POLICY ISSUE
(Information)

September 15, 2016 SECY-16-0105

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: STAFF ASSESSMENT OF ISSUES RAISED IN COMMISSION MEETING WITH STAKEHOLDERS

PURPOSE:

The purpose of this paper is to inform the Commission of the U.S. Nuclear Regulatory Commission (NRC) staff actions related to the issues raised in the Commission's July 26, 2016, meeting with NRC Stakeholders. This paper does not address any new commitments or resource implications.

BACKGROUND:

At the April 6, 2016 hearing of the U.S. Senate Committee on Environment and Public Works, Chairman Inhofe suggested the NRC hold another nuclear energy stakeholder meeting, similar to the 1998 meeting held by then Chairman Jackson. On July 26, 2016, the Commission held an all-day meeting where the NRC invited a number of external stakeholders to share their perspectives on the NRC's programs and performance. The meeting participants included state and tribal representatives, nongovernmental organizations, industry, organized labor, vendors, academia, and the medical community, as well as a former NRC Commissioner and a former NRC Chairman.

CONTACT: Robert J. Lewis, OEDO
(301) 415-1712

Enclosure

On August 9, 2016, the Commission issued a staff requirements memorandum (SRM-M160726) that directed the NRC staff to identify each substantive issue or recommendation raised at the meeting or related correspondence through August 15, 2016. In addition to identifying each substantive issue or recommendation, the Commission directed the NRC staff to identify its relationship to past NRC decisions, to current or planned NRC efforts, or to describe a path forward for evaluation. On August 4, 2016, one stakeholder, the Nuclear Energy Institute (NEI), provided supplementary written comments for the stakeholder meeting (NRC Agencywide Documents Access and Management System (ADAMS) Accession Number ML16218A271).

DISCUSSION:

The NRC staff has reviewed the stakeholder meeting transcript and written comments. There were a number of stakeholder comments that reflect the NRC's ongoing stakeholder interactions and its work to continually improve processes. The enclosure to this paper, "Summary of Substantive Issues and Recommendations from the July 26, 2016, Commission Meeting with Stakeholders," has grouped and summarized the substantive issues and recommendations raised. The grouping resulted in 18 topic areas, listed below. The issues and improvement areas raised at the meeting, or related correspondence for each topic area, are listed below. The staff attempted to reflect all stakeholder comments in the summaries. The staff acknowledges that the summarization process may result in loss of fidelity of information, and the staff is committed to working with the stakeholders to ensure that all comments are fully considered.

To assist the review of the substantive issues and recommendations raised, the NRC staff considered how each topic area relates to NRC's Principles of Good Regulation - Independence, Clarity, Openness, Reliability, and Efficiency. One purpose of the Principles of Good Regulation is to help focus the agency on safety and security while appropriately balancing the interests of NRC's stakeholders. Some topic areas touch upon multiple principles, but are only listed once below.

The principle of independence includes the concept of obtaining all available facts and opinions as part of regulatory decision-making. The NRC staff identified three topic areas relating to this principle: (1) NRC's safety culture, (2) greater recognition of the economic and environmental benefits of nuclear energy, and (3) maintaining technical skills and capabilities. The grouping of these topics under the independence principle reflects that, to operate as an effective and efficient independent nuclear regulator, NRC must maintain a work environment having freedom to raise concerns to fully inform decisions, must perform its functions in a manner that does not compromise its effective independence on safety and security decisions, and must maintain independent technical capabilities sufficient to support its regulatory decisions.

The clarity principle speaks to the coherence and practicality of NRC regulations, an understandable nexus of agency activities and positions to those regulations, and a direct tie to the agency's mission. Issues and recommendations raised in the stakeholder meeting suggested a focus on regulatory clarity is warranted in six topic areas: (4) development of an advanced reactor regulatory framework, (5) regulatory framework for new light water reactors and small modular reactors, (6) uranium recovery activities, (7) patient release criteria, (8) timeliness for resolving nonconforming conditions, and (9) Agreement State regulatory compatibility timeline.

Throughout the meeting, participants offered positive feedback on the openness and access to the NRC staff in their ongoing interactions with the NRC. The quality of the NRC staff's efforts towards communications and work relationships was recognized in several program areas. The stakeholders comments were grouped into two topic areas: (10) NRC information sharing systems and activities, and (11) improvements to transparency in invoices and fees.

With respect to the principle of reliability, several stakeholders identified issues with perceived changes to longstanding regulatory positions or previously approved approaches. These changes may decrease regulatory stability and predictability. Issues were grouped into four topics: (12) backfitting, (13) efficient and predictable licensing processes, (14) leveraging risk information to focus effort, and (15) stability of NRC security programs.

Commenters at the July 26 meeting, and comments in the NEI letter, provided examples of the agency's efficiency principle where they saw room for improvement, such as the need to continually upgrade our regulatory capabilities, to ensure that regulatory activities are commensurate with the risk, and to improve the timeliness of NRC regulatory decisions. The topic areas identified included: (16) sustaining improvements on effectiveness, efficiency, and agility, (17) regulatory programs not sized commensurate with the risk of the regulated activity, and (18) NRC's ability to keep pace with a changing environment.

For 16 topics listed above and described in the enclosure, the NRC staff concluded that the issues and areas for improvement raised by stakeholders were consistent with ongoing efforts in that topic area, and the concerns raised will be considered in those activities. The staff does not intend to initiate activities to address topic (2), "greater recognition of the economic and environmental benefits of nuclear energy," because consideration of the benefits of nuclear energy is inconsistent with the NRC's statutory responsibilities. The Staff does not intend to initiate activities to address topic (9), "Agreement State regulatory compatibility timeline," because the Commission recently rendered its decision, to maintain the current requirement for compatibility within three years.

The stakeholder meeting provided valuable insights to focus efforts to ensure safety and security while appropriately balancing the interests of NRC's stakeholders. The feedback reflects and reinforces the insights gained from the NRC's sustained, conscious efforts in recent years to engage and inform the public and other stakeholders. NRC holds over 1,000 public meetings every year, and the NRC will continue to ensure meaningful opportunities for the public and other stakeholders to participate in NRC regulatory activities, consistent with the openness strategies in NRC's strategic plan.

RESOURCES:

Resources to conduct the work identified are addressed within existing resource requests.

COORDINATION:

The Office of the General Counsel has reviewed this Commission paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper and determined that there are no resource implications.

/RA/
Victor M. McCree
Executive Director
for Operations

Enclosure:
As stated

cc: SECY
OGC
OCA
OPA
CFO

Summary of Substantive Issues and Recommendations from the July 26, 2016 Commission Meeting with Stakeholders

On July 26, 2016, the U.S. Nuclear Regulatory Commission (NRC) held a meeting with NRC Stakeholders. The meeting participants identified a number of substantive issues and recommendations. In addition, on August 4, 2016, one stakeholder provided a letter with supplementary comments (NRC Agencywide Documents Access and Management System (ADAMS) Accession No. ML16218A271). The issues and recommendations from the meeting and letter are each addressed using the NRC's Principles of Good Regulation, and further categorized into 18 topical areas in this document. This document briefly describes related staff activities and previous Commission decisions, and provides the NRC staff's assessment on: (a) how concerns have been previously dispositioned, (b) whether current NRC activities are responsive to the concern, or (c) the need and plans for additional NRC actions to be responsive to the concern. The NRC staff believes that the meeting provided valuable insights to focus NRC efforts to ensure safety and security while appropriately considering the interests of NRC's stakeholders.

INDEPENDENCE PRINCIPLE

The principle of independence includes the concept of obtaining all available facts and opinions as part of regulatory decision-making. The NRC staff identified three topic areas relating to this principle: (1) NRC's safety culture, (2) greater recognition of the economic and environmental benefits of nuclear energy, and (3) maintaining technical skills and capabilities. The grouping of these topics under the independence principle reflects that, to operate as an effective and efficient independent nuclear regulator, NRC must maintain a work environment having freedom to raise concerns to fully inform decisions, must perform its functions in a manner that does not compromise its effective independence on safety and security decisions, and must maintain independent technical capabilities sufficient to support its regulatory decisions.

1. NRC's Safety Culture

Issues and Recommendations

Some participants and some recent survey results indicate gaps in trust and perceptions between NRC senior management and staff. The concerns suggest that the NRC should work on safety culture issues including raising differing views, ensuring diversity, communicating bases for decisions fully, and clarifying NRC's decision-making model.

Related Staff Activities and Commission Decisions

On June 9, 2016, the Executive Director for Operations (EDO) issued an Agency Action Plan (ADAMS Accession No. ML16148A210) that detailed the steps NRC is taking based on the results of the 2015 Nuclear Regulatory Commission Office of the Inspector General Safety Culture and Climate Survey, recent Federal Employee Viewpoint Survey, and other information. The focus area of the plan is "Fostering a greater climate of trust at the NRC," and the plan details actions and timelines intended to (1) strengthen the positive environment for raising concerns; (2) promote a culture of fairness, empowerment, and respect across the agency, and (3) establish clear expectations and accountability for NRC leaders. The Agency Action Plan will be implemented through the end of fiscal year (FY) 2017.

2. Greater recognition of the economic and environmental benefits of nuclear energy

Issues and Recommendations

Some participants recommended that NRC consider undertaking activities, including Congressional engagement to ensure that nuclear power remains a domestic energy source and new technologies are brought to market.

Related Staff Activities and Commission Decisions

Although the NRC actively engages with other Federal agencies, States, Tribes, the U.S. Congress, stakeholders, and the public on issues potentially affecting nuclear and radiation safety, the nature of NRC's interactions is limited consistent with NRC's regulatory responsibilities and mission to protect public health and safety and the environment and promotion of the common defense and security. The NRC does have activities related to regulatory efficiency (such as Project AIM), which are addressing the concerns related to unnecessary regulatory burden. Such activities are appropriate since they address efficiency while avoiding promotional features.

NRC staff concludes that interactions that are, or could be perceived to be, promotional towards regulated activities are inconsistent with NRC's statutory role as an independent regulator. Accordingly, although there is no current NRC initiative or activity that would address this concern, the NRC staff's view is that NRC actions in this area are not appropriate.

3. Support for technical skills and capabilities

Issues and Recommendations

NRC should continue to support workforce development (i.e., nuclear engineering and health physics programs) at universities, increase opportunities for students to participate in NRC research, include curriculum development grants as part of the Integrated University Program (IUP), and support efforts to ensure advanced reactors, nuclear security, and international nuclear initiatives are part of the curricula.

Related Staff Activities and Commission Decisions

NRC staff notes that the IUP includes faculty development but not a separate curriculum development program. Curriculum development funding has not been part of NRC's IUP since FY 2012. Nuclear security falls within the scope of the National Nuclear Security Administration's IUP activities, but not the NRCs IUP. While advanced reactors and international nuclear initiatives are not explicit disciplines within NRC's IUP, the existing disciplines supported by NRC and other agencies have application to those areas.

CLARITY PRINCIPLE

The clarity principle speaks to the coherence and practicality of NRC regulations, an understandable nexus of agency activities and positions to those regulations, and a direct tie to the agency's mission. Issues and recommendations raised in the stakeholder meeting suggested a focus on regulatory clarity is warranted in six topic areas: (4) development of an advanced reactor regulatory framework, (5) regulatory framework for new light water reactors and small modular reactors, (6) uranium recovery activities, (7) patient release criteria, (8) timeliness for resolving nonconforming conditions, and (9) Agreement State regulatory compatibility timeline.

4. Development of an advanced reactor regulatory framework

Issues and Recommendations

A new regulatory framework is needed to regulate advance reactor technologies. The new framework would incorporate discrete stages; be predictable, efficient, risk-informed and performance based, and cost-effective for advanced reactors; be technology-inclusive; and would maximize the use of current regulations while recognizing limitations of light-water reactor centric features. Currently available regulatory processes increase the uncertainty for business models for these emergent technologies. NRC's advanced reactor regulatory framework development activities should be undertaken outside of the NRC fee recovery activities.

For advanced reactors, NRC should leverage the opportunity to improve upon approaches in the 10 CFR Part 52 regulatory framework (e.g., design certification), and should consider the Canadian Nuclear Safety Commission's (CNSC's) phased licensing approach.

Related Staff Activities and Commission Decisions

The NRC is actively preparing to review advanced non-light water reactors (non-LWRs). These efforts include evaluating our overall infrastructure for licensing advanced reactors. In May 2016 the NRC made its draft "Vision and Strategy: Safely Achieving Effective and Efficient Non-light Water Reactor Mission Readiness" (ADAMS Accession No. ML16139A812) publicly available. The Vision and Strategy document was subsequently published in the Federal Register on July 21, 2016, for public input. The NRC staff expects to finalize this document in early 2017. To help ensure a path to success, the Vision and Strategy document establishes three strategic objectives: enhance technical readiness; optimize regulatory readiness; and optimize communication. The objectives are intended to be actionable and measurable and are organized into three categories based on expected commencement and completion: near-term (0-5 years), mid-term (5-10 years), and long-term (greater than 10 years). The staff is currently developing implementation action plans (IAPs) for the contributing activities (i.e., staff work), which (when considered in the aggregate) capture the work required to efficiently and effectively review and regulate non-LWRs. The IAPs will include the identification of tasks to be performed, estimate of order-of-magnitude

costs, duration of work, etc. The IAPs for the near-term strategies are expected to be complete by the end of September 2016; the long-term IAPs are expected to be complete by February 2016.

Examples of near-term strategies include, but are not limited to: acquire/develop sufficient knowledge, technical skills, and capacity to perform non-LWR regulatory reviews; establish a more flexible, risk-informed, performance-based, non-LWR review process; and facilitate industry codes and standards need to support the non-LWR life cycle. Examples of mid-term strategies include, but are not limited to: identify and resolve technology-specific policy issues that impact the review of non-LWR NPPs; and initiate and develop a new non-LWR regulatory framework (if necessary). The long-term strategy is to finalize a new non-LWR regulatory framework. The Vision and Strategy document lists contributing activities to support each strategy:

To highlight recent accomplishments, in April 2016, the NRC issued draft Advanced Reactor Design Criteria (ADAMS Accession No. ML16096A420) for informal public comment. These design criteria would provide high-level guidance to support the design of non-LWR technology. The NRC plans to publish these criteria for public comment in a draft Regulatory Guide in early 2017. Public comments will be considered for incorporation into a final regulatory guide and published in late 2017. The NRC is also evaluating staged and phased review processes to provide increased flexibility for potential applicants. These ongoing evaluations include consideration of CNSC's approach.

In addition, NRC staff, working with the U.S. Department of Energy, has an ongoing program to host workshops on advanced reactor issues; two have been conducted and additional workshops are being planned. The focus of this series of workshops is to open a dialogue among key stakeholders to discuss current and potential regulatory requirements and related challenges in the commercialization of non-LWR technologies and to discuss appropriate alternatives. The workshops have also helped to inform the NRC's Vision and Strategy document.

With respect to the new framework development being non-fee-recoverable, as a part of its FY 2017 budget request, the NRC requested legislative language that would provide the NRC with $5 million for activities related to the development of regulatory infrastructure for advanced nuclear technologies and would exclude this funding from the statutory fee recovery requirement. The Senate-passed FY 2017 appropriations bill included legislative language that would provide $5 million in non-fee-recoverable funding for this purpose.

5. Regulatory framework for new light water reactors and small modular reactors

Issues and Recommendations

With respect to the effectiveness of the current regulatory framework for new reactor designs, stakeholders identified potential opportunities for improvement (reductions) in the level of detail required in applications based on risk, level of security required, whether off-site power is required for small modular reactors (SMRs); and implementation of inspections, tests, analyses, and acceptance criteria (ITAAC).

Concerns were also raised that Tier 2* and ITAAC have created unnecessary regulatory burdens, which should be reevaluated for SMRs. Meeting participants suggested that generic issues that can be resolved before an application is submitted to provide for greater clarity and stability for potential SMR applicants on issues such as emergency planning zone, control room issues, and security program expectations.

Related Staff Activities and Commission Decisions

In the SRM to the Briefing on Strategic Programmatic Overview of the New Reactor Business Line, dated September 16, 2014 (ADAMS Accession No. ML14259A359), the Commission directed the staff to continue the practice of conducting lessons learned reviews of the experience implementing 10 CFR Part 52 (Part 52), "Licenses, Certifications, and Approvals for Nuclear Power Plants." In particular, NRC staff was directed to address whether the NRC could capture greater efficiencies in the Part 52 review process and whether the NRC should update the estimates for the length of time it will take to perform new reactor reviews under Part 52, based on experience. To address this direction, the Office of New Reactors provided the Commission a Memorandum, "Response to Staff Requirements Memorandum M140910 – Staff Report: 10 CFR Part 52 Application Reviews - Efficiency Opportunities and Review Timelines", (ADAMS Accession No. ML15114A452) describing the insights from Part 52 reviews and NRC staff's actions to address them. NRC staff had already completed a Lessons Learned Paper (ADAMS Accession No. ML13059A239) in 2014 and had implemented these changes for the readiness and the acceptance reviews related to the APR1400 design certification application. These enhancements have shown great improvements in the effectiveness of NRC staff review and in the predictability of the NRC review schedule.

NRC is evaluating whether changes to the current Tier 1, Tier 2, and Tier 2* designation structure are appropriate. The NRC is considering comments from the Nuclear Energy Institute (NEI) December 19, 2014 (ADAMS Accession No. ML14357A079), letter, and has conducted public meetings on this topic (most recently in June 2016). NRC staff is developing a paper to inform the Commission of planned improvements in usage of the Tier 2* designation in future design certifications, including related plans to improve descriptions of Tier 1 and Tier 2 information and associated infrastructure updates.

The NRC has been evaluating generic issues that can be resolved before an application is submitted to provide greater clarity and stability for potential SMR applicants. In SECY-10-0034, "Potential Policy, Licensing, and Key Technical Issues for Small Modular Nuclear Reactor Designs" (ADAMS Accession No. ML093290268), the NRC identified a range of potential policy issues to be resolved for both light water and non-light water SMR designs, including emergency preparedness, control room staffing, and security requirements. NRC staff updated the Commission on the status of efforts to resolve these policy issues in SECY-14-0095, "Status of the Office of New Reactors Readiness to Review Small Modular Reactor Applications" (ADAMS Accession No. ML14073A710). More recently, NRC staff provided a rulemaking plan to the Commission to conduct a rulemaking on emergency preparedness for SMRs and other new technologies, such as non-LWRs and medical isotope production facilities (SECY-16-0069, ADAMS Accession No. ML16020A388). In an SRM to SECY-16-0069 (ADAMS Accession No. ML16174A166) the Commission approved the rulemaking plan,

and NRC staff is beginning to develop a draft regulatory basis, which will be published for stakeholder comment early in 2017.

6. Uranium recovery activities

Issues and Recommendations

The overlapping statutory authority of Federal agencies for uranium recovery activities contributes to regulatory uncertainty. There was significant NRC and industry effort to develop the Generic Environmental Impact Statement (GEIS) for In-Situ Leach (ISL) Uranium Milling Facilities, and an associated roadmap to improve the efficiency and consistency of NRC environmental reviews for ISL applications, yet recent applications have had to employ a high amount of site-specific analyses.

Related Staff Activities and Commission Decisions

The NRC staff agrees that dual regulation can reduce regulatory certainty and has taken steps to avoid or minimize dual regulation. In cases where another government agency is issuing rules that impact NRC licensees, the NRC has provided its perspectives on the need to avoid dual regulation throughout the rulemaking process. For example in the area of uranium recovery, NRC staff signed a Memorandum of Understanding with the Bureau of Land Management on February 12, 2013, documenting how information would be shared between the agencies to avoid duplication of efforts related to environmental reviews for uranium recovery license applications. More recently, NRC staff worked with the Environmental Protection Agency (EPA) on EPA's 40 CFR Part 192 ground-water standards for in-situ leach facilities to avoid or minimize dual regulation.

Additionally, the NRC is undertaking an internal review of the uranium recovery licensing process that will include a review of the implementation of the GEIS for in-situ leach facilities. That being said, licensing reviews for uranium recovery facilities do involve several site-specific factors, consultations under the National Historic Preservation Act, which may impact the time needed for licensing.

7. Patient release criteria

Issues and Recommendations

Some stakeholders encouraged NRC to review the basis for patient release criteria (10 CFR 35.75), particularly for iodine-131 therapy, and the possible public health and safety impacts to family members or at hotels near treatment sites.

Related Staff Activities and Commission Decisions

The Commission provided the staff direction in the SRM to COMAMM-14-0001/COMWDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance," (ADAMS Accession No. ML14118A418) to evaluate whether significant regulatory changes to the patient release program are warranted, including whether the current patient release standard, which

allows family members, caregivers, and hotel workers to be exposed to dose levels above those permitted for the general public, is appropriate. The NRC staff is in the process of implementing that direction. The NRC Office of Nuclear Regulatory Research is conducting a study on "Patient Release: Post-Radioisotope Therapy," to collect information on any potential impacts of patient release on members of the public. On November 16, 2015, the NRC staff issued a Federal Register Notice to collect information on patient release issues associated with medical treatment with sodium iodide I-131. The results of the survey are expected in September 2017. The insights gained from the survey results and other activities will be provided in a SECY Paper due to the Commission in FY 2018.

8. Timeliness for resolving nonconforming conditions

Issues and Recommendations

Some meeting participants indicated that fewer NRC and industry resources should be directed at non-conforming conditions that pose little or no safety risk. Current regulatory approaches do not efficiently facilitate the use of compensatory measures that can provide equivalent protection of public health and safety. Some low-risk, low safety significance issues may benefit from a timetable for coming into compliance or a process that allows indefinite enforcement discretion, or no additional regulatory action. However, some other stakeholders cautioned that such an approach might miss the cumulative impact of multiple low risk nonconforming items.

Some stakeholders indicated that the implementation of fire protection regulations, and the implementation of post-Fukushima requirements for plants that have announced plans to decommission, are two examples that illustrate NRC is not taking timely, meaningful action consistent with established requirements. One stakeholder specifically questioned NRC's conclusion that plants that have announced plans to shut down and have obtained relief from post-Fukushima requirements have demonstrated adequate protection for the period before shutdown.

Related Staff Activities and Commission Decisions

NRC staff recognizes that not all non-conforming conditions represent an immediate threat to safety. In such cases, if the licensee implements appropriate timely compensatory measures, immediate action may not be warranted. The current practice of expending resources urgently on low risk and low safety significance non-conforming conditions may reduce safety by diverting NRC and licensee resources away from more safety significant activities. To address this, NRC staff is working on an initiative that ensures that design basis non-compliance issues affecting operability are resolved on a schedule commensurate with their risk and safety significance. Specifically, NRC staff is currently considering an improvement to the Notice of Enforcement Discretion process to address non-conformances with current licensing basis design requirements. If implemented, the process improvement would allow licensees to request enforcement discretion for low risk/low safety significance design issues affecting operability of a technical specification structure, system, or component. If, after reviewing the licensee's request and considering the licensee's defense-in-depth, safety margins and compensatory measures, NRC staff concludes that the risk of continued operation with

the non-conforming condition is low and that there is no undue risk to public health and safety, then NRC staff could exercise discretion not to take enforcement action for the noncompliance created by the design issue.

The Commission approved the staff's use of interim enforcement discretion for licensees transitioning to the risk-informed, performance-based fire protection rule (NFPA 805) beginning in 2004 with the SRM to SECY-04-0050 (ADAMS Accession No. ML041320185). The Commission has periodically approved adjustments to the appropriate portion of the Enforcement Policy since that time. The Commission provided this enforcement discretion as an incentive for licensees to transition to NFPA 805.

Following the issuance of the post-Fukushima orders (EA-12-049, EA-12-051, and EA-13-109), some licensees have requested, and the Director of the Office of Nuclear Reactor Regulation (NRR) has granted relaxation or rescission of one or more conditions of these orders when the licensee demonstrated good cause. Upon receipt of each request from a licensee, NRC staff has conducted a thorough analysis of the basis for the request and the current capabilities of the plant (which in many cases has included compensatory measures) in relation to order requirements, for the period of time during which the order requirements will be relaxed or rescinded, and has documented the decision and the basis for the decision in a publicly-available response letter to the licensee. Such requests have only been approved when the NRC finds that adequate protection of public health and safety continues to be maintained.

9. Agreement State regulatory compatibility timeline

Issues and Recommendations

At the stakeholder meeting, the Organization of Agreement States representative proposed a tiered approach to adoption of compatible regulations. Such an approach would assist prioritization, and consider health and safety implications together with burden to states.

Related Staff Activities and Commission Decisions

SECY-15-087, "Agreement State Program Policy Statement and Program Recommendations" (ADAMS Accession No. ML15002A131) provided an option for a multifactor approach that would have used risk significance to inform the compatibility determination of regulations during the rulemaking process and allow flexibility for a tiered-time approach for rule adoption based on safety and security significance of the regulation. In the SRM to SECY-15-0087 (ADAMS Accession No. ML16082A514) the Commission directed the continuation of the current approach (a 3-year adoption period for all relevant regulations was appropriate).

OPENNESS PRINCIPLE

Throughout the meeting, participants offered positive feedback on the openness and access to the NRC staff in their ongoing interactions with the NRC. The quality of the NRC staff's efforts towards communications and work relationships was recognized in several program areas. The

stakeholders comments were grouped into two topic areas: (10) NRC information sharing systems and activities, and (11) improvements to transparency in invoices and fees.

10. NRC information sharing systems and activities

Issues and Recommendations

There were mixed views on the availability of NRC information through ADAMS, and NRC's use of plain language (e.g., a critical comment was made regarding the overuse of the term "stakeholder"). Some maintained that NRC communications related to low-risk, high-interest issues (e.g., groundwater movement of tritium) have not been effective or timely.

Others stated that NRC public engagement and openness activities are not always tailored to the local audience. For example, open houses work at some places better than others do, and some end of cycle public meetings could be grouped together for co-located reactors (especially in areas of traditionally lower local interest).

The agency's progress in recent years in dealing with tribal governments was recognized, and NRC was encouraged to conduct its outreach in ways that acknowledge both the differences between tribes and the independence of tribes.

Related Staff Activities and Commission Decisions

NRC staff agrees that the openness of NRC is an area for continuous improvement and will take action to address these comments, as appropriate, within the scope of NRC staff's activities related to the agency Communications Council. Consistent with the priority focus areas of the EDO, NRC staff plans to renew the efforts of the Communications Council as a tool to provide strategic direction in agency internal and external communications, and to exchange information about NRC communications activities. Additionally, the Communication Council will address effective and timely communications of low-risk high-visibility issues.

NRC's Inspection Manual Chapter 0305, "Operating Reactor Assessment Program," Section 09, "Public Stakeholder Involvement," provides guidance regarding the conduct of engagements with the public and interested stakeholders on the performance of a particular site and the role of the NRC in ensuring safe plant operations. Specifically, the Manual Chapter identifies how the NRC might elect to interact with the public and where that interaction could take place, e.g., on-site or near the site. The guidance provides the NRC's regional offices with varying options to tailor the meetings for the public and includes an open house for the public, poster sessions, virtual meetings, or other similar activities that allow for effective communication. NRC's regional offices carefully weigh, among other things, historical and current public interest in plant performance, any discussion the NRC needs to have with the licensee, and any other areas of public interest. As mentioned above, other means for communicating beyond the meeting location itself are available.

With respect to Tribal outreach, on August 19, 2016, staff provided SECY-16-0098, "Tribal Consultation Policy Statement and Protocol," (ADAMS Accession

No. ML16144A777), to the Commission, and an associated Commission Briefing is scheduled on September 19, 2016.

The stakeholder concerns related to Tribal outreach are within the scope of the policy statement currently being considered by the Commission. The staff notes that Tribal representatives are representatives of sovereign nations and are not stakeholders as the term is generally used within the NRC.

11. Transparency in invoices and fees

Issues and Recommendations

There is a need for greater NRC transparency in invoices and fees. NRC should communicate a schedule and expected hours for each licensing action, and should notify licensees upon a departure from the budget estimate or planned schedule.

Related Staff Activities and Commission Decisions

On August 15, 2016, staff provided SECY-16-0097, "Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule," (ADAMS Accession No. ML16210A472) to the Commission, and an associated Commission Briefing is scheduled on September 16, 2016. That paper provides staff's response to the SRM to SECY-15-0015, "Project Aim 2020 Report and Recommendations," (ADAMS Accession No. ML15159A234) and its direction to undertake an effort to: (1) simplify how the NRC calculates its fees, (2) improve transparency, (3) improve the timeliness of the NRC's communications about fee changes, and (4) modify input to, and accuracy of, invoices. NRC staff's proposed approach would institutionalize continuous improvement for fee transparency across NRC programs.

RELIABILITY PRINCIPLE

With regard to the principle of reliability, several stakeholders identified issues with perceived changes to longstanding regulatory positions or previously approved approaches. These changes may decrease regulatory stability and predictability. Substantive issues and recommendations were grouped into four topics: (12) backfitting, (13) efficient and predictable licensing processes, (14) leveraging risk information to focus effort, and (15) stability of NRC security programs.

12. Backfitting

Issues and Recommendations

Stable, reliable regulation is challenged by inconsistent implementation of 10 CFR 50.109 (backfitting), with respect to the compliance exception and qualitative factors. Also, backfitting requirements preclude NRC from requiring reasonable, low-cost measures because of the cost-benefit analyses (e.g., real time radiation monitoring around power plants). A specific comment was made that NRC should update the valuation of a statistical life (VSL) used to evaluate cost-benefit, including for backfitting. In a letter received after the meeting, one stakeholder requested the Commission to

provide NRC staff clear direction on the use of the compliance exception to ensure that its use is consistent with the policy direction provided in the preamble to the 1985 backfitting rule.

Related Staff Activities and Commission Decisions

Based in part upon similar stakeholder feedback in early 2016, NRC staff initiated an effort, through its Committee to Review Generic Requirements (CRGR), which includes a review of questions regarding the proper application of the compliance exception. Details of this effort can be found in the EDO's June 9, 2016, memorandum, "Tasking Related to Implementation of Agency Backfitting and Issue Finality Guidance," (ADAMS Accession No. ML16134A004). The CRGR held a public meeting on this topic on September 13, 2016. The CRGR is continuing its evaluation of training, guidance, and knowledge management in response to the EDO's tasking. Although staff acknowledges the comment in support of additional Commission direction, the staff considers this NRC staff-initiated effort to be responsive to the concern.

With respect to the concerns on NRC staff's use of qualitative factors in regulatory decisions, in the SRM to SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," (ADAMS Accession No. ML15063A568) dated March 4, 2015, the Commission provided direction on the use of qualitative factors. This direction included updating guidance regarding the use of qualitative factors to improve the clarity, transparency, and consistency of the agency's consideration of qualitative factors in regulatory analyses and backfit analyses. As part of this direction, NRC staff is also updating the three main cost-benefit guidance documents. NRC staff is consolidating these three documents into one single guidance document, which NRC staff plans to complete early in calendar year 2017. In the February 23, 2016, SRM to SECY-15-0129 (ADAMS Accession No. ML16034A441) the Commission directed the CRGR to develop and provide to the Commission, "criteria and implementing guidance to clarify at what stage and under what conditions the NRC staff is expected to request a review of proposed rulemaking packages." On May 23, 2016, the CRGR responded to the Commission direction (SECY-16-0064, ADAMS Accession No. ML16070A214) and issued new staff guidance for CRGR review of rulemakings that rely on qualitative factors.

Regarding the VSL, in September 2015 NRC staff published for public comment a proposed revision to NUREG-1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy." This revision updates the dollar per person-rem conversion factor, recommends using low and high dollar per person-rem conversion factor estimates for sensitivity analysis, establishes a method for keeping the dollar per person-rem conversion factor current, and provides guidance on how to adjust the cancer risk coefficient for high-rate exposure scenarios. The comment period has closed and NRC staff has reviewed and incorporated the comments, as appropriate, in to the proposed revision. NRC staff plans to complete NUREG-1530, Revision 1, by November 2016.

Recommendation 11.3 of NRC's Fukushima Near-Term Task Force was for the NRC staff to study the efficacy of real-time radiation monitoring on site and within the emergency planning zones. NRC staff's activities related to real time radiation monitoring are discussed in SECY-15-0137, "Proposed Plans for Resolving Open

Fukushima Tier 2 and 3 Recommendations," (ADAMS Accession No. ML15254A006), and Enclosure 7 of that paper. NRC staff plans to provide a Commission paper on this topic in December 2016.

13. Efficient and predicable licensing processes

Issues and Recommendations

There is a lack of clear expectations, process discipline, and common understanding for NRC licensing activities. These concerns span reactor and non-reactor programs, and NRC does not appear to effectively share licensing practices and experience across programs.

Lessons learned for initial applications in "new" areas (e.g., digital instrumentation and controls (Digital I&C), dry cask relicensing, emergency preparedness, and security for recently shut down plants), should be captured to make subsequent applications more efficient.

The resources necessary for a licensing action are unpredictable and too-often not commensurate with the risk significance of the activity. Simpler licensing amendments and topical reports can be issued in a more timely fashion (for example, the NRC's timeliness metric does not distinguish between simple and complex cases). For complex applications, licensing process information is not sufficient to support well-informed investment decisions.

Discipline is needed to limit the number of requests for additional information (RAIs), and to avoid multiple rounds of RAIs.

The fuel cycle facility regulatory issues integrated schedule was offered as a successful communications tool that might find use in other NRC programs, and could be used to inform prioritization of multiple activities affecting a given licensee or type of licensee.

Some stakeholders requested the development of a process for sharing information when NRC is working on licenses that reside in Agreement States where there is not exclusive Federal jurisdiction and the Agreement State has a licensee. Specifically, licensees with "dual" licenses – both NRC and Agreement State – would be best served if the NRC and Agreement States could work together through their licensing process, mainly because the license deficiencies during both the Agreement State and NRC reviews will almost always be the same."

Spent fuel storage licensing needs to be focused on those items that have a significant impact, Certificates of Compliance (CoC) revisions by rulemaking are inefficient, and there is a lack of processes to convert from a general license to a specific license, without a new license application.

Timely review of topical reports (TRs) can eliminate inefficient, redundant reviews of multiple licensing amendment requests (LARs). Treating a safety evaluation (SE) for the first LAR for a given topic in a manner equivalent to an SE for a TR can save significant resources. Although recent improvements to TR prioritization and metrics through staff

TR review procedures (ADAMS Accession No. ML091520370) were noted, additional possible process improvements were offered including automatically updating TRs to reflect industry codes that are a part of a subsequent related license amendment and minimizing reviews of subsequent, similar applications once a technical matter is reviewed and accepted in an application.

The draft Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report and draft Standard Review Plan for the Review of Subsequent License Renewal Applications for Nuclear Power Plants (SRP-SLR) contain several instances where the inspection scope and inspection frequency for aging management programs were increased or expanded without supporting operating experience or a technical basis.

Related Staff Activities and Commission Decisions

In the area of Digital I&C, efforts are currently underway to improve the timeliness, efficiency, and predictability of the licensing and oversight process. NRC staff has prepared an integrated action plan with near term and long term goals for the modernization of the regulatory infrastructure, and has provided this plan to the Commission in SECY-16-0070 (ADAMS Accession No. ML16126A137). The goals of the integrated action plan were developed with input from stakeholders. The goals addressed those areas most in need of improved clarity in NRC staff's expectations and processes.

Near term issues with the treatment of common cause failure and the use of 10 CFR 50.59 in the licensing of Digital I&C applications are the first items in the integrated action plan. These items were identified as areas where lack of clarity in NRC staff's expectations and processes presented a challenge to the implementation of Digital I&C systems. NRC staff is continuing to collaborate with stakeholders to identify unnecessary regulatory impediments to the advancement, in nuclear applications, of digital technology.

In NRR, the redirection of Agency resources to process Fukushima related actions caused a decrease in the timely completion of licensing actions. Starting in 2014, resources and management attention were increased to reduce the resulting backlog of licensing actions and a number of specific improvement initiatives were initiated which included process reviews, case specific lessons learned, and reinforcement of program expectations. Most recently, in April 2016 (ADAMS Accession No. ML16202A029) and in the August 22, 2016, Memorandum, "Status of the U. S. Nuclear Regulatory Commission Operating Reactor Regulatory and Licensing Review Process" (ADAMS Accession No. ML16225A003), management again communicated additional expectations to NRC staff regarding several key aspects of licensing reviews, including adherence to established office procedures and discipline in the RAI process.

Currently, NRR is completing actions faster than we are receiving them and often completing simpler licensing actions in 6 to 9 months and emergent licensing actions in less than 6 months. The effectiveness of these efforts continues to be monitored under Project AIM, Action 19 and consistent with the SRM to SECY 15-0015 (ADAMS Accession No. ML15159A234). NRR does utilize a work prioritization process, which

considers the safety impact and exigency of licensing submittals, and NRC staff routinely works to process actions based on licensee requests and outage schedules. Also resulting from Project AIM efforts, by October 1st, NRC staff will implement a new process to communicate to licensees the level of effort for reviews and any significant schedule changes. Although the amount of resources needed for reviews usually correlates with the technical complexity and not the risk-significance of the activity, this new communication allows transparency in resources expenditures and schedules.

The NRC staff is in the process of completing a detailed review of the decommissioning transition process, which addresses the transition of the licensing process in various areas including emergency preparedness, security, and captures infrastructure improvements implemented for the latest four plants entering decommissioning. In addition, interim staff guidance was issued for emergency preparedness and security exemptions associated with decommissioning plants. The report notes that efficiencies were gained over this period of time (e.g., resources to complete emergency preparedness reviews were reduced by approximately 40% from the first to the fourth plant reviewed). NRC staff plans to make the report publicly available no later than September 30, 2016.

NRC staff also recognizes that the focus on addressing the research and test reactor license renewal backlog has delayed the review of some license amendments for these facilities. NRC staff has mitigated the impact by promptly processing licensing actions that have been identified as most time-sensitive for these licensees. Moreover, the agency is exploring non-expiring licenses for research reactors as discussed on March 3, 2016, with the Advisory Committee on Reactor Safeguards (ADAMS Accession No. ML16075A306) and has provided a proposed draft rule, “Non-Power Production or Utilization Facility License Renewal” (SECY-16-0048, ML16019A048), to the Commission for their deliberation.

The Office of New Reactors (NRO) staff is aware of the stakeholder feedback that license reviews should be more predictable and commensurate with the risk significance of the activity. NRC staff is working to develop an enhanced safety focused review approach for the design certification application for NuScale while incorporating use of the NuScale Design Specific Review Standard. These activities will help improve efficiency by focusing on the most important aspects of the design. Further, NRC staff has developed and improved guidance on readiness and acceptance reviews as a result of lessons learned on prior 10 CFR Part 52 applications. This improved guidance for the readiness and acceptance review activities will support stability of the review schedule by focusing efforts, prior to docketing, on having sufficient information in the application to conduct the review. NRO is also reviewing practices on the use of requests for information and audits, such that appropriate information is requested, or audited, to render a safety decision on the application.

In the area of spent fuel storage licensing, NRC is focusing on improving the efficiency of the dry cask licensing process. For example, Division Instruction SFM-26, “Operational Strategies and Management Expectations” (SFM-26) was issued August 8, 2016, as part of ongoing internal assessments to identify and implement process efficiencies, and is publicly available (ADAMS Accession No ML16222A251). SFM-26 delineates expectations for RAIs and acceptance reviews in order to facilitate a more efficient and

effective licensing process, as well as to clarify workload priorities. NRC is working collaboratively with industry as part of the NEI's Regulatory Issue Resolution Protocol process to develop graded approach criteria to reduce the level of detail of dry cask storage technical specifications by focusing on the most safety significant aspects of dry cask loading, transfer, and operations. A pilot project is planned for later this year. This action is intended to streamline the dry cask licensing process by reducing the need for CoC amendments, thereby achieving the goals stated in Petition for Rulemaking 72-7 while eliminating the need for rulemaking and the associated resource burden.

The Office of Nuclear Materials Safety and Safeguards (NMSS) understands the Agreement States' interest in a process for sharing information when NRC is working on licenses that reside in Agreement States where there is not exclusive Federal jurisdiction and the Agreement State regulates the same licensee. As a recent example, for dual licensees (i.e., where the entity has both an NRC and Agreement State license), the NRC is working cooperatively with Agreement States to share security-related details of 10 CFR Part 37 security inspections and associated findings. The NRC is in the process of exploring the possibility of the NRC and Agreement States working cooperatively for certain licensing reviews with "dual" licensees. In addition, as part of the National Materials Program, the NRC and Agreement States maintain awareness of and oversee the performance of licensing practices of the Agreement States. NRC will use good practices developed by Agreement States to enhance its own effectiveness and efficiency

Due to the redirection of Agency resources to process Fukushima related actions and reduce the licensing action backlog, there was a decrease in the timely completion of TRs. The NRC has increased management oversight of TR reviews and enhanced communication with vendors, as indicated in the Office of the Executive Director's letter to AREVA, dated July 6, 2016 (ADAMS Accession No. ML16168A208). NRC staff has also formed an interoffice Working Group to revise the current TR guidance, LIC-500, "Topical Report Process," (ADAMS Accession No. ML13158A296). The revised guidance will include lessons-learned from recent reviews, a new prioritization scheme, and metrics that more appropriately capture the varying priorities of TRs. As a part of this effort, NRC staff plans to engage external stakeholders via public meetings or workshops beginning this fall, with the overarching goal of revising LIC-500 by next summer.

NMSS staff routinely engages in stakeholder interactions to obtain feedback about the license renewal regulatory process. These robust feedback mechanisms primarily consist of public comment periods for draft documents and public meetings that are held by NRC staff.
During the July 26, 2016, Commission Stakeholder meeting, NEI discussed the draft SLR guidance documents. NEI followed up the discussion with a letter citing these documents. Similar comments to those expressed in the NEI letter were submitted to the NRC during the public comment period for the draft GALL-SLR Report and draft SRP-SLR (ML15348A111, ML15348A153, and ML15348A265).

Further, to understand public views of SLRs, NRC staff facilitated public meetings during the comment period on January 21 and February 19, 2016. Moreover, after reviewing the comments received, NRC staff held additional public meetings on April 26, June 1,

June 2, June 16, June 23, and July 28, 2016, to discuss the SLR guidance documents, as well as the comment included in NEI's letter regarding the July 26th Commission Stakeholder Meeting.

These public meetings – as well as the NRC's solicitation of comments – afforded industry and interested stakeholders multiple opportunities to provide their feedback to NRC staff. NRC staff believes that the SLR guidance documents are appropriately supported by plant operating experience, lessons learned from license renewal application reviews, research results, and other technical studies.

Feedback mechanisms such as public comment periods and public meetings provide interested stakeholders, including industry, opportunities to substantively participate in the NRC's processes. These processes include inspection activities. In the case of the SLR draft guidance documents, the validity of these feedback mechanisms are proven because NRC staff is making numerous changes to the documents as a result of these public interactions.

14. Leveraging risk information to focus effort

Issues and Recommendations

Risk information can be better leveraged to improve focus on safety and security, and to more efficiently disposition issues having low impact on safety. Several examples were provided: (a) fire risk assessment realism; (b) focusing license renewal review on areas of increased importance beyond validating the scoping and screening results; (c) ensuring feedback mechanisms are in place to adjust inspection activities, and (d) crediting the Diverse and Flexible Coping Strategies (FLEX), put in place in response to mitigating strategies requirements issued following the accident at Fukushima Daiichi.

The frequency and extent of Component Design Basis Inspection (CDBI) activities are not commensurate with the risk and safety benefit. Although pilot activities to improve CDBI inspections were acknowledged, the pilot did not achieve anticipated reductions in resources.

There is a lack of clarity regarding the nexus between risk informed and deterministic approaches, and concerns with the use of non-public risk information to inform regulatory decisions.

Related Staff Activities and Commission Decisions

The NRC continues to support the development of more realistic fire modeling. A summary of recent and future work in this area is available on the NRC's public website at: http://www.nrc.gov/about-nrc/fire-protection/fire-safety-res.html.

Since 1998, the NRC has issued 83 renewed nuclear power plant licenses. Of those, 81 plants are still operating and 45 are in the period of extended operation – meaning they have been operating for more than 40 years. During the past 18 years of license

renewal reviews, the NRC has continually reviewed its processes, and captured ways or lessons learned, to more effectively, and efficiently focus these reviews. Only 2 years after receiving the first license renewal application, in July 2001, the NRC published those lessons learned in NUREG-1801, "Generic Aging Lessons Learned (GALL) Report". The NRC updated those lessons learned in 2005 and 2010.

The GALL report contains NRC staff's generic evaluation of the existing plant programs and documents the technical basis for determining where existing programs are adequate without modification to manage the aging effects for structures or components for license renewal and where those programs should be augmented for the period of extended operation. The GALL results are incorporated into other guidance documents such as NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR). The SRP-LR is the roadmap NRC technical safety reviewers use to evaluate the adequacy of license renewal applications. One example of risk-informed inspections can be found in Revision 2 of the GALL, issued in 2010. In that revision, buried and underground pipe directed inspection locations are based on risk insights including the susceptibility to degradation and the consequences of failure. Risk-informed considerations are also present in the statement of consideration to the license renewal rule and the SRP-LR. Specifically, the statement of consideration for the license renewal regulation states that "[i]n license renewal, probabilistic methods may be most useful, on a plant-specific basis, in helping to assess the relative importance of structures and components that are subject to an aging management review by helping to draw attention to specific vulnerabilities (e.g., results of an IPE or IPEEE)" (see 60 FR 22468). Additionally, the SRP-LR states "[t]he risk significance of a structure or component could be considered in evaluating the robustness of an Aging Management Program. Probabilistic arguments may be used to develop an approach for aging management adequacy."

The NRC's license renewal regulatory processes are efficient and predictable. Leveraging lessons learned to focus license renewal reviews provides clear expectations, process discipline, and common understanding for NRC licensing activities. The agency strives to capture lessons learned, regularly updates those lessons learned, and may consider risk-informed approaches during the license renewal review.

The NRC risk-informed steering committee directed NRC staff to evaluate how FLEX equipment may be credited in various risk-informed regulatory decisions. In November 2015, NEI submitted two white papers on this topic for staff review. In August 2016, NRR issued a letter (ADAMS Accession No. ML16167A034) explaining how NRC intends to use the industry white papers in evaluating licensees' requests to credit FLEX in risk-informed decision making; the letter also provided a road map on how staff plans to develop additional guidance to supplement NEI's whitepapers.

NRC staff plans to implement a revised CDBI procedure starting in calendar year (CY) 2017. The enhancements to the CDBI procedure address recommendations from the 2014 Reactor Oversight Process (ROP) Baseline Inspection Program Enhancement Project (staff's comprehensive review of ROP inspection program effectiveness), the 2014 Commission-directed ROP Independent Assessment, and feedback received from external stakeholders during several public meetings held in CY 2015 and 2016. The

enhancements will also be informed by the results of pilot CDBI inspections that were completed in 2016, including public and industry feedback from this effort. The anticipated changes to the CDBI procedure are being addressed by a staff working group. They may include a less resource-intensive CDBI inspection, and may combine elements of other engineering inspections, such as the plant modifications inspection, with the intent that the overall engineering inspection resource expenditure is more evenly spread across a 3-year period. The changes will also likely include a programmatic inspection to assess licensee implementation of key engineering programs.

Several efforts are underway to enhance risk-informed decision making, which includes clarification of the nexus between risk insights and deterministic information such as defense-in-depth considerations. In the SRM to SECY-15-0168 (ADAMS Accession No. ML16069A370), the Commission directed the staff to expeditiously complete the revision of Regulatory Guide 1.174 on defense in depth to improve the clarity of the guidance. An inter-office working group has been formed. The working group is currently updating this guidance, with significant stakeholder involvement (e.g., public meetings to solicit input).

15. Stability of NRC security programs

Issues and Recommendations

The stakeholders offered mixed perspectives on the state of the nuclear security threat environment, and the size, organization, and activities of NRC's regulatory security program.

Related Staff Activities and Commission Decisions

NRC staff has several ongoing activities that aim to take an introspective look at the NRC's security programs and make any necessary adjustments. For example, in response to feedback that the Force on Force (FOF) program could benefit from evaluation and improvements, NRC staff provided SECY-16-0073, "Options and Recommendations for the Force-on-Force Inspection Program in Response to the SRM to SECY-14-0088," dated June 1, 2016 (ADAMS Accession No. ML16021A313) to the Commission. SECY-16-0073 evaluated findings made by the FOF Tactics, Techniques, and Procedures working group, and provided two options to the Commission. Both options would include improvements to the current baseline security inspection program.

Regarding NRC oversight of cyber security, approximately 60 licensees have requested additional time to complete implementation of the cyber security requirements. Based on implementation of the phase 1 activities (milestones 1 – 7) and protections already in place, the NRC has approved those requests. As the industry moves to fully implement the cyber security requirements in 2017 (phase 2/milestone 8), the NRC is conducting training and tabletop exercises, and is continuing to engage with stakeholders on the requirements to ensure the NRC staff and industry are aligned in what successful implementation looks like. Lastly, NRC staff engages with the Commission on policy matters to allow an opportunity to provide direction to the scope of the Office of Nuclear Security and Incident Response's (NSIR) focus.

The NRC staff plans to address perspectives about the organizational structure of NSIR by continuing to engage the Commission through periodic reviews of programs and activities as discussed above.

EFFICIENCY PRINCIPLE

Commenters at the July 26 meeting and comments in a subsequent letter provided examples of the agency's efficiency principle where they found room for improvement, such as the need to continually upgrade our regulatory capabilities, to ensure that regulatory activities are commensurate with the risk, and to improve the timeliness of NRC regulatory decisions. The topic areas identified included: (16) sustaining improvements on effectiveness, efficiency, and agility, (17) regulatory programs not sized commensurate with the risk of the regulated activity, and (18) NRC's ability to keep pace with a changing environment.

16. Sustaining improvements on effectiveness, efficiency, and agility

Issues and Recommendations

Various stakeholders complimented the NRC for the improvements that are being made as part of Project Aim. They went on to comment that the NRC should sustain the improvements made under the Project AIM initiative, and continue to look for improvements in effectiveness, efficiency, and agility. The efficiencies gained from Project Aim may not keep pace with NRC's external operating environment (e.g., prematurely closing reactors), resulting in continued fee pressure. However, some stakeholders cautioned that Project Aim should not become a vehicle to reduce NRC resources in light of industry economic constraints. In a comment received by letter after the meeting, one stakeholder requested that NRC institutionalize the Project Aim re-baselining gains through the establishment of processes that periodically assess the importance and priority of emerging activities and assess the continued importance and effectiveness of existing activities.

Another stakeholder commented that the NRC should develop a system to track all ongoing activities affecting a particular category of licensee, to facilitate prioritization and informed decision making regarding cumulative effects and the potential impact of new initiatives.

Related Staff Activities and Commission Decisions

NRC staff developed and applied the common prioritization methodology in formulating the FY 2018 Performance Budget and in performing a one-time re-baselining assessment in SECY 16-0016. The results of common prioritization were used to inform the FY 2018 budget formulation, including the lower priority list. NRC staff updated the Agency Workload Add/Shed/Defer Procedure to establish a consistent approach using the common prioritization methodology to evaluate the emergent work throughout the NRC. This procedure includes an integrated prioritization of agency work, which will be updated periodically, and outlines the process for prioritizing, implementing, communicating and documenting the adding, shedding, and deferring of work. In addition, NRC staff is finalizing a change management plan to institutionalize the goal of

Project Aim to fulfill the NRC's safety and security mission, while systematically improving our effectiveness, efficiency, and agility.

17. Regulatory programs not sized commensurate with the risk of the regulated activity

Issues and Recommendations

NRC should reduce the resources applied to regulation and oversight of fuel cycle facilities, uranium recovery, and non-power reactor and utilization facilities given the relatively low risk profile that they represent. The fees for certain categories of fuel facilities exceed those of operating reactors, despite a significantly lower risk to public health and safety.

Related Staff Activities and Commission Decisions

While there are certain fuel cycle facility activities that involve relatively low radiological risk, there are other aspects of operations that could potentially impact the health and safety of workers, members of the public, and the environment. NRC staff focuses its resources based on operating experience and the risk-significance of licensees' activities through the Licensee Performance Review and Agency Action Review Meeting processes that provide opportunities to adjust resources based on licensees' performance. For example, as part of the Project AIM re-baselining effort, NRC staff recently adjusted the licensing resources. NRC staff is working towards incorporating the most significant functions into the inspection program without increasing oversight resources. Additionally, NRC staff holds public meetings on Cumulative Effects of Regulation (CER) between NRC staff and stakeholders. During these meetings, the NRC staff seeks feedback from stakeholders on regulatory activities. For example, in the upcoming October 2016 CER meeting, the industry plans to present their perspective on fuel cycle facility inspection program efficiencies. The NRC staff continues to assess its licensing and oversight programs to evaluate potential efficiencies, improve predictability of regulatory processes, and to minimize duplication of inspection efforts while reducing planned workload, while continuing to ensure the adequate protection of public health and safety.

For regulating uranium recovery facilities, the NRC also seeks to focus on the most risk significant items. To enhance this approach, NRC staff continues to consider specific review areas that the industry recommends be further risk informed. As part of our outreach efforts, NRC staff held a public teleconference on September 7, 2016 to address various health physics issues. Similarly, NRC staff plans to host a workshop to discuss the issue of radon in the spring of 2017. In addition, the NRC is currently undertaking a review of the uranium recovery licensing process to identify opportunities for potential efficiencies. This review will include an evaluation of the scope of licensing reviews to determine whether adjustments should be made to the process based on the safety significance of licensing activities.

Regarding the Research and Test Reactor licensees, as NRC staff discussed at the 2014 Commission Meeting on Research and Test Reactor Initiatives (ADAMS Accession No. ML14352A095), the limited fission product inventory and distinct missions of

research and test reactors present unique risk profiles. Regulations and companion review guidance for safety evaluations of research and test reactors are tailored to the hazards at these facilities, which are primarily related to the manipulation of radioactive materials within the facility (i.e., experiments) and are not expected to result in significant radioactive releases outside the facility. Moreover, according to Commission direction (SRM to SECY-08-0161, ADAMS Accession No. ML090850159), NRC staff is applying a graded approach to conducting license renewals of research and test reactors. This graded approach allows facilities with licensed power levels of less than 2 MW(t) to undergo a limited-scope review focusing on the most safety-significant aspects of the facility.

18. NRC ability to keep pace with changing environment

Issues and Recommendations

NRC's regulations and inspection criteria are not agile with respect to the pace of change.

One commenter identified that opportunities exist for improvement in inspections, inspector experience, and regulations to keep pace with new technology for medical diagnostic and therapeutic uses of radioactive materials.

The decommissioning rulemaking is not occurring on a pace to support the current reactors that have announced plans to cease operation.

Recent NRC rulemakings did not fully envision the impacts to all types of affected licensed activities, nor recognize the significantly lower risk for some types of licensed activities, or plant conditions.

Related Staff Activities and Commission Decisions

The NRC staff understands that new medical technologies are being developed at a rapid pace. To that end, 10 CFR 35.1000 was developed to address any new medical technologies that are not otherwise specifically addressed in 10 CFR Part 35. In addition, in emergent medical situations, NRC staff works with licensees on a case-by-case basis to ensure that patient studies/treatments can be safely authorized as quickly as possible. NRC staff has worked with licensees to issue special license authorizations and conditions in short periods to safely accommodate patient care needs.

In the SRM to SECY-14-0118, (ADAMS Accession No. ML14364A111) the Commission directed the staff to set an objective of early 2019 for completion of the decommissioning rulemaking and to continue processing current and pending applications for decommissioning amendments and exemptions until that regulatory work is complete. In SECY-15-0127 (ADAMS Accession No. ML15211A095) NRC staff communicated to the Commission the resource estimates and resource impacts of the decommissioning rulemaking. In this paper, NRC staff indicated that it would maintain its focus on the current decommissioning transition licensing actions, while proceeding on an aggressive schedule to finalize the decommissioning rule in CY 2019. Separately, NRC staff has implemented lessons learned from the prior decommissioning reviews for

those plants that have or will permanently shut down prior to completion of the revised decommissioning rule. These efforts will support NRC staff in conducting the decommissioning licensing reviews in a more efficient and effective manner. The staff plans to issue the decommissioning lessons learned report, as a publicly available document by October 2016.

Consistent with the SRM to SECY 15-0015, and as approved in the SRM to SECY-15-0143, “Project AIM Centers of Expertise” (ADAMS Accession No. ML16053A500) dated February 22, 2016, the agency is working to consolidate its rulemaking activities into a “Center of Expertise.” This organizational structure will allow for more interaction between rulemaking staff for all NRC business lines, which should increase the opportunities to identify potential unintended impacts of a rulemaking.