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MEMORANDUM TO: Margaret M. Doane
Executive Director for Operations
Office of the Executive Director for Operations

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SUBJECT: IMPLEMENTING COMMISSION DIRECTION ON APPLYING
RISK-INFORMED PRINCIPLES IN REGULATORY DECISION
MAKING

This memorandum responds to your memorandum, dated October 15, 2019 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML19280A771), about the identification of actions to ensure consistent implementation of the Commission direction contained in the Staff Requirements Memorandum (SRM) SECY-19-0036, "Application of the Single Failure Criterion to NuScale Power LLC's Inadvertent Actuation Block Valves", dated July 2, 2019 (ADAMS Accession No. ML19183A434).

In directing the staff, the Commission observed that:

This approach is consistent with the Commission's safety goal policy and associated core damage and large release frequency goals and existing Commission direction on the use of risk-informed decision making, as articulated in the 1995 Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities and the White Paper on Risk-Informed and Performance-Based Regulation (in SRMSECY- 98-0144 and Yellow Announcement 99-019). In any licensing review or other regulatory decision, the staff should apply risk-informed principles when strict, prescriptive application of deterministic criteria such as the single failure criterion is unnecessary to provide for reasonable assurance of adequate protection of public health and safety.

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I. Background

The Atomic Energy Act of 1954, as amended (AEA), does not explicitly direct the agency to use a particular approach, including deterministic (also referred to as traditional engineering), risk-informed, or risk-based, for its regulatory framework or analysis. However, the U.S. Nuclear Regulatory Commission (NRC) regulatory structure for ensuring that a licensed facility is designed, constructed, and operated without undue risk to the health and safety of the public has always been inherently risk-informed.¹ Deterministic approaches served the NRC well during the initial licensing of the first several generations of utilization and production facilities.² While deterministic in nature, these approaches contain implied elements of risk-informed thinking (i.e., what can go wrong, how likely is it, and what are the consequences). For example, the spectrum of design basis events selected to be analyzed for a reactor design reflects an assessment of their likelihood and potential consequences, while quality assurance and other activities mitigate risk by reducing the likelihood of reactor pressure vessel rupture to a level where it is not included as a reactor design basis event. Similarly, defense-in-depth and safety margins were applied to ensure redundancy and protection against single failures and address uncertainties, especially in the early decades with limited operating experience. These concepts remain vital aspects of a fully integrated, risk-informed, decision making process.

Because of the additional information, understanding, and modeling derived from several decades of operating experience, the agency has improved the fidelity and increased the use of analytical tools that provide better risk insights to inform regulatory decision making. One of the NRC's first systemic evaluations of realistic risk assessments was documented in NUREG-75/014, "Reactor Safety Study" (WASH-1400), October 1975. Since that study, the NRC has conducted additional studies, issued policy, and provided guidance on the appropriate use of risk insights in regulatory decisions. Some seminal policies, analyses, guidance, and rules issued by the agency to advance the state-of-the-art in risk-informed decision making from the 1980s through early 2000s include:

- NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," December 1990;
- Rulemakings
 - Title 10 of the *Code of Federal Regulations* (10 CFR) 50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants;
 - 10 CFR 50.48c, National Fire Protection Association Standard NFPA 805;
 - 10 CFR 50.69, Risk-informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors;
- Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis;" and
- Management Directive 8.3, "Reactor Oversight Process."

Significant policy direction that is relevant to this effort includes:

- Severe Reactor Accidents Considerations for Future Designs (1985);
- Safety Goals of Operations of Nuclear Power Plants, 51 Fed. Reg. 30028 (Aug. 21, 1986);

¹ Although the staff has traditionally distinguished deterministic approaches from the more recent risk-informed approaches, deterministic analysis represents one method of handling risk.

² Similar deterministic requirements have also proved useful to the agency to balance risk in licensing material use.

- Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, 60 Fed. Reg. 42622 (Aug. 16, 1995) (PRA Policy Statement);³
- Discussion on Safety and Compliance, COMSAJ-97-008, (1997);
- NRC White Paper on Risk-Informed and Performance-Based Regulation, SECY-98-144, (1998); and
- Stabilizing the PRA Quality Expectations and Requirements, COMNJD-03-0002 (2003), as it initiated a number of activities, including the development and endorsement of a PRA Standard and peer review process, which obviates the need for an in-depth review of the licensee PRA by staff, allowing them to focus their review on key assumptions and other key areas of concern relevant to the application.

Aspects of the Commission's direction in SRM-SECY-19-0036 are found in the PRA Policy Statement including:

- The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.
- PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule).
- The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

The PRA Policy Statement, however, warns that risk-informed processes are not to be used to excuse compliance with existing regulations, stating "the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised."⁴

Elaborating on the nexus between compliance, safety, and risk, in 1997, the Commission approved a memorandum discussing safety and compliance⁵ to "be incorporated in the Enforcement Policy, Inspection Manuals, Project Managers Handbook, and other staff guidance, as appropriate." This memorandum notes that when a noncompliance is found, "the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance [...] Based on the NRC's evaluation, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions

³ See *also*, Staff Requirements Memorandum (SRM)-SECY-98-144, White Paper on Risk-Informed and Performance-Based Regulation, March 1, 1999, available at

<https://www.nrc.gov/reading-rm/doc-collections/commission/srm/1998/1998-144srm.pdf>;

SRM-COMSECY-97-008, Discussion on Safety and Compliance, August 25, 1997, available at

<https://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/1997/1997-008comsrm.pdf>.

⁴ Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, 60 Fed. Reg. 42622, 42629 (Aug. 16, 1995)

⁵ SRM-COMSECY-97-008, Discussion on Safety and Compliance, August 25, 1997, available at <https://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/1997/1997-008comsrm.pdf>

or assessments, such as increased oversight (e.g., increased inspection).” When determining appropriate actions to handle a noncompliance, the memorandum states that “[t]he NRC has the authority to exercise discretion to permit continued operations—despite the existence of a noncompliance—where the noncompliance is not significant from a risk perspective.” In instances when the NRC concludes generically that requirements do not have a safety benefit, the memo states that “the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licenses. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative impact on safety. They also can tend to create an inappropriate NRC and licensee focus on ‘safety versus compliance’ debates.”

In 1999, the Commission approved the issuance of a white paper.⁶ The 1999 white paper defined the terms and Commission expectations for risk-informed and performance-based regulation for use by the NRC and interested parties. The Commission noted that most of the agency’s regulations were developed without the benefit of quantitative estimates of risk, and that the resultant deterministic and prescriptive requirements relied mostly on experience, testing programs, and expert judgment. They also noted that significant advances and experience with risk assessment methodology since 1975 called for “an appreciation of the transitional period in which the agency and industry currently operate.” The Commission identified an “opportunity to enhance the traditional approach by more explicitly addressing risk and incorporating insights thus gained.”

The NRC’s application of risk-informed decision making continues to evolve as improved realism, evaluation techniques, and additional information are applied to improve regulatory decision making. For example, the agency has improved the realism in force-on-force exercises and integrated safety analyses for fuel facilities. These efforts to incorporate risk insights in a more realistic manner continue throughout the NRC even today by focusing its efforts to expand the systematic use of appropriate risk insights through its current transformation efforts to become a modern risk-informed regulator.

The concepts necessary to expand our use of risk insights were documented as part of SECY-18-0060, “Achieving Modern Risk-Informed Regulation”⁷ and built upon in the agency’s current transformational activities focused on accepting risk in decision making. These agency activities are supported and reaffirmed by indications from Congress on the need to further the use of risk insights in agency decision making. For example, in the recently enacted Nuclear Energy Modernization Act (NEIMA), Congress directed the NRC to “develop and implement ... strategies for the increased use of risk-informed, performance-based licensing evaluation techniques and guidelines for commercial advanced nuclear reactors within the existing regulatory framework.”⁸ In accordance with NEIMA, the NRC recently transmitted a “report for increasing ... the use of risk-informed and performance-based evaluation techniques” and

⁶ Staff Requirements Memorandum (SRM)-SECY-98-144, White Paper on Risk-Informed and Performance-Based Regulation, March 1, 1999, available at <https://www.nrc.gov/reading-rm/doc-collections/commission/srm/1998/1998-144srm.pdf>;

⁷ The staff withdrew SECY-18-0060 because it was overcome by events (see SRM-SECY-18-0060, ML19283B998); many of the concepts explored in this memorandum, however, are similar to those discussed in SECY-18-0060 and those we are currently pursuing as part of the agency’s transformation efforts.

⁸ Pub. L. No. 115-439, § 103(a)(2), 132 Stat. ____.

guidance for commercial advanced nuclear reactor licensing within the existing regulatory framework.⁹

II. Current efforts directed at applying risk-informed principles:

The staff are engaged in efforts to broadly apply risk-informed principles in the NRC's decision making across the agency. We received input from the staff on these efforts, which cross offices and business lines, and reside in several different areas, including inspections and oversight, licensing, rulemaking, and preparation for new technologies.

A. Inspection and Oversight:

The Office of Nuclear Reactor Regulation (NRR) is optimizing the focus of staff oversight activities in the Reactor Oversight Process (ROP) through improved use and application of risk-informed principles. Similar efforts are underway for oversight programs for materials users, fuel cycle facilities, and spent fuel facilities within the Office of Nuclear Materials Safety and Safeguards (NMSS). Both offices are engaged in activities aimed at resolving low-safety-significant issues through targeted revisions to inspection procedures and changes to the Task Interface Agreement (TIA)/Technical Assistance Request (TAR) processes that will more effectively resolve issues commensurate with their significance. The Office of Nuclear Security and Incident Response (NSIR) is improving the realism of force-on-force inspections, including allowing credit for multiple layers of security at a site and site-specific characteristics, such as the proximity and capabilities of local law enforcement agencies.

B. Licensing:

Numerous efforts are underway to remove barriers to the consideration of risk insights and directly incorporate risk-informed decision making principles into licensing processes across the agency. NRR and NMSS are engaged in efforts to apply graded approaches in the licensing processes for operating reactors, fuel cycle facilities, spent fuel storage, and uranium recovery operations. For example, in FY19, NMSS initiated a graded-approach methodology in the licensing reviews of spent fuel dry cask storage systems. Application of qualitative risk insights optimized the licensing process by making certificates of compliance (CoC) requirements more performance-based, which provided additional flexibility for licensees to make non-risk significant changes through the 10 CFR 72.48 process.

Within the new reactor business line, to more fully integrate the use of risk insights into application review activities and enhance the review process, the former Office of New Reactors (now part of NRR) developed the Enhanced Safety Focused Review Approach (ESFRA). The intent of ESFRA was to establish a graded level of review effort that was commensurate with safety. Another example of a graded approach is contained in the licensing guidance of NUREG 1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," that is being applied to the review of the SHINE operating license.

NRR and NMSS are also working to integrate risk-informed principles into the Standard Review Plan (SRP) as part of the SRP modernization effort.

⁹ Pub. L. No. 115-439, § 103(c)(1), 132 Stat. ____.

C. Rulemaking:

Some current rulemakings are utilizing risk insights to help identify and improve the proposed rules. For example, a rulemaking for 10 CFR Part 61 is evaluating whether greater than class-C waste can be disposed of through near surface disposal using risk insights. In addition, NMSS is considering reevaluating the deterministic thresholds for the amount of material licensees can possess without requiring financial assurance and a decommissioning funding plan to determine if a more risk-informed approach could be applied.

The decommissioning rulemaking contains several proposals for right sizing our approach to account for the decreased risk of a plant undergoing decommissioning.

More holistically, NMSS is reevaluating the rulemaking process to determine whether all current steps are needed and to streamline the process where possible. This is an important step toward enabling the agency to more swiftly implement the direction provided in SRM-COMSECY-97-008, "Discussion on Safety and Compliance," (discussed earlier in the Background) to remove or revise requirements in areas where regulations exist with no safety benefit.

D. Preparation for New Technologies

As part of efforts to become a modern, risk-informed regulator, the NRC staff are focused on preparing for the licensing of new technologies. For licensing of advanced non-light water reactors, staff are engaged in a technology-inclusive, risk-informed, and performance-based advanced non-light water reactor rulemaking effort (10 CFR Part 53). A companion effort is developing guidance based on the industry-led licensing modernization project (LMP), which is a technology-inclusive, risk-informed, and performance-based methodology intended for use in establishing key parts of the licensing basis for non-light water reactors. In addition, rulemaking efforts are in progress for emergency preparedness for small modular reactors and other new technologies (<https://www.nrc.gov/docs/ML1813/ML18134A086.html>) and options for physical security for advanced reactors (<https://www.nrc.gov/docs/ML1817/ML18170A051.html>).

The staff are improving the licensing process for digital instrumentation and controls (I&C) and accident tolerant fuel (ATF). Staff in NRR and the Office of Nuclear Regulatory Research (RES) are implementing an integrated action plan for digital I&C that incorporates a risk-informed graded approach to the application of the diversity and defense-in-depth analysis to address common cause failures in digital systems with different levels of safety significance. NRR, NMSS, and the Office of Nuclear Regulatory Research (RES) are working together to prepare for the licensing of ATF through participation in Phenomena Identification and Ranking Tables (PIRTs) to identify the most safety significant behaviors of the fuel.

Finally, in preparation for new medical technologies, the staff will be piloting a new process to streamline the review and guidance development for new emerging medical technologies. The new process provides for savings in both time and staff resources while remaining inclusive of regional, Agreement State, and Advisory Committee on the Medical Uses of Isotopes (ACMUI) contribution to the guidance development through formation of an expert committee early in the licensing process to identify risk significant aspects of the technology and write the guidance.

III. Challenges in fully meeting the intent of the SRM

The agency's culture includes a strong adherence to its mission to protect public health and safety and the environment and promote the common defense and security. This has served the agency well, is essential for our continued success, and has made us a reliable regulator. To become a risk-informed regulator and continue to fulfill our statutory mission, we must build on our strong culture and enhance it by identifying and resolving challenges and impediments to the appropriate and consistent integration of risk insights with deterministic concepts, such as defense-in-depth and safety margins. While the NRC has a long history of applying risk insights for some decisions (e.g., risk-informed licensing actions per Regulatory Guide 1.174), additional improvements through the integration of risk information into all regulatory practices will further enhance our regulatory effectiveness by focusing the agency's activities on the most important issues. We recognize that the key to making these improvements, facilitating successful transformation and fully applying risk insights, will require overcoming challenges that are both cultural and structural.

A. *Cultural challenges*

Over time the focus on mission (and fear of not meeting it) has created a culture **reluctant to adapt processes** even in cases where the process imposes a level of attention that is not commensurate with safety significance. While process is necessary for the agency to remain a clear, open, and reliable regulator, when our processes are overly prescriptive, not outcome-oriented, or ignore risk insights, they can result in unnecessary expenditures of effort and resources. In the agency's oversight process, this mindset can overemphasize compliance rather than performance. One prominent area where this dichotomy has occurred is in the area of enforcement. In enforcement, a deterministic, compliance-oriented enforcement policy does not in all cases align with the risk significance of non-compliance. Moreover, differences of opinion about the risk significance of a non-compliance have resulted in extensive resources being devoted to addressing identified violations that are ultimately determined to be of very low risk significance.

Not considering risk insights early in the process can lead to undue focus on issues that are not risk significant. Often, agency processes that are driven by timeliness create a barrier to facilitating the time necessary for thoughtful consideration of risk insights at the beginning of the project. While the agency has made strides in addressing this challenge through adoption of processes that stress early alignment on risk-informed decision making, more can be done to formalize these good practices and develop meaningful metrics to evaluate the effectiveness of the process.

Where regulations provide flexibility, overly **rigid interpretation of regulations** can hinder the application of risk-informed decision making. This is especially true with respect to the agency's effort to apply existing deterministic regulations to new technologies that may be viewed under a strict reading of the regulations to not meet the requirements, even when the technology meets the intent of the rule. A recent example of where the agency realized that flexibility exists in the regulations is the proposed change to the agency's interpretation of visual surveillance requirements for radiographers that is mentioned in the next section. The process for identifying flexibility in regulations may yield broader inclusion of new technology that meets the intent of the requirement, while deviating from traditional approaches to compliance.

While the agency has been successful in applying risk in many cases where the risk is discrete and well known, we also identified that **difficulty integrating the different aspects of a**

risk-informed decision can similarly lead to a lack of consideration of the risks associated with the action or decision. In many cases, risk insights are only apparent when taking a holistic view of the action and the associated decision that must be made. Decisions that do not fully account for and integrate all aspects of a complex issue may fail to recognize the full risks associated with the issue. For example, if an applicant can demonstrate that there are significant safety margins, then the NRC staff may be able to reduce the scope of their review without impacting safety. Similarly, there is a tendency to **overemphasize the negative attributes of a decision and not credit the positive attributes**. For example, new fuel concepts hold the promise of concrete safety benefits (e.g., improved performance under accident conditions) that are not always considered in discussing the technical basis for licensing decisions. This is a natural result of the agency's approach to evaluating safety, which typically strives to figure out what could go wrong. Another challenge arises when there are differences of understanding of the risks involved and differences of opinion of the level of risk that is acceptable. **Difficulty in accepting highly consequential events, no matter how low the likelihood**, presents a challenge when trying to make a regulatory decision. This can also occur when there are large uncertainties in the phenomenological understanding, risk models, or experiential data, which may be reflected in any aspect of the risk triplet (what can go wrong, how likely is it, or what are consequences). When **challenged with making a risk-informed decision in the presence of large uncertainties**, one may choose to follow more familiar deterministic processes and procedures, resulting in application of excess conservatism in regulatory decisions.

B. Structural challenges

A siloed organization, where staff responsible for different aspects of a review reside in separate organizations (e.g., risk experts separated from other technical reviewers, technical reviewers responsible for different components of a system are separated, and/or technical reviewers are separated from project managers), can present difficulties in fully integrating reviews and achieving early alignment on the review using risk insights. This structure, while providing benefits in terms of management of work, can result in individual reviews of acceptance criteria by discipline area without considering an integrated, holistic perspective and review alignment using risk insights early in projects. This challenge is felt across the agency, where guidance and processes do not emphasize early engagement with, and between, the technical reviewers, project managers, and first line supervisors to establish and document alignment on, a holistic perspective of the key aspects of an application. For example, insight gained through such a review could aid in establishing the specific review scope, focus, and level of detail for each aspect of the review. Instead, guidance is segregated by discipline, which further drives individual reviewers to perform their review in isolation. The recent reorganizations of NRR and NMSS, as well as the creation of several Centers of Expertise (COEs) since 2014, are positive steps to address this challenge. Expanding the use of COEs, and considering additional matrixed organizations, and requiring early integration, alignment on, and documentation of the risk significance of a regulatory activity and the associated decision to be made may assist in facilitating the use of risk-informed decision making. In addition, the recent experience of the ESFRA process for the NuScale review and the issuance of NRR Office Instruction LIC-206, "Integrated Risk-Informed Decision-Making for Licensing Reviews," have made progress in better integrating risk insights into the planning and implementation of licensing reviews.

The **lack of guidance and tools and/or lack of awareness that guidance exists** on how to apply and integrate risk-informed principles has limited the agency's progress in fully embracing a systematic, integrated risk-informed approach. Compounding this challenge is guidance that

has not been updated adequately to incorporate both qualitative and quantitative risk insights and ensure common nomenclature with current risk-informed decision making principles. Moreover, because Commission policies are not widely understood, **flexibilities in existing policies are not fully reflected in our guidance and tools**. To address these challenges, business lines within the agency are developing and updating tools and practical guidance to guide risk-informed decision making. Recent memorandums issued from several of the agency's business line owners provide high-level generic guidance. This guidance development is also occurring in specific technical areas. For example, NMSS has engaged RES to develop a risk insights tool to guide reviews of the movement and storage of spent fuel in dry casks. More can be done, however, to formalize and expand the good practices currently being implemented by the business lines, as well as to make the staff more knowledgeable of these practices.

Given differing staff views on the risks associated with various activities and different levels of support in the agency for risk-informed decision making, there has been **inconsistent management expectations and support for risk-informed decision making**. This has resulted in a **rewards and performance tracking systems that do not always incentivize risk-informed decision making**. This is evidenced by metrics that focus on output versus outcome, such as completion of licensing acceptance reviews within a designated period of time rather than whether the review addressed the appropriate issues from a risk-informed perspective. Mis-aligned metrics and rewards further compound the cultural challenge addressed earlier which constrains staff from devoting the necessary time early in the process to align new risk insights to the current issue. While senior agency management considers risks in decision making using the enterprise risk management process, its broader use has not filtered down to the staff. Where processes do exist to drive the staff to consider risk insights in their decision making, there is no mechanism for monitoring the extent to which these processes are used. In addition, the agency's reward system for individual performance in many cases inadvertently reward employees for compliance findings regardless of risk significance, and agency awards are in most cases focused on results of activities rather than initiatives that further risk-informed thinking. While some organizations have put risk considerations into staffs' elements and standards, the degree to which this is considered in performance evaluations is inconsistent.

IV. Examples of key decisions- Making Progress One Decision at a Time:

The NRC staff are applying practical solutions to overcome the challenges to applying risk-informed principles in our decision making. We have identified several key solutions that have helped us rise above our cultural and structural challenges:

- Utilizing integrated teams, which help break down organizational silos, provide an integrated understanding of the risk insights and uncertainties associated with the action, and empower staff to develop risk-informed approaches.
- Considering risk insights early, which helps identify focal areas and ensure early alignment on the review approach.
- Where flexibility exists, allowing for the use of new or novel approaches for satisfying the regulatory and statutory requirements.
- Demonstrating a focus on safety performance versus solely compliance or process.
- Developing tools and guidance to aid in the staff in using risk-informed principles in properly addressing uncertainties.

We are using these solutions, among others, one decision at a time, to make progress in implementing the Commission's direction to apply risk-informed principles in our decision making. Some examples of key decisions that demonstrate this progress are:

- **Closure of Generic Safety Issue (GSI)-191.** Staff applied risk insights to help bring GSI-191, a decades-old generic safety issue related to emergency core cooling system (ECCS) performance, to closure. Over the years, both staff and industry developed significant additional information about the phenomena that can potentially contribute to the long-term degradation of ECCS cooling. Equipped with this new information, the GSI-191 cross-organizational team (which included staff from three offices, NRR, RES, and the Office of New Reactors (NRO)) began a systematic assessment of in-vessel effects. The team found that, given the accrued knowledge, the existing process allowed for closure of the generic issue in a manner commensurate with the safety significance at each plant.
- **Approval of Vogtle license amendment to remove inspections, tests, analyses, and acceptance criteria (ITAAC).** The staff recently applied risk insights in its review of a complex license amendment request for the Vogtle facilities under construction. Southern Nuclear Operating Company requested the amendment to remove a number of functional arrangement ITAAC. Working with the Office of General Counsel (OGC), the staff gained an understanding of the intended scope of functional arrangement ITAAC and developed review criteria to ensure that the ITAAC verifications to be removed were either duplicated by other ITAAC or were not safety significant. The staff also considered the oversight being provided by RII for functional arrangement of systems, structures, and components (SSCs). Through these coordinated efforts, the staff was able to ensure the licensee's activities would continue to demonstrate that the plant is being built to its certified design and is therefore safe.
- **Verifying containment reliability targets for NuScale.** In the course of evaluating the NuScale design against the Commission's containment performance goals as documented in SRM-SECY-90-012, the staff recognized that the level of uncertainty associated with predicting severe accident behavior made it difficult to verify conformance with the Commission's containment reliability targets for new reactors. To resolve the issue, the staff re-evaluated the overarching objective of the Commission's policy and developed alternate criteria that ensured a commensurate level of protection to the public, including explicit consideration of risk through the core damage frequency and large early release frequency. The staff's approach is described in SECY 19-0047, "Containment Performance Goals for the NuScale Small Modular Reactor Design."
- **New Approach to meeting the environmental qualification requirements for NuScale.** Due to certain unique features of the NuScale design, the design certification applicant ran into challenges in demonstrating that some risk-significant components met the environmental qualification requirements of 10 CFR 50.49. In evaluating the issue, the staff recognized that the challenge arose from an historical practice of applying a severe accident (core damage) source term to equipment that was only required to mitigate non-core damage design basis events. The staff then developed an approach that would apply more realistic environmental conditions to the equipment and alleviated the environmental qualification challenge (see SECY-19-0079, "Staff Approach to Evaluate Accident Source Terms for the NuScale Power Design Certification Application," for more information).
- **Hatch Operator license activation issues.** Region II issued enforcement action discretion to address operator license activation issues at Hatch that considered regulatory risk insights and evidence of conflicting NRC guidance on the matter. The

licensee had not been completing the required control room watch standing to reactivate the licenses for operators acting in the position of Refueling Floor senior reactor operator (SRO). There was confusion regarding guidance the licensee had received many years before. In reviewing the issue, it was determined that the lack of watch standing did not impact the operators' ability to perform as the Refueling Floor SRO and the guidance from the past was, in fact, confusing. As a result, individual enforcement actions were not pursued, but rather the issue was addressed more holistically, without unnecessary and burdensome issuance of numerous individual actions.

- **Limerick's spray ponds.** Limerick's spray pond headers were severely degraded and required repairs. Region I assessed the risk impact associated with the degraded system and factored that into its oversight, which allowed for a measured and systematic review of the extent of condition by the licensee, which took one header out at a time.
- **Expedited review of a transportation package for a breached Cesium-137 source.** When the capsule for a Cesium-137 source was breached during removal at the Harborview Research and Technology Center, contaminating the working area, the NRC received an application for shipment of the breached source in order to remove the source from the building prior to decontamination efforts. Prior to receipt of the application, NMSS formed a dedicated review team of risk and technical experts and held a phone call with the Department of Energy Contractor to discuss the proposed action to be reviewed by NRC and reach early alignment on how the application would address the risk-significant issue of package dose rates. NRC's review of the structural evaluation focused on the portions of the evaluation that were deemed most significant to ensure sufficient margin-to-failure existed. Use of an integrated tiger team enabled early identification of, and focus on, the risk significant aspects of approving a package to transport this breached Cesium-137 source on an expedited timeline, which resulted in a timely response and clean up to a major contamination event.

V. Planned Actions

As the examples above show, the ongoing risk activities in the agency are addressing many of the challenges we have identified. However, there remain specific actions that can be taken to reinforce the direction provided by the Commission.

Empower Staff to Adapt Existing Processes

The transformation initiative addressing risk will work with the Futures Core Team to develop a plan and timeline for a communications campaign (using videos, digital signage, etc.), to reinforce the concept that staff are empowered to adapt processes that they find are not working effectively and do not allow for appropriate consideration of risk insights in the decision making process. This action will be completed by April 2020.

Ensure that Tools Address Complexity in Risk-Informed Decision Making

As discussed in their charter (ML19319C438), the transformation initiative addressing risk is developing a generic framework for including risk insights in decision making. The framework being developed will explicitly address the challenges identified in this memorandum (e.g., difficulty integrating different aspects of risk, overemphasizing negative attributes, difficulty accepting low-probability high-consequence events, dealing with large uncertainties), and is expected to be completed by April 2020.

Following the development of this framework, we recommend that the EDO's office send a memorandum to the program offices asking them to review their programs and processes to ensure that they are appropriately incorporating risk-informed decision making principles, using this framework as a basis. Offices should be expected to strengthen existing tools for making complex, risk-informed decisions, and establish new tools only when necessary.

Avail Ourselves of the Flexibility Afforded by the Regulations

The staff should coordinate with OGC to ensure that the agency's requirements are fully understood. When staff is exploring possible interpretations of an NRC requirement, they should engage early with OGC to develop a common understanding of the legal positions that are or may be reasonably held by stakeholders both internal and external to the agency. Especially when considering novel requests or previously untested processes or approvals, it is particularly important for the staff to understand potential legal limitations and legal options before expending significant NRC resources.

When contemplating rulemaking, staff should consider the flexibilities that exist in the current regulations. To encourage this, we recommend that NMSS consider updating rulemaking guidance to emphasize the expectation that the discussion of regulatory options and alternatives to rulemaking should specifically discuss the flexibilities that exist in the current regulations and address why a change to the regulations is needed to address the underlying issue.

Implementation of Integrated Teams and Alignment on Incorporating Risk Insights

As discussed above, we have found that integrated teams are one of the key elements of effective incorporation of risk in our decision making for complex actions. Similarly, we have also found that early alignment within these teams (and with appropriate levels of management) on how to incorporate risk insights helps to focus activities on those that are risk-significant. We recommend that actions be taken to implement integrated teams for unusually complex actions that would most benefit from consideration of risk insights, and to encourage early vertical and horizontal alignment on the consideration of risk insights at all levels of decision making.

Specifically, we recommend that the Office Directors of NRR and NMSS incorporate integrated teams fully into licensing review processes and guidance as early as reasonably achievable, to break down organizational silos and drive early alignment on the incorporation of risk insights in the planning and conduct of licensing reviews.

Similarly, we recommend that the Office of the Executive Director for Operations (OEDO) issue a tasking/expectations memo to all offices making alignment and assignment meetings (as currently being done by NMSS) routine throughout the agency to align early on risk and integrate teams. This can be done immediately.

Training

The Commission has promulgated various policies on risk-informed decision making. All NRC staff that make risk-informed decisions in an area where Commission has provided a policy must understand the policies so that they may be adequately implemented. We recommend that the Office of the Chief Human Capital Officer (OCHCO), in consultation with OGC, the appropriate program offices, and the risk transformation initiative, begin developing training

modules on applicable Commission policy, to be deployed as soon as possible. We envision that there will be separate modules for licensing, oversight, and rulemaking.

The risk transformation initiative has an effort to work with individual offices to survey the most important existing tools, guidance, and policy covering risk-informed decision making at the NRC. This effort will be completed by February 2020. When the risk transformation initiative has finished their survey of the existing risk-informed decision making framework, they will work with OCHCO to develop mandatory training on risk-informed decision making to be disseminated to all internal stakeholders. The training developed as part of this effort will be appropriately aligned to the levels at which decisions are made at the agency and aligned to the enterprise risk management process. This effort will be completed by November 2020.

Performance and Metrics

The risk transformation team will provide recommendations on performance management, to ensure that appropriate consideration of risk insights is incentivized. This effort will be completed by August 2020.

We recommend that staff elements and standards and Senior Executive Service (SES)/Senior Level Staff (SLS) performance plans should require participation in risk-informed decision making. Guidance on considering contributions to risk informed decisions in performance reviews should be provided to rating officials to ensure accountability. For at least one element of the performance appraisal, staff and managers should be able to clearly point to at least one risk-informed decision they had a significant role in. A metric should also be developed that measures the extent to which risk-informed principles are utilized in our decision making.

Scott W. Moore, Executive Director, Advisory Committee on Reactor Safeguards	RidsACRS_MailCTR Resource
E. Roy Hawken, Chief Administrative Judge, Atomic Safety and Licensing Board Panel	RidsAslbpManagement Resource
Marian L. Zobler, General Counsel	RidsOgcMailCenter Resource
Catherine L. Scott, Director, Office of Commission Appellate Adjudication	RidsOcaaMailCenter Resource
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