

**POLICY ISSUE**  
**(Notation Vote)**

May 23, 2018

SECY-18-0060

FOR: The Commissioners

FROM: Victor M. McCree  
Executive Director for Operations

SUBJECT: ACHIEVING MODERN RISK-INFORMED REGULATION

PURPOSE:

The purpose of this paper is to request Commission approval of several significant and specific revisions to the U.S. Nuclear Regulatory Commission's (NRC's) regulatory framework and approaches to better enable the safe and secure use of new technology in civilian nuclear applications. This paper also informs the Commission of several activities that are currently underway or will be implemented as a result of the transformation initiative, including actions to enhance and sustain a culture that embraces transformation at the NRC. Such actions are integral to the success of the recommendations in this paper.

SUMMARY:

In January 2018, I tasked the Transformation Team (the Team) to identify potential transformational changes to NRC's regulatory framework, culture and infrastructure to further enhance our effectiveness, efficiency and agility. I directed the team to focus on transformation that enables the safe and secure use of new technologies. The Team harvested techniques, ideas, and information relating to novel technologies from internal and external stakeholders that, when implemented, would be transformational. The Team analyzed and considered the information gathered to identify specific areas to initiate transformation at the NRC. Based on this work, the staff recommends that the Commission direct the staff to:

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- develop an agencywide process and organizational tools to expand the systematic use of qualitative and quantitative risk and safety insights; thereby, enabling staff to scale the scope of review and the level of detail needed in licensing to make a finding of reasonable assurance of adequate protection of public health and safety, beginning with licensing reviews for reactors.
- revise Title 10 of the *Code of Federal Regulations* (10 CFR) 50.59, “Changes, Tests, and Experiments,” and comparable sections, as needed, to allow licensees additional flexibility to make facility changes without prior NRC approval while ensuring safety and security;
- develop a performance-based, technology-inclusive regulation as an alternative approach for licensing for non-light-water reactors; and
- develop a new regulation to define high-level performance-based I&C safety design principles and associated regulatory guidance that documents the acceptable standards that may be used to meet these principles.

Successful implementation of these recommendations will represent the beginning of a more modern, risk-informed approach to regulation. This paper also discusses several planned methods to enhance and sustain a transformative culture, which is necessary to ensure the agency’s success in enabling the safe and secure use of new technologies. The implementation of these recommendations is expected to facilitate the effective, efficient and agile regulation of new technologies while fulfilling the Commission’s safety and security mission in a manner that reflects the Principles of Good Regulation. If the Commission approves these recommendations, the staff will develop a detailed implementation plan as the next step in transformation.

#### BACKGROUND:

On January 25, 2018, I created the Team and directed it to identify potential transformation(s) to the NRC’s regulatory framework, culture, and infrastructure.<sup>1,2</sup> The NRC’s mission of providing reasonable assurance of adequate protection of public health and safety, promoting the common defense and security, and protecting the environment remains unchanged; however the agency’s current regulatory framework challenges the introduction and use of new and potentially safer technologies in the nuclear industry. Therefore, I identified specific areas of focus for potential transformation. These areas, discussed further below, include regulation of accident tolerant fuels, new materials and new manufacturing approaches, Big Data, DI&C, and small modular and advanced reactor designs. Enclosure 1 describes the current state of each of these technologies.

#### DISCUSSION:

This section summarizes: (1) the Team’s information gathering and methodology for idea evaluation, (2) common themes, (3) the need for cultural transformation at the NRC, and (4) recommended transformation initiatives. Information Gathering and Evaluation

The NRC has undertaken many recent efforts to improve NRC regulation and seek feedback on its regulatory approaches. These include Project Aim in January 2015; a stakeholder meeting

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<sup>1</sup> “Formation of NRC Transformation Team,” January 25, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18029A106).

<sup>2</sup> The assignment of this task followed my message to all staff on January 4, 2018 (ADAMS Accession No. ML18029A257), which explained the agency’s ongoing innovation initiatives as well as the need for transformation.

with the Commission in July 2016; and the Enhanced Strategic Workforce Planning initiative in April 2017. The Team reviewed the results of these activities to gather lessons and identify areas of change for consideration.

In addition, the Team gathered information on transformative approaches to the review of new technologies by interacting with both internal and external NRC stakeholders. These interactions included discussions at regional, office, and division-level meetings as well as meetings with the nuclear industry, other Federal agencies, and non-governmental organizations. Enclosure 2 provides details on the specific stakeholder interactions.

The internal and external outreach resulted in more than 700 diverse ideas from stakeholders, which are summarized in Enclosure 3. Enclosure 4 describes how the Team evaluated the feedback received.

## I. Common Themes

The Team identified a number of common and crosscutting themes regarding ways in which the NRC could transform the regulatory framework to better prepare the agency to regulate new technologies.

An overarching theme that emerged from internal and external stakeholder outreach is the need for systematic and expanded use of risk and safety insights in decisionmaking. Out of this theme, the Team identified the need to appropriately scale the scope of review and level of detail needed from an applicant to enable the staff to make licensing decisions, consistent with the standard of reasonable assurance of adequate protection of public health and safety. In other words, there is a need for a regulatory scheme that continues to hold licensees accountable for safe and secure operation of licensed facilities and use of radioactive materials, including compliance with the Commission's regulation, but that also adjusts the scope and content of NRC staff reviews in the following ways:

- focuses staff resources and expertise on the most safety-significant portions of a licensing decision;
- focuses staff effort on reaching a "reasonable assurance" conclusion based on the entire system performance rather than an individual component; and
- enables the staff to acknowledge that a new technology may be safer than an existing technology although it may lack operating experience and years of performance data or may not meet the regulatory review standards developed for the existing technology.

Related comments urged greater consideration of existing information and programs in making licensing decisions. Existing sources include operating experience; approvals and certifications by other Federal agencies; conformance with other broadly applied, appropriate consensus codes or standards (not necessarily formally endorsed by the NRC); and operational oversight programs to ensure compliance with regulations.

Risk-informed regulation has been at the forefront of the NRC's reform efforts for several decades. Earlier this year, the Commission approved the Agency Strategic Plan for Fiscal Years 2018-2022, which encourages the staff to focus its regulatory activities on the most safety-significant issues associated with a given licensing or oversight action. In addition, in approving the Project Aim recommendations, the Commission directed the staff to "identify and consider additional opportunities to apply more broadly risk insights to enhance our

decisionmaking beyond traditional technical issues [including] our corporate and infrastructure programs.”<sup>3</sup> Accordingly, the staff has been consistently engaged in the development and advancement of agencywide initiatives and business-line specific activities aimed, in part, at increasing staff capabilities to use risk-information in decisionmaking.<sup>4</sup> Despite the long history in this area, these efforts have yielded incremental improvements. A description of a few of the previous and ongoing efforts that were leveraged by the Team during the development of its recommendations is found later in this paper and in Enclosure 5. In spite of these previous efforts and the agency’s existing policies on risk-informed regulation, most of the comments received were related to the need for continued progress in this area.

The Team received many recommendations for decisionmaking that is more efficient and open to alternative resolutions of technical or regulatory issues, particularly in areas where precedent or existing guidance may not apply to a new situation or technology. Although the NRC is bound by legislative requirements and remains committed to and guided by its Principles of independence, openness, efficiency, clarity, and reliability, stakeholders encouraged the agency to seek solutions that are not constrained by current processes while focusing on timeliness as well as safety. In short, the feedback indicated that the principles of efficiency, clarity and reliability should be emphasized just as strongly as independence and openness.

The Team also received many suggestions for more performance-based regulations that are not necessarily tied to one particular technology.<sup>5</sup> Several suggestions urged the NRC to allow new technologies to enter the regulatory process at an earlier stage to provide for clearer identification of potential roadblocks and issues. Several suggested changes would permit more flexibility for licensees to make changes without prior NRC approval while continuing to ensure safety and security.

In addition, although the Team’s efforts were focused on evaluating issues related to new technologies, both internal and external stakeholders submitted comments outside this scope; including, the need for transformation of the Reactor Oversight Process (ROP), enforcement, and the rulemaking process (described further in Enclosure 6). Although these areas are outside the scope of the transformation initiative, they have been referred to the responsible offices for further evaluation and appropriate action.

Based on feedback the Team received from internal and external stakeholders, the staff developed recommendations which are outlined below. These changes will help to realize the staff vision of the NRC as a modern, risk-informed regulator that enables the safe and secure use of new technology, consistent with the Principles of Good Regulation.

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<sup>3</sup> Staff Requirements Memorandum SECY-15-0015, “Project AIM 2020 Report and Recommendations,” June 8, 2015 (ADAMS Accession No. ML15159A234).

<sup>4</sup> A summary of past and current activities in the area of risk-informed regulation can be found at the NRC Web site, Risk-Informed Activities, available at <https://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.

<sup>5</sup> Similar to risk-informed regulation, the NRC also has a long history of increasing the use of performance-based approaches as evidenced by Commission expectations. SECY-98-144, “Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulation,” dated March 1, 1999 (ADAMS Accession No. ML003753601). In addition, there have been many past and ongoing staff activities related to performance-based regulation such as the development of NUREG/BR-0303, “Guidance for Performance-Based Regulation,” December 2002 (ADAMS Accession No. ML023470659).

## II. The Need for Cultural Transformation at the NRC

A shift in NRC culture will be key to the success of the transformation initiative. Yet, cultural change is widely considered the most significant barrier to an organization's ability to successfully transform itself. The NRC's existing culture, like that of any organization, took a long time to form and is based on our regulatory framework as well as our shared philosophies, ideologies, values, assumptions, attitudes, and beliefs. Therefore, changing our culture will be disruptive and uncomfortable for some NRC employees.

Throughout our history, the NRC has aspired to apply risk insights in a systematic manner to focus the attention of the regulator and the regulated on matters of true safety significance.<sup>6</sup> Despite this history, the Team learned from internal and external stakeholders that both the NRC staff and licensees continue to believe that current regulatory practices lead to unnecessary burden evidenced by the expenditure of undue effort on matters of low safety significance across all technical areas. For example, with respect to the use of new or novel technologies in existing facilities, such unnecessary regulatory burden can discourage the introduction of technologies (such as DI&C) that may have safety benefits in the form of improved reliability, and reduced frequency of initiating events and mitigating system malfunctions. For future non-light water reactors (LWRs), this results in inefficient licensing processes that require applicants to obtain exemptions from rules that do not apply to the proposed technology.

Consequently, the staff believes the NRC is at a crossroads for using risk information in regulatory decision-making and determining review scope and level of detail, and the direction we take will impact the future of the agency. Either we embrace change in the industry or we will, through the continued use of dated, inflexible, and inefficient regulatory approaches, be an unnecessary barrier to technology advances. The technologies that the agency will regulate in the next 40 years will be different than the technologies that we have regulated in the previous 40 years. Therefore, our continued success as a safety and security regulator will be impeded by the application of existing approaches to the licensing and oversight of new technologies. Instead, as a modern, risk-informed regulator, we would keep pace with technological innovations, and remove unnecessary barriers to enable the safe and secure use of new technology.

Central to transformation is the staff's sense of urgency and its view that "Modern risk-informed regulation cannot wait." Implementation of the recommendations, if approved, will be the first step in making the necessary cultural shift. The staff's recommendations are a recognition that as the NRC's regulatory programs evolve, the agency must accept a greater degree of risk and uncertainty in areas of low safety or risk significance as the staff appropriately balances the regulatory principles of reliability, clarity, and efficiency. This shift, initiated through the staff's recommendations, will involve endorsing and implementing approaches for accepting an appropriate level of risk in our regulatory, legal, and corporate decisionmaking, focusing NRC approaches on the most important and safety significant issues, and developing solutions

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<sup>6</sup> For example, in 1986, the Commission issued a Safety Goal Policy Statement to clarify its expectations about acceptable levels of risk. Volume 51 of the *Federal Register* (FR), page 30028 (51 FR 30028), "Safety Goals for the Operation of Nuclear Power Plants; Policy Statement," dated August 21, 1986 (republished) (ADAMS Accession No. ML051580401). In 1995, the Commission further articulated its expectations about the use of probabilistic risk assessment (PRA) information in regulatory decisionmaking to reduce the burden of unnecessary conservatism in the licensing of operating reactors. Volume 60 of the *Federal Register*, page 42622 (60 FR 42622; August 16, 1995), "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement" (ADAMS Accession No. ML021980535).

without being unnecessarily constrained by current and sometimes overly conservative processes. We will embrace opportunities to take informed risks on new methods to achieve reasonable assurance of adequate protection of public health and safety. These actions will require behaviors from NRC staff that are substantially different from many of our longstanding practices.

Although the initiatives recommended in this paper apply to specific agency programs, the modern risk-informed approach that is necessary to ensure our future success applies to all employees in each office and region. The basic concepts of risk-informed decisionmaking and risk management apply broadly to all of the Commission's technical program areas, as well as stewardship of the agency's corporate programs and processes. In general, to determine the appropriate course of action the staff will be guided by the risk triplet.<sup>7</sup> Creating shared understanding and fully engaging the staff will be essential to the advancement of transformation.

In the past, the agency has demonstrated that it has the tools and the ability to transform its processes. These include revising the ROP to provide a more objective approach to oversight, developing process options for licensing new reactors in 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," and making other incremental changes to its regulatory approaches. The recommendations in this paper will build upon these important past successes, enabling and sustaining the cultural transformation that will be necessary for the NRC to continue to evolve its regulatory framework on pace with technological advancements.

The Team sought to learn how other innovative organizations have been successful in engaging their staff in the change process. A variety of themes in this area emerged, including:

- Most successful organizations have strong senior leadership support to become innovative and transformative, including a willingness to devote sufficient resources to transformation.
- Innovative and transformative organizations ensure the diversity of thought in the organization. This was commonly accomplished through introducing individuals into the organization who have proven success in changing organizational culture, or further developing individuals within the organization through short-term developmental assignments to other innovative organizations.
- Most organizations that have successfully embraced a transformative culture created the necessary incentives in support of the endeavor.

The agency has already begun efforts to foster and sustain a transformative culture through the ongoing development of the Leadership Model and the Innovation Program. Several of the characteristics outlined in COMSECY 17-0006, "Re-examination of the Need for a U.S. Nuclear Regulatory Commission Leadership Model," dated February 6, 2017,<sup>8</sup> are essential to this change. Specifically, "Innovation and Risk Tolerance" and "Receptivity to New Ideas and Thinking" directly address agility and the support for new ways of doing work. The staff plans to leverage the characteristics and behaviours described in the Leadership Model as well as the formal process for identifying and evaluating new ideas afforded by the Innovation Program.

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<sup>7</sup> The "risk triplet" refers to the questions "what could go wrong?", "how likely is it?", and "what are the consequences?".

<sup>8</sup> COMSECY-17-0006, "Re-examination of the Need for a U.S. Nuclear Regulatory Commission Leadership Model," February 6, 2017 (ADAMS Accession No. ML16348A323).

To launch these efforts, the agency will engage organizational development experts to assist in change management activities. The characteristics and behaviours of the Leadership Model, which are closely tied to a culture of transformation, will be integrated into formal agency leadership development as well as other human capital processes. To ensure that NRC's culture supports innovation and transformation, the agency plans to appoint a senior manager as "Chief Innovation Officer" (CINO). The CINO, who will report directly to the Executive Director for Operations, will, among other duties, act as the primary sponsor of transformation initiatives and provide direction and leadership to the change management efforts.

### III. Recommended Transformation Initiatives

#### a. Strategy to Transform the Agency Licensing Review Process

Risk-informed and performance-based approaches provide for greater focus on items of highest safety or security significance, enable more efficient use of agency resources, and reduce unnecessary burdens to licensees. Previous efforts to risk-inform and performance-base NRC regulations more holistically include the development of a Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing,<sup>9</sup> a Proposed Risk Management Regulatory Framework,<sup>10</sup> and the Fukushima Near-Term Task Force Recommendation 1.<sup>11</sup>

In addition, there are several ongoing business-line specific initiatives aimed at increasing staff capabilities to use risk information in decision-making activities.<sup>12</sup> Several activities associated with these initiatives are included in an action plan for the operating reactor business line.<sup>13</sup> Enclosure 5 provides an overview of these efforts. Through partial implementation of these initiatives, the agency has made incremental progress, which has advanced the understanding of how risk-informed, performance-based regulation could be implemented agencywide. Despite these advancements, licensing has evolved separately in the various NRC program areas, and these areas use risk-informed and performance-based concepts, tools, and techniques to varying degrees. In addition, some stakeholder feedback indicates a need to expand the the concepts previously explored by the agency to include explicit expectations on topics such as leveraging existing information and increasing risk tolerance in situations when short-term uncertainties can be effectively managed and would result in a longer term safety benefit. To better focus and apply the agency's resources to the most safety significant aspects of its work, an agencywide approach is needed to incorporate more fully risk insights into decisionmaking.

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<sup>9</sup> NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," Volumes 1 and 2, issued December 2007 (ADAMS Accession Nos. ML080440170 and ML080440215).

<sup>10</sup> NUREG-2150, "A Proposed Risk Management Regulatory Framework," issued April 2012 (ADAMS Accession No. ML12109A277).

<sup>11</sup> SECY-13-0132, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," dated December 6, 2013 (ADAMS Accession No. ML13277A413 (Package)).

<sup>12</sup> SECY-17-0112, Plans for Increasing Staff Capabilities To Use Risk Information in Decision-Making Activities, dated November 13, 2017 (ADAMS Accession No. ML17270A192).

<sup>13</sup> "Action Plan Risk-Informed Decision-Making Operating Reactor Business Line," dated January 23, 2018 (ADAMS Accession No. ML18005A911).

As noted during a 2017 Commission meeting,<sup>14</sup> while there has been noteworthy progress, in the area of risk-informed and performance-based regulation the agency has not sustained the trajectory set by the Commission in the 1990s. There are several reasons for the change in trajectory, including significant events such as the terrorist attacks of September 11, 2001, and the NRC response to the accident at Fukushima-Daiichi, as well as NRC and industry technical, resource, and cultural readiness for wholesale changes to the regulatory framework.

However, recent changes in the external environment (e.g., the introduction of new technologies, the difficult market conditions for the nuclear industry), provide a compelling opportunity to better focus NRC resources on the most safety and security significant aspects of our work, while continuing to enhance the effectiveness, efficiency and agility of our licensing and oversight functions. Now more than ever, adoption of approaches that use qualitative and quantitative safety and risk insights to scale the level of review needed to make a finding of reasonable assurance of adequate protection are essential to the future success of the NRC. Such approaches will help us to focus on the most important aspects of our work, while accepting an appropriate level of uncertainty and informed risk in areas of low safety significance.

The staff recommends a phased approach starting with the development of a strategy to transform the agency's licensing review process. This is appropriate given that the agency's licensing activities most directly enable the safe use of new technology. The revised licensing process would involve the following:

- expanding the use of qualitative and quantitative risk insights to scale the scope and depth of licensing reviews depending on the safety and security significance of the matter being reviewed;
- balancing the uncertainty of new technologies with their expected safety benefit;
- expanding the ability to leverage existing internal and external information such as operating experience, third party approvals, and the use of consensus standards; and
- using organizational tools to facilitate timely decisionmaking.

The revised licensing process would not require changes to the current regulations and applicants would still need to satisfy regulatory requirements. However, the depth of information needed to reach a licensing decision that provides reasonable assurance of adequate protection would be commensurate with the safety or security significance of the commercial power reactor matter under review. Because of the maturity of existing risk assessment tools and the broad industry support for adoption of risk-informed initiatives, the NRC would first implement the revised licensing process in the reactor program. After applying lessons learned, this approach would be expanded to licensing in all business lines.

The staff recommends: (1) the development of agency-level guidance that facilitates staff's increased use of risk and safety insights (both qualitative and quantitative) to determine the appropriate scope and depth of safety, security, and environmental reviews completed for licensing actions; and (2) the expanded use of organizational tools to facilitate more timely licensing decisions.

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<sup>14</sup> Briefing on Risk-Informed Regulation, 9:00 A.M., Thursday, May 11, 2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance," dated June 26, 2017 (ADAMS Accession No. ML17135A407)).



The Team received feedback that to fully realize current Commission policy relating to risk-informed principles, there is a need for additional clarifying guidance for using risk insights to determine the appropriate level of detail to make a finding of reasonable assurance of adequate protection. Such guidance would ensure that a fundamental understanding of the necessary legal and regulatory bases for achieving “reasonable assurance of adequate protection” (i.e., compliance with the regulations) exists across the agency. For example, in many cases prescriptive adherence to guidance such as standard review plans (SRPs) is applied as the basis for compliance with regulations even though this is not required. Such guidance would better inform the level of detail necessary for both staff reviews of licensing applications as well as the documentation of staff reviews. Enclosure 5 provides additional detail on the purpose and contents of the recommended guidance.

Initially, the agencywide guidance would provide a framework for using qualitative and quantitative information on safety and environmental hazards, their consequences, and their frequency, to determine the appropriate scope and depth of licensing reviews and the degree to which specific SRP guidance needs to be applied. The guidance would also address the appropriate use of internal and external information such as operating experience or third party approvals, in a manner commensurate with safety and security significance. In the longer term, the guidance would be supplemented with tools to assist the staff in updating the SRPs to scale reviews. This approach would appropriately scope all three steps of the current licensing process to: (1) better inform the content of incoming submittals, (2) adjust the scope and depth of staff safety and environmental reviews, and (3) streamline the staff’s documentation of regulatory safety and environmental decisions to be result-oriented and focused on matters of safety, security, and environmental significance.

To effectively implement the risk-informed licensing framework, the staff recommended expanding the use of several organizational tools: (1) expert panels to guide reviews of incoming submittals for new technologies and major licensing actions, (2) internal small groups of NRC staff and management to guide the licensing process (called “guiding coalitions”), and (3) “tiger teams” consisting of small groups of NRC staff who are empowered to identify alternative solutions to resolve licensing challenges, without being unnecessarily constrained by current processes or past practice. The details of these tools, or alternatives found to be more effective in practice, would be developed in implementing Commission approval of this proposal. Enclosure 7 provides additional detail on these organizational tools.

#### b. 10 CFR 50.59 and Similar Change Processes

10 CFR 50.59, “Changes, Tests and Experiments,” and other similar change processes in NRC regulations define the criteria by which licensees determine whether they may make changes to their facility or procedures and conduct tests or experiments without prior NRC approval through a license amendment. As stated in 10 CFR 50.59(c)(1), a licensee can make changes to the facility and procedures as described in the final safety analysis report (FSAR) (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining a license amendment pursuant to 10 CFR 50.90, “Application for Amendment of License, Construction Permit, or Early Site Permit,” only if a change to the technical specifications is not required and the change does not meet any of the criteria in 10 CFR 50.59(c)(2). Similar requirements govern standard designs certified pursuant to 10 CFR Part 52, Subpart B (see § VII.B.5 to Appendices A through E of Part 52) and Combined Licenses (COLs) that reference a standard design. Section 50.59 governs the plant-specific portions of the COL FSAR (i.e., those portions of the FSAR outside the scope of the certified design). Other comparable requirements

apply to nonreactor licensees, including fuel processing facilities licensed under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” (see § 70.72), and spent fuel storage licensed pursuant to 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste” (see § 72.48). The regulations in 10 CFR 50.54(p) and 50.54(q), which differ significantly from section 50.59, govern changes to reactor security and emergency preparedness plans, respectively.

The Team received feedback that the current version of 10 CFR 50.59 is not sufficiently clear about which facility changes, including the adoption of new technologies, require prior NRC review and approval. Further, the feedback indicates that the current criteria are not risk-informed and may result in licensees completing screenings for facility changes and/or the NRC reviewing amendments that have very low safety significance. A change to the regulations to better define the scope and threshold for prior NRC approval and to risk-inform the regulation would provide needed clarity, would allow licensees greater flexibility to pursue plant changes of low safety significance without prior NRC approval, and would facilitate changes to licensed facilities that would accommodate new technologies in cases where the change is not safety significant. While allowing greater flexibility, the licensee will remain responsible for following the regulations, complying with its license, and ensuring that the plant is safe. The NRC will continue to review plant changes, through the current inspection or the license amendment processes, as applicable, and will continue to take appropriate regulatory action—including enforcement actions—if a change raises a safety or compliance issue.

The staff recommends initiating a rulemaking to modify 10 CFR 50.59 and comparable sections of each Appendix to 10 CFR Part 52 (e.g., Section VIII.B.5) to give licensees greater flexibility to make plant changes without prior NRC approval while continuing to ensure safety and security. Similarly, the NRC could revise requirements governing emergency planning and security program to clarify when changes must be submitted for NRC approval. As part of its analysis of potential changes to other provisions in section 50.59, the staff also recommends considering expanding the scope of changes which could be excluded from 10 CFR 50.59 due to being subject to other change process criteria. Currently, section 50.59(c)(4) excludes from the section 50.59 analysis changes to the facility or procedures where the regulations establish more specific criteria for such changes. Expanding section 50.59(c)(4) to explicitly exclude from 50.59 evaluations changes made in accordance with the technical specifications and certain guidance documents, in addition to regulations, could provide more flexibility than the current regulation.

The new rule would be a risk-informed, voluntary alternative to the existing section 50.59 available to licensees with an approved 10 CFR 50.69 or a similar program. Changes to the requirements for the alternative may include: (1) reliance on an approved section 50.69 or similar program; (2) changes to the scope of section 50.59; (3) changes to the threshold for requiring a license amendment under section 50.59; and (4) changes to other similar regulations in sections 50.54(p) and 50.54(q) and in Part 52. While rulemaking is in progress, the NRC would pursue changes in guidance associated with these rules to allow some changes that are consistent with the existing regulations to occur in a more timely fashion. Should the Commission approve this activity, the staff will initiate a rulemaking plan. Enclosure 5 gives additional details on the staff’s recommendation.

### c. Advanced Reactors

The NRC reactor license review process has remained largely unchanged from that developed to license traditional LWRs in the 1960s and 1970s, with the exception of establishing the one-step licensing process for new reactors in 10 CFR Part 52. Some stakeholders indicated that, while the NRC staff has found innovative ways to review new technologies under its existing framework, a performance-based and technology-inclusive regulatory structure would most effectively and efficiently support the review of diverse non-LWR technologies. Stakeholders also indicated that some new vendors may be reluctant to engage with the NRC due to a lack of clarity in the NRC's current staged and incremental review process. Enclosure 8 provides the staff's evaluation of the need for revisions to the NRC's current staged licensing process and current activities associated with clarifying the early design review processes.

The staff recommends creation of a new rule for the licensing of non-LWRs. The new rule would provide an optional performance-based, technology-inclusive set of safety criteria for licensing the design and operation of advanced reactor technologies. This new scheme would focus on achieving reasonable assurance of adequate protection of public health and safety—namely, that the operation of the facility will pose no undue risk to the public—by meeting high-level risk-informed, performance-based criteria. The staff would, to the extent practical, build on previous work initiated in this area. See Enclosure 5 for more detail regarding the staff's recommendation and a summary of previous efforts related to developing a technology-inclusive, performance-based rule for advanced reactors. Should the Commission approve this activity, the staff will initiate a rulemaking plan.

#### d. Digital Instrumentation and Controls

The Institute of Electrical and Electronics Engineers (IEEE) 603-1991, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations," a technology-inclusive standard incorporated by reference in 10 CFR 50.55a(h), serves as the capstone requirement for instrumentation and control (I&C) safety systems. Internal and external stakeholders indicated that the IEEE 603 standard is adequate to assess safety; however, relying on this standard as the primary method to demonstrate compliance may not provide the desired flexibility for new DI&C systems associated with both operating and advanced reactors. Increasingly, DI&C technology manufacturers are international companies that provide supplies to both the nuclear and non-nuclear industries. These manufacturers have developed highly reliable systems likely to criteria other than IEEE 603. The current staff review process is burdensome to these technologies as it drives the licensees or manufacturers to demonstrate detailed compliance with no commensurate safety improvement to the design. In addition, the incorporation by reference of IEEE 603 into the regulation applies the same criteria to all safety systems and to all technologies, which does not lend itself as easily to application of a risk-informed review. Specifically, the staff's review of DI&C systems, involves evaluation of systems against IEEE 603, in conjunction with the current version of the SRP and interim staff guidance -06. This approach promotes a clause-by-clause, compliance-based approach to I&C safety system reviews that is focused on component-level design rather than a more performance-based, risk-informed approach that permits a broader consideration of overall plant safety and system performance.

The staff recommends changing the paradigm for licensing reviews of DI&C systems from a strictly bottom-up approach using specific standards to a risk-informed, performance-based approach. Such an approach would enable effective, efficient, and agile use of multiple alternative standards and methods, in addition to IEEE 603. In the short term, this would involve developing guidance to define high-level, performance-based I&C safety design principles and the acceptable use of a variety of industry standards, including alternatives to the

IEEE standards specified in 10 CFR 50.55a(h). In the long term, the staff recommends a rulemaking that incorporates these high-level performance-based I&C safety design principles into the regulations and development of associated regulatory guidance that documents the acceptable standards that may be used to meet these principles. Should the Commission approve the recommended rulemaking to incorporate high-level, performance-based I&C safety design principles, the staff will initiate a rulemaking plan.

In addition, existing guidance applicable to DI&C development processes, including software, typically reference additional prescriptive IEEE standards as an acceptable method to meet the regulations. Although alternative methods to those endorsed in NRC licensing guidance are permitted, vendors and the staff have experienced challenges in aligning on the acceptability of some alternatives. Actions by the staff, such as pro-actively engaging the I&C vendor community to identify widely-applied alternative standards with a track record of use in developing highly-reliable DI&C systems and establishing a position on their acceptability for use in meeting NRC requirements, would enable near-term use of alternatives to IEEE DI&C development process standards currently incorporated into NRC regulatory infrastructure and reduce the burden of review for new DI&C systems. Staff determinations regarding standards acceptable for use in DI&C development, which would include the current set of IEEE standards, would be incorporated in regulatory guidance.

To efficiently implement these changes, as further explained in Enclosure 5, staff would transition associated regulatory reviews of quality assurance aspects of DI&C development processes, including software, to the vendor inspection program. This will be accomplished by a revision to the associated review guidance, including the SRP, while retaining the review of the digital design, including software, within the instrumentation and control licensing program. To the extent practical, the staff would leverage third-party reviews (or other certification) of DI&C development processes to focus the scope and depth of the quality assurance aspect of the DI&C licensing reviews.

#### RECOMMENDATIONS:

The staff recommends<sup>15</sup> that the Commission approve the following four staff initiatives:

1. Transform the agency licensing review process by development of an agencywide process and organizational tools to expand the systematic use of qualitative and quantitative risk and safety insights; thereby, enabling staff to scale the scope of review and level of detail needed to make a finding of reasonable assurance of adequate protection, beginning with the licensing reviews for reactors;
2. Revise 10 CFR 50.59 and other similar requirements to allow additional flexibility for licensees to make facility changes without prior NRC approval;
3. Initiate an optional performance-based, technology-inclusive regulation for non-LWRs; and;
4. Initiate rulemaking to define high-level performance-based I&C safety design principles and develop associated regulatory guidance that documents the acceptable standards that may be used to meet these principles.

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<sup>15</sup> In addition to these recommendations, the staff has outlined actions that do not require Commission approval and are currently in progress or planned in the near future in Enclosure 8. In Enclosure 6, the staff outlines a number of potential future transformations that would require Commission approval for the staff to pursue them in the future. At this time, the staff is not recommending action on the items discussed in Enclosure 6.

If the Commission approves these recommendations, the staff will develop a detailed implementation plan. The plan will clearly outline an iterative approach involving incremental actions that will start in the near term and that deliver both short and long term value. The plan will include the actions needed to ensure that these recommendations are embraced, understood, efficiently implemented, and used by the staff.

RESOURCES:

The resources required to implement the recommendations in this paper are discussed in Enclosure 9 (non-public).

COORDINATION:

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the General Counsel has reviewed this paper and has no legal objection.

**/RA/**

Victor M. McCree  
Executive Director  
for Operations

Enclosures:

1. Current State of New Technologies
2. Summary of Outreach Activities
3. Summary of Ideas Submitted to the Transformation Team
4. Idea Harvesting, Screening, Prioritization, and Dispositioning Process
5. Additional Details on Areas of Transformation
6. Potential Areas for Future Transformation
7. Additional Detail on Expert Panels, Guiding Coalitions, and Tiger Teams
8. Information on Ongoing New Technology Initiatives
9. (Non-public) Resource Estimates for Recommended Transformations

RECOMMENDATIONS FOR TRANSFORMING THE AGENCY’S REGULATORY FRAMEWORK FOR THE SAFE USE OF NEW TECHNOLOGY IN CIVILIAN NUCLEAR APPLICATIONS, DATED \_\_\_\_\_

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**\*via email**

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