Additional Detail on Areas of Transformation

a. Strategy To Transform the Agency Licensing Process

The Transformation Team found during its outreach that several other government agencies that have transformed their regulatory approaches in recent years have developed tools, guidance, and organizational approaches to scale the depth and scope of their review based on the significance of the work using risk insights. The risk insights take many forms, both qualitative and quantitative, and address the risk triplet[1] (i.e., "What can go wrong?" "How likely is it?" and "What are the consequences?"). Transformed organizations are able to fully leverage risk insights by adopting organizational structures to guide and monitor the implementation of these concepts. For example, several other Federal Government organizations use expert panels to evaluate and guide their organization's review of new technologies in accordance with principles informed by risk insights or have developed tools to scale their level of review and focus consistent with safety and risk insights, or both. Additionally, several organizations used small, flexible groups to develop solutions without the constraints of current processes or past practices; oftentimes the larger organization adopts these solutions and successfully applies them.

The U.S. Nuclear Regulatory Commission (NRC) has a history of exploring the concept of risk-informed decisionmaking as evidenced by Commission policy[2,3] the Principles of Good Regulation,[4] and many agencywide and business-line specific initiatives.[5] In developing the Strategy To Transform the Agency Licensing Process, the Team reviewed many of these past[6] and ongoing[7] iniatives seeking to enable and expand upon existing innovative approaches. The

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[1] "Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999 (Agencywide Documents Access and Management System ADAMS Accession No. ML003753601).
[2] Volume 60 of the Federal Register (FR), 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).
[3] 51 FR 30028, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement," dated August 4, 1986 (republished) (ADAMS Accession No. ML051580401).
[4] "Principles of Good Regulation," COMKR-90-001, April 6, 1990 (ADAMS Accession No. ML15083A026). The NRC Principle of Efficiency states that, "Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted."
[5] 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.
[6] Among the many past innovative agencywide initiatives that the Transformation Team leveraged include 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); NUREG-2150, "A Proposed Risk Management Regulatory Framework," issued April 2012 (ADAMS Accession No. ML12109A277); and 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)). NUREG-1860 establishes the feasibility of developing a risk-informed and performance-based regulatory structure for the licensing of future nuclear power plants. NUREG-2150 provides a strategic vision and options for adopting a more comprehensive, holistic, risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material. Recommendation 1 of the Near-Term Task Force Report states that the NRC establish a logical, systematic, and coherent regulatory framework that appropriately balances multiple layers of protection and risk considerations to deal with events beyond the current NRC design basis.
[7] SECY-17-0112, "Plans for Increasing Staff Capabilities To Use Risk Information in Decision-Making Activities," dated November 13, 2017 (ADAMS Accession No. ML17270A197) summarizes many of the ongoing initiatives leveraged by the Team. These include initiatives for the operator reactor fleet outlined in "Action Plan Risk-Informed

NRC has used risk insights to inform its decisions on a number of different applications over the last 30 years (e.g., Reactor Oversight Process, fuel cycle facilities) and has recently focused on expanding the use of quantitative and qualitative risk-insights, particularly in the area of reactor licensing.[8] However, the agency does not fully use risk insights in all aspects of its licensing work. In addition, the agency has not fully explored the degree to which information not independently developed by the staff can be used as the basis for licensing decisions.

The NRC has consistently made a distinction between "risk-based" and "risk-informed" regulation. The former describes a regulatory approach that relies exclusively on the quantitative results of a probabilistic assessment of risk (generally on a plant-specific basis). The latter describes NRC's current regulatory approach that blends risk-based insights with a maintenance of the existing largely "deterministic" licensing basis (i.e., a basis that generally evaluates safety in terms of the consequences of a predetermined bounding subset of accident sequences). Although the distinction between risk-based and risk-informed regulation is largely recognized, in practice, it is not always easy to implement risk-informed approaches in every application. For example, it is particularly challenging in the context of initial licensing, which does not have an established deterministic licensing basis to serve as the foundation for risk-informed decisionmaking.

The feedback that the Transformation Team received indicated that the agency's conservative culture can drive us to embrace prescriptive approaches to facilitate efficient and standardized licensing reviews. The feedback the team received also indicated that there is a perceived absence of clear organizational endorsement of alternative approaches that incorporate qualitative and quantitative risk insights or third-party information or approvals. In particular, there is a perceived expectation that detailed, independently generated information is needed to justify a determination of reasonable assurance of adequate protection of public health and safety, even in cases of low safety or security risk significance. Therefore, without specific tools and organizational focus, incorporation of risk insights and existing information, which provides insights into the safety significance of an issue in decisionmaking, is not always used where it would be appropriate under existing Commission direction.

Figure 1 is an example of a two-by-two "binning" approach that illustrates one means for scaling the level of review according to qualitative and quantitative risk and safety insights and the availability of information or processes that may provide additional mitigation or confidence in the safety of an issue. The NRC could use this two-by-two "binning" concept to aid in the development of agencywide guidance on using standard review plans in the short term, and to update them in the long term. As the NRC is a both a risk-informed and performance-based

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Decision-Making Operating Reactor Business Line," dated January 23, 2018 (ADAMS Accession No. ML18005A911) as well as new and advanced reactor initiatives including those promulgating from SECY-11-0024, "Use of Risk Insight to Enhance the Safety Focus of Small Modular Reactor Reviews," dated February 11, 2011 (ADAMS Accession No. ML110110691) . The Action plan seeks to enhance the integration of risk information into the organization's decision-making practices and processes to improve the technical basis for regulatory activities, increase efficiency, and improve effectiveness. SECY-11-0024 requested approval of the staffs recommendations to adopt a risk-informed and integrated review framework for efforts pertaining to integral pressurized-water reactor (iPWR) designs and to develop, over the longer term, a risk-informed and performance-based regulatory structure for the licensing of advanced reactor designs.

[8] Summarized in SECY-17-0112, Plans for Increasing Staff Capabilities To Use Risk Information in Decision-Making Activities, dated November 13, 2017 (ADAMS Accession No. ML17270A192).

regulator, it is anticipated that staff would, to the extent possible, increase use of performance-based review approaches while implementing its risk-informed review tools.[9]

Notably, this conceptual "binning" approach does not negate the importance of existing regulatory control mechanisms; however, it does realize the benefits of incorporating the current state-of-knowledge in the regulatory decisionmaking process. This approach, is expected to assist the staff in continuing to make risk-informed performance-based regulatory improvements as needed and in an incremental manner consistent with Commission direction.[10]

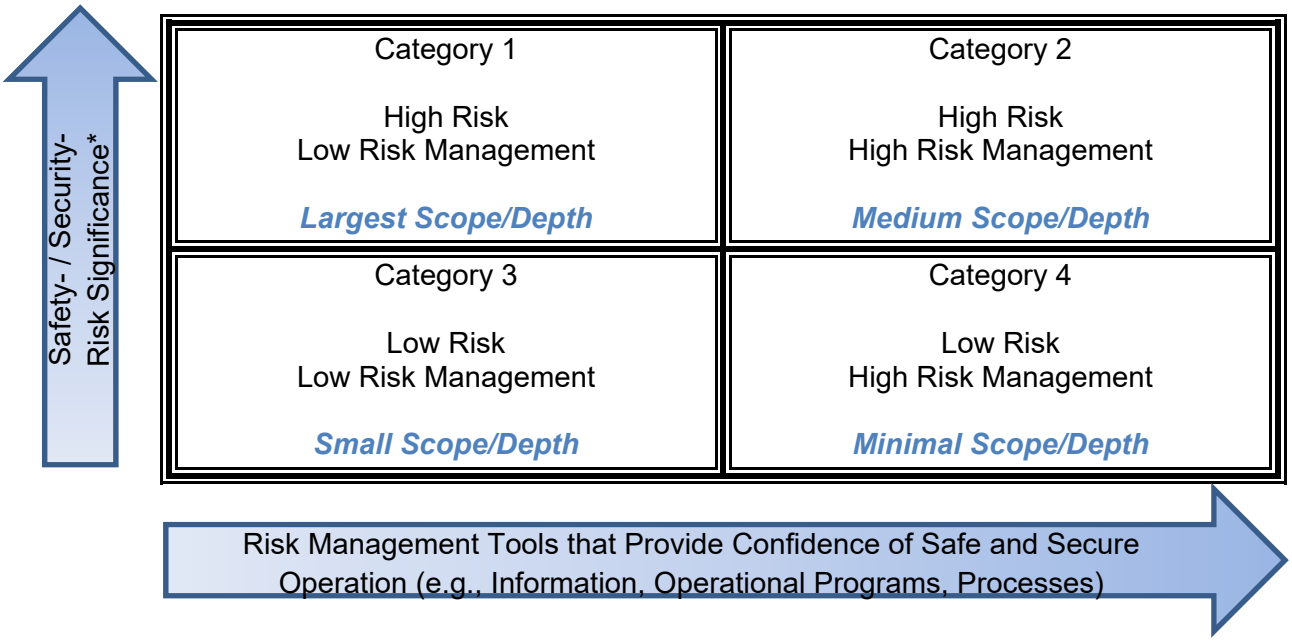

Figure 1: A conceptual generalized "binning" tool for evaluating the scope and level of detail of reviews.

** Safety or Security/ Risk significance can be determined by either traditional quantitative risk assessment techniques such as probabilistic assessment (PRA) or alternative quantitative or qualitative tools, as defined by the risk triplet (i.e., "What can go wrong?" "How likely is it?" and "What are the consequences?"). In this context, risk significance is broader than quantitative metrics such as core damage frequency or large early release frequency.*

[9] SECY-98-144 states that risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment, and performance history are used, to (1) focus attention on the most important activities, (2) establish objective criteria based upon risk insights for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, and (4) focus on the results as the primary basis of regulatory decision-making. There are many past and ongoing staff activites related to performance-based regulation as evidenced by the development of NUREG/BR-0303, "Guidance for Performance-Based Regulation," December 2002 (ADAMS Accession No. ML023470659).

[10] SECY-15-0168, "Recommendations on Issues Related to Implementation of Risk Management Regulatory Framework," dated December 18, 2015 (ADAMS Accession No. ML15302A135 (package)).

The staff could apply the above two-by-two "binning" tool in many scenarios and with many considerations as the axes. For example, the y-axis would not be limited to quantitative risk insights from PRA and could include alternative risk insights from tools such as integrated safety analyses, failure modes and effects analyses, vulnerability assessments, or more qualitative methods relying on engineering and scientific judgment, as appropriate to the regulated activity. Notably, the NRC is a risk-informed regulator; therefore, the assessment of safety or security risk significance would also integrate considerations such as safety margins, defense-in-depth, and performance measurement processes.[11] The x-axis could also consider other factors such as third party approvals or use of industry standards.

The staff proposes to develop an agencywide guidance document requiring the NRC to use systematic tools, such as those described above, to assess risk and to establish appropriate risk tolerance. The agencywide guidance document would provide additional considerations that could be applied to varying degrees depending on the "bin", and would guide the scope and depth of review necessary. These considerations include: (1) accepting well-managed uncertainty while still maintaining adequate protection during the development of new technologies that may provide a longer term safety benefit (further described below), (2) utilizing operational experience to provide confidence in integrated operation, (3) leveraging existing government approvals or utilization of standards and methodologies not previously reviewed by the NRC; (4) leveraging third-party certifications as assurance of results, (5) additional reliance on the applicant's conformance with consensus standards or appropriate alternatives, (6) granting a limited-scale approval based on initial information and requiring confirmatory testing/orinspections (further described below), and (7) reducing the level of detail required for a safety finding in regulatory areas that have existing operational programs for which potential operational problems will be self-revealing or will be managed through compliance with alternative regulations that also assure safety or security (e.g., Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, Standards for Protection against Radiation").

As described above, several NRC organizations are already implementing or developing tools to help increase staff capability to use risk information in decisionmaking. A few of these efforts specifically relate to using risk information to scope the level and depth of licensing reviews. For example, the Office of New Reactors recently applied an enhanced safety focused review approach to the design certification review for NuScale. Similarly, the Office of Nuclear Reactor Regulation is developing tools to use risk insights to better focus operating reactor licensing reviews. Although these efforts reflect substantial progress, the NRC may realize even greater safety focus when it adopts risk-informed approaches agencywide and couples them with the additional considerations proposed herein.

One example of how the new licensing strategy could enable efficient management of scope and depth of licensing reviews is in the area of Digital instrumental and control (DI&C). Because the current licensing approach is largely compliance-based, an initial licensing of DI&C equipment or amendments to modify analog systems to digital does not presently scale based on risk insights or additional considerations. As such, the agency typically evaluates DI&C systems at the component level, rather than considering the overall impact of the component on the plant. When the system is classified as a safety system in the licensing basis, the current licensing practice applies all portions of the Standard Review Plan for the Reivew of Safety

[11] Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant Specific Changes to the Licensing Basis," Revision 2, issued May 2011 (ADAMS Accession No. ML100910006).

Analysis Reports for Nuclear Power Plants: LWR Edition—Instrumentation and Congtrols (NUREG-0800, Chapter 7) applicable to safety-related DI&C systems in that review, including a licensing review of the digital components' development. That is, the review scope and depth would be Category 1 in the two by two matrix. In the new approach, the review of the digital system would consider its overall impact on plant safety and security and leverage third party certifications, applicable operating experience, and conformance to appropriate standards or alternatives. These considerations would reduce the scope and depth of these reviews, based on available information, to one of the other categories. This optimizes the review efforts and enables the staff and licensee to focus on matters of safety significance. These recommendations build on the progress already being made under the DI&C Integrated Action Plan and are consistent with the intended outcomes of Modernization Plans #1A, #3 and #4.

The agency's accident tolerant fuel (ATF) project plan, which already contains several of the above considerations, can also benefit from fully incorporating the strategies dicussed above. Full transition to some of the longer term ATF concepts is a high safety and risk significant change with little precedent in nuclear regulatory history. These concepts depart drastically from the uranium dioxide/zirconium alloy fuel used in operating light water reactors. Given limited operational experience and high safety significance of these longer-term ATF concepts, under the current paradigm the change likely requires a "Category 1"—a review of maximum depth and scope. However, under the revised approach, the staff can apply a phased approach where the licensee gets limited approval initially and the restrictions are removed as the requisite data become available. This would allow further testing from test reactors and lead test assemblies as well as operating experience to demonstrate safety for unrestricted implementation, consistent with consideration (6) above. Another consideration is early engagement through expert elicitation, which can allow NRC to focus its review efforts on the most significant technical issues expected for each ATF concept. Furthermore, significant review efficiencies may be realized by utilizing non-NRC (e.g., commercial or Department of Energy) codes when a comparable NRC tool would require significant development. These considerations will help to appropriately manage the scope and depth of NRC review necessary to make a finding of reasonable assurance of adequate protection to enable the use of a new technology with potential safety benefits such as ATF.

Establishing a new agencywide licensing framework would involve challenges. Most notably, it would require initial resource expenditure to develop an agencywide guidance document and business line specific procedures to align with the agencywide guidance. In addition, scaling the scope and depth of reviews according to safety and security significance and expanding the degree to which existing information is leveraged to reduce the degree of independent analysis would involve a cultural shift in the agency that some may perceive as reducing the agency's safety focus. However, this effort would ensure the agency remains focused on the most important information and supports a shift that ensures the licensees maintain their prime responsibility for the safe and secure operation of nuclear facilities and the use of nuclear materials. This effort will lead to long term resource savings for the NRC that would enable the agency's full attention on the most important safety and security aspects of its work and better enable the use of new technologies that may have safety benefits.

As noted in the above example related to ATF, one of the concepts that the agency could expand in the revised licensing review approach is the use of limited approvals that would require followup confirmatory testing. When the NRC and industry approach licensing a new material or technology, they are often faced with the challenge of how to balance the uncertainty of the new technology's performance with the need for operating experience to confirm safe

performance. Laboratory test results are generally used as evidence to build the safety case for a technology application, but they also raise the question of how representative the testing is of actual plant conditions. The NRC and industry both strongly value operating experience as critical to demonstrating safe performance. The challenge often centers on providing the NRC staff with enough technical basis to approve use of the new technology without having much, if any, actual in-plant operating experience.

Implementaton of this recommendation would facilitate the NRC and industry pursuing the broader use of limited approvals that would require followup confirmatory testing. This would support phased implementation of new technologies to bridge the gap from industry's desire for full implementation approval to the NRC's need for a strong technical basis to make a safety evaluation. By providing limited-scale approval for the use of a new technology, the NRC and industry can build valuable operating experience that increases NRC confidence in the full-scale implementation approval, while allowing industry to continue to develop and refine the technology. A key aspect of this idea is the concept of accepting well-managed limited short-term risk and uncertainty to achieve potential long-term safety and operational benefits. This change in mindset and process by both the NRC staff and industry can help provide a more predictable, reliable, and timely path to full-scale implementation of a new technology with reduced risk and uncertainty.

In addition, expansion of the innovative practices already in use in the agency, such as the NRC staff's increased use of audits, could further transform the licensing process. Increased use of audits and informal communications with licensees to clarify and resolve minor technical questions should be a regular practice to allow reviews to proceed efficiently without undue delay. Appropriate and expanded use of audits and informal communications in the NRC's licensing review process can help ensure that the NRC is fully embodying all of the Principles of Good Regulation by operating efficiently while still maintaining openness to the public and other stakeholders. The NRC would establish processes to ensure full transparency when conducting informal communications and compliance with the it's public meeting policy

The tools to implement these strategies would vary across the agency's business lines. Therefore, each business line would need to use the agency-level guidance to develop specific operational-level guidance for its licensing products.

Streamlining Environmental and Safety Reviews

The process outlined above would do more than change the scope and focus of the staff's licensing reviews. Focusing the majority of effort in licensing reviews on the most significant issues—while applying more limited effort on issues of lesser significance—would also have a significant impact on the length and detail of both the safety and environmental documents resulting from streamlined staff reviews.

The Council on Environmental Quality (CEQ) issues regulations in 40 CFR Part 1500, "purpose, Policy and Mandate", that interpret the National Environmental Policy Act of 1969 (NEPA).[12] These regulations place particular emphasis on reducing paperwork and page length in environmental impact statements (EIS). According to CEQ regulations, efforts to reduce paperwork associated with EISs are designed to emphasize the information useful to the

[12] As an independent agency, the NRC is not required to follow CEQ regulations, but the agency does consider CEQ regulations to be a persuasive authority on NEPA compliance.

decisionmaker and the public, and reduce background material. In developing its regulations, CEQ notes that while all potential environmental impacts from a proposed project must be considered, the discussion of impacts should be in proportion to their significance. An EIS should fully cover significant impacts, but discussion of small impacts should be akin to that of a "finding of no significant impacts"—there should be only enough information to show why additional study is unwarranted. Accorindg to CEQ regulations, duplication of effort should be avoided as much as possible. If a prior environmental document covers an issue, it should be incorporated by reference. Although the NRC's EISs are adequate under NEPA, and the NRC does make some efforts to streamline its reviews such as developing Generic EISs in areas such as license renewal, closer adherence to the streamlining principles in the CEQ regulations could result in environmental documents that provide a clearer, more focused discussion of environmental impacts that would benefit both NRC decisionmakers and interested members of the public.

Based upon feedback received during its effort, the Transformation Team believes that a similar philosophy should be used to streamline safety evaluation reports (SERs). SERs must include a finding that the application meets all applicable regulatory requirements as well as a sufficient explanation of the NRC's staff's review. Such explanation must be detailed enough to show that the decision that the regulatory requirements have been met is not arbitrary and capricious. Just as EISs should focus on significant issues and avoid duplicative efforts, SERs should focus on the most significant issues. An SER should not duplicate the license application, but rather refer to the appropriate section of the application, as long as that particular section of the application is otherwise publicly available and the NRC staff does not disagree with the information presented in the application. References to prior SERs, similar safety evaluations by other agencies, and widely-accepted codes and standards may be sufficient to document the review, as long as the relevance of such prior work is sufficiently explained. Consistent with the staff's recommendation to transform the agency's licensing strategy, SERs would focus primarily on safety-significant issues. Nonsafety-significant issues could be largely omitted as long as the discussion sufficiently explains the omission. By producing streamlined SERs that eliminate unnecessary information, the staff would clarify its review process and place appropriate emphasis on safety- and security-significant issues.

b. 10 CFR 50.59, "Changes, Tests and Experiments"

The staff recommends that the scope of section 10 CFR 50.59 and comparable sections of 10 CFR Part 52 (e.g., section VIII.B.5 of the appendices) be modified to exclude changes to certain structures, systems, and components (SSCs), rather than the current scope which includes the entire facility as described in the updated final safety analysis report (UFSAR). The proposed change to 10 CFR 50.59 could use the categorization scheme of section 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," to determine which plant SSCs are in scope. To use the alternative section 10 CFR 50.59 process, a licensee would need to have implemented section 10 CFR 50.69 through an approved license amendment. For example, Risk-Informed Safety Class 1 (RISC-1) and RISC-2 perform safety significant functions and would be in scope and subject to a certain risk-informed threshold for requiring NRC approval before licensees made any changes. RISC-3 SSCs are safety related but perform low safety significant functions and would have a higher risk informed threshold, meaning that, while prior approval may be required for some changes in this area, it would be less likely to be necessary than changes to RISC-1 and RISC-2 SSCs. RISC-4 SSCs would be out of scope of the newly revised 10 CFR 50.59, and changes to RISC-4 SSCs would not require prior NRC approval, unless such a change would otherwise require a license amendment.

This proposed approach has some limitations. Licensees may choose to apply the 10 CFR 50.69 categorization scheme only to certain SSCs, which might limit the usefulness of a revised 10 CFR 50.59. To address this limitation, the NRC could revise 10 CR 50.59 without reference to 50.69 but provide guidance on an acceptable method to limit the scope to only risk and safety significant SSCs. Such an alternative approach would be developed to rescope comparable sections of 10 CFR Part 52.

Additionally, the staff recommends modifying threshold of 10 CFR 50.59 and of comparable sections of 10 CFR part 52 by changing the criteria in section 50.59(c)(2) and the equivalent criteria in 10 CFR Part 52. This would allow the licensee to make changes without prior approval if an evaluation can be completed that demonstrates both that the change in risk is low and that the overall risk of plant operations remains low following the change. Integrated risk criteria using the metrics and guidance of Regulatory Guide 1.174 would support the revised risk-informed change process thresholds. In addition, the staff would consider rule changes for other regulations that govern when licensee changes require license amendments, such as 10 CFR 50.54(p) and (q). While rulemaking is in progress, the NRC would pursue changes in guidance with regard to these rules to allow some change to occur that are still in compliance with the regulations in a more timely fashion.

It is anticipated that changing to scope of 10 CFR 50.59 could substantially reduce the scope of plant changes that must be screened against the criteria in the rule. A staff assessment of 10 CFR 50.59 (ADAMS Accession No.ML13066A237) previously estimated that licensees conduct approximately 49,000 screenings and evaluations per year across the operating fleet. The current scope of 10 CFR 50.59 includes all SSCs described in the UFSAR, many of which are nonsafety- related SSCs. A staff presentation on 10 CFR 50.69 at the May 11, 2017 Commission briefing on risk-informed regulation[13] estimated that approximately 99 percent of non-safety related SSCs are also in RISC-4.[14] Although it is not possible to estimate the exact number of screenings that would no longer be required, it is clear that the number could be significantly reduced with no adverse safety impacts. For those SSCs remaining within the scope of the rule, the number of license amendment requests (LARs) would also be modestly reduced by changing the criteria, since most LARs also involve technical specification changes.

Currently, approximately 12 LARs for 10 CFR 50.69 are under review or anticipated to be submitted in the near term. Industry has indicated that many more applications will be submitted. The NRC staff has stated it can review approximately 10 applications per year on a staggered basis. At this rate, the agency would approve a majority of the operating reactor fleet to use 10 CFR 50.69 in approximately 5 years. If a revised 10 CFR 50.59 were coupled with 10 CFR 50.69, the staff estimates that the majority of the operating fleet would be able to apply a revised 10 CFR 50.59 scope and criteria in a similar timeframe of 5 to 7 years.

The recommended changes to the comparable sections of Part 52 are intended to ensure outcomes with equivalent demonstrations of adequate safety and security. Also considering that 10 CFR 50.59 applies to new reactors during operation, the recommended change to Part 52 would provide consistency for change processes for reactors during the facility construction and operation. The revised Part 52 change process could use risk-informed criteria similar to

[13] SRM-M170511, "Staff Requirements – Briefing on Risk-Informed Regulation, 9:00 A.M., Thursday, May 11,2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to PublicAttendance," dated June 26, 2017 (ADAMS Accession No. ML17177A397). Meeting transcript ADAMS Accession No. ML17135A407.
[14] Value estimated based on classification of selected SSCs at one facility.

50.69 categorization scheme or an acceptable alternative to prioritize SSCs and focus the scope of prior NRC approval on safety significant SSCs.

Since reactor designs with passive safety features typically have lower risk estimates and less complex systems compared to designs with active safety features, the proposed risk-informed change process should also benefit these plants. This change is complementary to the staff's efforts to focus on more safety significant components and aligns the constructs in part 50 and part 52. Similar to operating reactors, this approach could reduce the scope of changes that must be screened against the current criteria. As benchmark, about 10% of submitted amendments for the Vogtle site contained Tier 2* information that could potentially be subject to facility changes without NRC approval under the proposed revision.

These regulatory changes, if implemented, are not without drawbacks. While the change processes in Parts 50 and 52 are quite similar, they are not identical. One of the driving factors behind the decision to implement distinct change processes in Parts 50 and 52 was the Commission's goal of maintaining standardization. Revising the Part 52 change process would be a policy shift away from standardization. Two additional key drawbacks are the costs associated with developing and implementating the recommended rulemaking and the time period required for a licensee to develop a fully implemented revised section 10 CFR 50.59 scope and criteria. Also for operating and new reactor licensees without an approved 10 CFR 50.69 program, the development of a risk-informed SSCs' categorization scheme will be necessary. In addition, a key concern is the risk that, even though the proposed changes are grounded in current principles of risk categorization, altering the threshold or scope for regulatory review of a plant change may be perceived as less safe than the current regulatory process. In addition, although these proposed changes are expected to be useful to implement new technology, in the early stages applying the revised rule, it may be difficult to quantify risk for the new and novel technologies that have a different design or material, since they do not have prior operating experience.

However, the staff believes that the benefits of the proposal outweigh the drawbacks. One benefit of the recommended risk-informed change process would be the improved focus of NRC licensing reviews on plant changes of greater safety and risk significance. As revised, the change process would allow licensees to make more changes to use new technologies without potentially burdensome licensee screenings and NRC regulatory review while still ensuring safety through applicable regulations and oversight including inspection and enforcement. The revised rule would also appropriately distribute safety burdens among the licensees and the NRC by emphasizing that licensees would have the prime responsibility for plant safety while the NRC uses its resources and expertise to provide effective, focused oversight. In particular, the staff notes that proposed changes to 10 CFR 50.59 could provide significant benefits in the area of digital I&C because of the unique challenges of upgrades under the current regulation. Although the current criteria in section 10 CFR 50.59 do consider concepts such as the likelihood of an occurrence or the likelihood of malfunction, there is no integrated evaluation of systems-level significance. These revisions would provide the appropriate overall safety focus in a clear, objective manner. Lastly, the proposed revision would clarify which changes would require NRC review and licensee screenings.

c. Advanced Reactors

The Implementation Action Plans for non-light water reactors (non-LWRs), which support the Vision and Strategy document[15], include the consideration of a new rule as a midterm and longterm action item. Currently, the staff is focusing its efforts on nearterm, technology-inclusive activities, such as advanced reactor design criteria and rulemaking on emergency preparedness. The staff proposes a new, optional, technology-inclusive, risk-informed, performance-based rule for reviewing the design and operation of advanced reactors. At this time, the staff proposes that the rule be limited to providing the design and operating criteria for licensing a non-LWR. However, as part of the rulemaking process, the staff would consider whether it should include alternate licensing process(es) based on lessons learned from applying 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." The new regulation would present alternative licensing criteria for non-LWR applicants.

The NRC has considered the development of a risk-informed, performance-based regulatory framework for advanced reactors several times with a variety of concepts. The agency published some of the reactor-related reviews of these concepts in NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing, issued December 2007, and NUREG 2150, "A Proposed Risk Management Regulatory Framework," issued April 2012; in the Risk Management Regulatory Framework; and in the early 2010s under the Fukushima Near-Term Task Force Recommendations.

In 2006, with the Commission's approval, the staff published an advance notice of proposed rulemaking (ANPR) in the Federal Register seeking comment from stakeholders and the public on a risk-informed, performance-based approach to revising of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," in furtherance of a new 10 CFR Part 53.[16] The staff also met with stakeholders after issuing the ANPR to discuss the document's topics and questions. The NRC received comments from ten stakeholders including, but not limited to: the Nuclear Energy Institute, the American Society of Mechanical Engineers, and the American Nuclear Society. Although stakeholders generally supported the plan as outlined in the ANPR to develop risk-informed and performance-based requirements for future reactors, there was feedback that the initiation of rulemaking was not necessary at that time. There were concerns at that point that rulemaking would detract from the resources available to complete the licensing of the next generation of near-term LWRs and review of design certifications. Feedback was also mixed as to whether the "10 CFR Part 53" requirements should be technology-inclusive or technology-specific. Accordingly, in SECY-07-0101,"Staff Recommendations Regarding a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," dated June 14, 2007, the staff requested Commission approval to defer such a rulemaking until after the development of the licensing statement for the Next Generation Nuclear Plant or receipt of an application for design certification or a license for the Pebble Bed Modular Reactor. The Commission approved the staff's recommendation. This was based, in part, on the positive staff progress in risk-informed initiatives without rulemaking, and the lack of

[15] NRC "Vision and Strategy for Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness" , issued December 2016(ADAMS Accession No. ML16356A670). NRC Non-Light Water (Non-LWR)Vision and Strategy Staff Report:" Near-Term Implementation Action Plans", Volume 2 (draft) (ADAMS Accession No. ML16334A495). NRC Advanced Reactor Vision and Strategy: Mid-Term and Long-Term Implementation Action Plans (draft) (ADAMS Accession No. ML17054D483).

[16] "Approaches to Risk-Informed and Performance-Based Requirements for Nuclear Power Reactors," 71 Fed. Reg. 26267, May 4, 2006.

interest from the advanced and operating reactor community at the time. It was also based on the consideration that other designs in development at the time had not yet sufficiently matured.

However, today's advanced reactor community is expanding and is largely interested in non-LWRs. It is reported that more than 50 companies[17] are working on advanced reactor projects. Congress and other stakeholders have also shown an interest in ensuring that the United States remains an innovative leader in the development and use of nuclear technology. As a result, a new optional framework based on risk-informed, performance-based, technology-inclusive regulations, potentially "10 CFR Part 53", and guidance would provide greater applicability for non-LWR applicants and minimize the need for exemptions.

Developing and implementing technology-inclusive criteria for regulation could enhance the NRC's focus on regulating of safety principles or functions (as opposed to supporting technology-specific safety functions),. One potential option for criteria for consideration in a potential rulemaking is for an applicant to demonstrate that the operation of the facility would pose no undue risk to the public and the environment, meeting risk-informed, performance-based criteria that include topics such asno off-site dose above regulatory limits from all activities expected or probable within the life of the facility, including anticipated operational occurrences, licensing basis events, anticipated transients and activities, internal and external hazards, and operating modes.

Development of a new framework for licensing will present challenges and benefits. Some stakeholders asserted to the Transformation Team that such a rulemaking is unnecessary and too resource intensive. Rulemakings require financial and human capital resources for development and implementation stakeholders expressed some concern that the resources required to implement a rule could interfere with ongoing current licensing work. The staff could use resources from across the business lines to complete the rulemaking in a time and manner such that it would not interfere with current advanced reactor licensing work and, if the Commission approves of the rulemaking, would use off fee- based funding for rulemaking activities. A technology-inclusive framework could also present the potential for more ambiguity in the licensing process and some argue potentially less certainty on what is necessary to demonstrate an applicant's safety case.

However, moving forward with a technology-inclusive framework also has many benefits. Vendors and others involved in the development of potential new reactor technologies have expressed the long-term desire for a high-level, technology-inclusive framework. This framework would provide potential licensees with flexibility in multiple ways. The focus on high-level safety principles and performance criteria for regulation not only could enhance the regulatory focus on the most safety significant aspects of new reactor design, they could also, by allowing for greater regulatory flexibility, reduce or eliminate the need for exemptions from regulations under Parts 10 CFR 50 or 10 CFR 52. In developing the rulemaking, the staff would build on other performance based, risk-informed efforts, such as the licensing of special nuclear material in 10 CFR Part 70,"Domestic Licensing of Special Nuclear Material."

Regulatory design and operation criteria, in a new rule, would be truly transformative if based on high-level nuclear safety principles that are unwavering over time and applicable regardless of the type of technology. Each applicant would make its safety case based on the unique features of its design to meet the high-level safety principles. Further, the staff would consider and build on previous rule proposals and feasibility studies for advanced reactors, as practical.

[17] *Keeping Up with the Nuclear Industry*, Third Way Advanced Nuclear Summit, 2018.

The timing for a new rule is ideal right now, in that it will signal to the rising non-LWR community and other stakeholders that the NRC is committed to reviewing and licensing new reactor technology in a timely manner and in a way that relates directly to tomorrow's technology.

d. Digital Instrumentation and Controls

The Institute of Electrical and Electronics Engineers (IEEE) standards that the NRC uses for both evaluation of I&C design (i.e., IEEE Std. 279 and IEEE Std. 603) and digital system development processes (i.e., IEEE standards endorsed by RGs 1.168 – 1.173 and leveraged in BTP 7-14) have been effective in enabling staff to reach reasonable assurance of adequate protection findings for DI&C systems over the years. However, there are many highly reliable DI&C systems that have been designed to standards other than IEEE-603 and developed using standards other than those endorsed by the NRC. These systems perform safety critical functions in foreign nuclear markets and non-nuclear industries. However, the NRC does not take a formal regulatory position on the acceptability of these other standards for use in the US nuclear market. At present, the expense of demonstrating that these standards are adequate for use in the US nuclear market is a deterrent for DI&C vendors pursuing NRC approval and eventual introduction of their systems in the US nuclear market.

If the NRC wishes to enable use of additional and newer DI&C systems in the U.S. nuclear market, formally expanding the standards designated acceptable for use by licensees, applicants, and vendors in designing and developing DI&C systems is needed. Proactive action on the part of NRC is essential as prior licensing activities associated with non-IEEE standards have resulted in challenges for both staff and licensees or vendors.

The staff recommends development of high level performance-based I&C safety design principles to be used as an alternative to compliance with IEEE Std 603, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations", or IEEE Std 279-1971, "Criteria for Protection Systems for Nuclear Power Generating Stations". Overall, this recommendation would eliminate requests for exemptions or alternatives to either IEEE Std 279-1971 or IEEE Std 603-1991, currently in 10 CFR 50.55a(h), would provide additional flexibility in the manner in which requirements could be met, and would focus licensing reviews of DI&C systems on their preservation of plant principle design criteria. In the near term, the staff recommends engaging stakeholders and developing guidance, as needed, that could be used by licensees or applicants to support a request to use an alternative standard to IEEE 603 under 10 CFR 50.55a(z). In the long term, the staff recommends establishing high–level, performance-based I&C safety design principles in the regulation. Starting with an advanced notice for proposed rulemaking (ANPR), the staff would develop a draft performance-based regulation and associated guidance. The regulatory guidance would demonstrate how a variety of appropriate standards, including IEEE 603, could be acceptable for use.

The IEEE standards (IEEE 279 and IEEE 603) provide functional design criteria for I&C that are consistent with the high-level I&C safety design principles within the International Electrochemical Commission (IEC) standards. The nuclear power industry outside the United States commonly uses IEC standards. Some of the principles are also reflected in nonnuclear standards (e.g., Federal Aviation Administration) for digital systems. Therefore, transforming the regulatory structure toward high-level performance-based I&C safety design principles should enable efficient use of alternative standards or methods, facilitate further industry development of joint IEEE/IEC standards, and remove barriers to the incorporation of DI&C in U.S. nuclear plant safety systems.

Independence, predictable and repeatable behavior, defense-in-depth, and diversity are examples of high-level I&C safety design principles within the U.S. regulatory structure that are also reflected in alternative standards. These safety design principles directly support the longstanding nuclear safety engineering principle of concentric barriers to radiation release with an established design basis and margin that addresses uncertainty. Defense-in-depth and safety margin are also common to the NRC's approach to risk-informed regulation. Addressing these principles provides a basis for reasonable assurance of adequate protection.

NRC successfully evaluated I&C systems for the NuScale design certification using an approach consistent with high-level I&C safety design principles, the 10 CFR 50.69 categorizations, and reliance on the quality assurance vendor inspection organization. The application of the NRC's Design Specific Review Standard (DSRS) for the NuScale I&C design achieved improvements in licensing efficiency and is being further enhanced through a lessons-learned activity. Some of the licensing efficiency is attributable to NuScale's I&C design approach, which directly addresses high-level I&C safety design principles (e.g., defense-in-depth and diversity).

The IEEE standards (and the U.S. regulatory approach) differ from IEC standards (and some international regulatory approaches) in the manner by which they establish the adequacy of I&C system designs. The following are three examples of significant differences:

(1) The IEEE standards do not establish functional requirements that clearly define the relationships among different elements of a "*defense-in-depth*" architecture. The IEEE standards instead contain features that I&C safety systems must provide or requirements they must meet to ensure independence between (a) safety systems and the effects of design basis events; and, (b) between safety systems and other systems. In I&C licensing reviews, defense-in-depth is primarily addressed through guidance in I&C Branch Technical Position 7-19, "Guidance for Review of Diversity and Defense-in-Depth in Digital Computer-Based Instrumentation and Control Systems," issued August 2016. In contrast, IEC standards require establishing the relationships in design basis in consideration of '*lines of defence,*' which is equivalent to a '*defense-in-depth*' architecture.

(2) Despite the categorizations provided in 10 CFR 50.69 (RISC-1 through RISC-4), the IEEE standards address a single system classification ("protection" in IEEE 279 or "safety" in IEEE 603). This leaves other classifications (and equipment that may be of safety significance, but not designated as a "safety" system) unaddressed. This also may overemphasize safety systems of low safety significance. As such, use of the current standards does not necessarily reflect an accurate measurement of a system's or component's safety significance within the overall context of plant safety. In contrast, IEC standards provide more and different classifications of systems and components that result in a better-defined graded approach to the level of rigor applied in their design. The IEC classifications are based on systems' or components' role(s) and any interdependencies within and among '*lines of defense.*' This provides a somewhat improved measure of safety significance within the overall context of plant safety. The level of rigor applied in design is based on the classification.

3) The IEEE standards do not establish specific quantitative criteria for functional reliability —even for "safety" systems. The IEEE standards instead allow for reliability goals and contain features that individual I&C safety systems must provide or

requirements they must meet (e.g., minimum redundancy, single-failure criteria, manual system actuation, independence between redundant portions of a safety system, diverse protection functions, quality, and equipment qualification). These requirements are intended to yield sufficient functional reliability for safety systems. In contrast, IEC standards establish quantitative criteria for functional reliability based on the classification, absent similar prescriptive requirements.

The success of non-IEEE standards for DI&C in foreign nuclear markets and nonnuclear industries supports transforming the NRC regulatory structure to enable use of these standards, which, in turn, will provide greater flexibility for DI&C to licensees, applicants, and vendors.

The development of a rule based on the ANPR effort and associated regulatory guidance would establish high-level performance-based I&C safety design principles, and include a revision to 10 CFR 50.55a(h). In doing so, IEEE 603, as well as alternative standards and methods, could be used to meet the resulting regulations. In the development of the new regulatory guide for use with the proposed new rule, staff may elect to subsume or otherwise supersede other regulatory guidance (e.g., RGs 1.105, 1.152, 1.153 and portions of 1.168). This recommendation would remove a barrier to incorporating DI&C in U.S. safety systems.

The staff's recommendation on identifying which additional DI&C, including software, development standards are acceptable and leveraging third-party certifications would include the creation of guidance to determine which alternative DI&C development standards and third-party certification approaches are acceptable.

The recommendations would be accompanied by a transition of the lead role for review of the quality assurance aspects of DI&C development, including software, to quality assurance vendor inspection staff through revisions to staff guidance, while retaining the review of the digital design, including software with the instrumentation and control staff. In general, the quality assurance vendor inspection staff would make determinations about the adequacy of quality assurance programs for the DI&C development processes and ensure compliance making use of licensing reviews, audit(s), or inspection(s) as appropriate for the DI&C activity and plant licensing basis. Subsequently, the quality assurance vendor inspection organization would provide oversight of quality assurance consistent with its standard practices, including support by the I&C technical staff, as needed. These recommendations build on the progress already being made under the DI&C Integrated Action Plan and are consistent with the intended outcomes of Modernization Plans #3 and #4. These activities would leverage industry support in a coordinated development of associated guidance. In the development of the new regulatory guidance, staff may elect to subsume or otherwise supersede portions of RG 1.168 and RGs 1.169 – 1.173 with a single regulatory guide that provides criteria for technology-specific acceptable methods and references standards acceptable for use in meeting the criteria (as needed). This guidance would also establish the process by which third party reviews (or other certifications) of vendor quality could be credited towards safety determinations.

The success of these recommendations depends on developing and sustaining a transformational culture. These recommendations, coupled with the recommendation for a Strategy To Transform the Agency Licensing Review Process, the proposed revisions to 10 CFR 50.59, and the staff's activities under the DI&C Action Plan, would result in a transformation in the agency's approach to DI&C reviews. The agency will establish a core team with clear decisionmaking authority as a means to facilitate these DI&C initiatives in the timeliest fashion.