Mo-99/Tc-99m and Sr-82/Rb-82 generators
- Associate Radiation Safety Officers - allowed to be named on the license
- Grandfathering of certain certified individuals – result of a petition for rulemaking
Process – Part 35

• June 2016 – NRC staff submitted the final rule to the Commission; Commission approval – August 2017

• June 2018 – Received clearance from the Office of Management and Budget (conducts review of information collection burden)

• Rule published July 16, 2018

• Effective 180 days from publication in the Federal Register (January 16, 2019)
Low-Level Radioactive Waste

Purpose: Amend 10 CFR Part 61 regulations that govern LLRW disposal facilities to:

- Require new and revised site-specific technical analyses
- Permit the development of site-specific criteria for LLRW acceptance based on the results of these analyses
- Align the requirements with current health and safety standards
- Rule would affect NRC and Agreement State Licensees
- Working group has OAS representatives
- June 2009 – NRC published an FRN (74 FR 30175) to get public input
Process-Part 61

- March 2015 – Published Proposed Rule, 90 public comments
- September 2017 – Commission directed NRC staff to make significant revisions to the draft final rule
  - Revise the compliance period to 1,000 years for all sites instead of using a 1,000-year or 10,000-year compliance period dependent upon the quantity of long-lived radionuclides being disposed
  - Reinstate the use of a case-by-case basis ("grandfather provision") for applying new requirements to only those sites that plan to accept large quantities of depleted uranium for disposal
  - Revisit regulatory analysis
- October 2017 – Published FRN requesting cost information related to low-level waste disposal; held public meeting, received 13 letters
- Late 2018 – NRC staff scheduled to issue a supplemental proposed rule for public comment
Material Control and Accounting for Special Nuclear Material

- The NRC is amending its regulations to update, clarify, and strengthen the MC&A requirements.

- Under the Commission’s Agreement State Program Policy Statement (82 FR 48535), this rule is classified as compatibility “NRC”

- There are no changes for the Agreement States or their licensees contained in the draft final rule. The changes in § 150.17 are plain language revisions and conform to the plain language revisions to material status reporting requirements in § 74.13

- The existing 350 gram regulatory threshold for special nuclear material under the jurisdiction of the Agreement States was retained.
Process – Part 74

• December 2013 – NRC published revised proposed rule; received 27 comments

• March 2016 – Rule placed on hold

• August 28, 2018 – Public meeting to discuss implementation of the final rule; Implementation date 180 days from publication in the Federal Register

• September 2018 – Draft Final Rule Package will be sent to the Commission
Other Regulatory Activities

• Petitions
  – Naturally-Ocurring and Accelerator-Produced Radioactive Materials (Organization of Agreement States)
  – Linear No-Threshold Model and Standards for Protection against Radiation (3 Petitioners)
  – Petition For Rulemaking And Rulemaking Plan On Individual Monitoring Devices For Industrial Radiographic Personnel (3 petitioners)

• Rulemaking Plans
  – Financial Assurance for Category 1 and 2 Sealed Sources

• Regulatory Bases
  – Parts 32, 40, and 70 - Items Containing Byproduct Material Incidental to Production
  – Part 61 - Greater-Than-Class-C Transuranic Waste
  – Part 71 - Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards
Naturally-Occurring and Accelerator-Produced Radioactive

April 2017 PRM submitted by OAS re: 10 CFR Part 30 Appendix B - used for calculating decommissioning funding requirements Materials (PRM-30-66)

- Default possession thresholds for unlisted radionuclides are too restrictive

- In 2005 Congress authorized NRC to regulate discrete sources of NARM; NRC has not updated Appendix B to add NARM radionuclides

- Regulators either must apply burdensome decommissioning funding obligations or evaluate exemptions – options that hinder introduction of new technologies and adversely affect patient care
Naturally-Occurring and Accelerator-Produced Radioactive Materials (Continued)

- Petitioner’s request (PRM-30-66)
  - Amend Appendix B to “add appropriate nuclides and their corresponding activities, as determined by a rulemaking working group”
NRC Action on PRM-30-66

- August 2017 – NRC noticed the petition in the *Federal Register* and requested public comment

- 20 comment letters – none opposed the requested rulemaking

- April 2018 – Staff formulated a recommendation and conducted a Petition Review Board (internal)

- Staff is preparing the recommendation and *Federal Register* notice for Commission review and decision
Linear No-Threshold Model and Standards for Protection against Radiation

February 2015 – Three PRMs request NRC amend the basis of radiation protection regulations from the Linear No-Threshold (LNT) model to the radiation hormesis model (PRM-20-28, 29, 30)
Linear No-Threshold Model and Standards for Protection against Radiation (continued)

- Requested changes to 10 CFR Part 20:
  - Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic
  - Remove ALARA entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless, but may be hormetic
  - Raise public dose limits to same level as worker dose limits, as these low doses may be hormetic
  - End differential doses limits for pregnant women, embryos and fetuses, and children under 18 years of age
NRC Action on PRM-20-28, 29, & 30

- June 23, 2015 – Noticed the PRMs (80 FR 35870); accepted comments through November 2015
- 3,262 letters (2627 form letters, 635 unique)
- ~100 of the 635 letters agreed with petitioners
- NRC staff considered all comments, including input from several other Federal agencies, ACMUI
- May 2018 – Staff considered NRCP published Report 27, “Implications of Recent Epidemiologic Studies for the Linear-Non-threshold Model and Radiation Protection ” reaffirming the LNT model.
- Staff is preparing recommendation and FRN for Commission review and decision

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34
Individual Monitoring Devices for Industrial Radiographic Personnel

Petition for rulemaking on individual monitoring devices for industrial radiographic personnel (PRM-34-07).

Petitioner requested:

- Dual-function devices (functions of alarm ratemeter and direct reading personnel dosimeter) be allowed to meet § 34.47(a) requirements
- Digital output personnel dosimetry be allowed for dose of record under § 34.347(a)

May expand to include Parts 36 (irradiator) and 39 (well logging) for use of digital output personnel dosimeters
NRC Action on PRM 34-7

- November 9, 2016 published a notice of docketing and requested public comment on the petition
- 13 comment submissions were received – all in favor of the petitioner’s request – 2 out of scope
- Staff is currently resolving the petition – plans to have SECY paper to Commission early fall 2018
Radiation Safety Requirements For Industrial Radiography

Â Staff developing a rulemaking plan
Â Areas being considered in rulemaking plan:
   ï Revise language for 34.41(a) to allow “working nearby” and change compatibility category B to C
   ï Revise language for 34.51 to allow “working nearby” and keep at compatibility category C
   ï Revise training requirements for radiographers and assistants to require at least 40 hours of training.
Â Dosimetry (from PRM-34-7)
   ï Consider multi-function devices to satisfy personnel monitoring requirements in 34.47(a)
Financial Assurance For Disposition Of Category 1 And 2 Byproduct Material For Radioactive Sealed Sources

- October 2016 – Staff submitted a rulemaking plan on financial assurance for disposition of Category 1 and 2 byproduct material radioactive sealed sources
  - Revision to 10 CFR 30.35, “Financial assurance and recordkeeping for decommissioning”
  - Expand the financial assurance requirements to include all byproduct material Category 1 and 2 sources tracked in the National Source Tracking System

- Staff will include the financial assurance considerations in the planned Integrated Source Security rulemaking
Items Containing Byproduct Material Incidental to Production

- The Commission approved PRM-30-65 in 2012 for consideration in rulemaking.
- Staff is currently developing a draft regulatory basis to support rulemaking activities.
- Staff will solicit feedback, via Federal Register Notice, on the current uses and users of items containing byproduct material incidental to production to help inform the regulatory basis.
- Anticipated publication date is late 2019 or early 2020.
Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards

- Staff is currently developing a regulatory basis to support rulemaking activities

- The draft regulatory basis will be published for public comment in late Fall 2018 and finalized in early 2019

- The proposed rule would amend Part 71 to harmonize domestic regulations for Type B and fissile radioactive material transportation packaging with the 2012 Edition of the International Atomic Energy Agency (IAEA) Safety Standards Regulations for the Safe Transport of Radioactive Material (SSR-6).
Questions? Call me!

Kimyata Morgan-Butler
Chief, Materials Rulemaking and Project Management Branch

Kimyata.Morgan-Butler@nrc.gov
301-415-0733