



A FRAMEWORK FOR
**REGULATORY
TRANSFORMATION**



MARCH 2018

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1 PURPOSE

The U.S. nuclear industry's safety record is exemplary and a model for the nuclear industry worldwide. For years, NRC regulation had served to support this global leadership. However, recent changes in technology, understanding of risks and margins, and improvements in licensee performance have created a landscape where new regulatory approaches are needed to maintain NRC effectiveness. These new approaches must achieve change beyond an incremental evolution to enable the modernization of the U.S. nuclear industry. Transformation is needed now in how NRC conducts its regulatory activities.

This document provides recommendations for key elements of the vision for a transformed NRC, along with an initial set of actions to achieve the needed change in a timely, effective and sustained manner. These recommendations build on the NRC's Principles of Good Regulation – independence, openness, efficiency, clarity, and reliability – complementing them with additional attributes to position the NRC to be effective when facing current and future changing needs and priorities.

2 THE NEED FOR TRANSFORMATION

From its inception, the NRC has been predominantly focused on driving safety through deterministic, prescriptive regulation while licensees (nuclear utilities) absorbed the costs of compliance. In the more than 40 years since the NRC was formed, both the industry's and NRC's understanding of risk have matured and the shared focus on risk-significant operations and structures, systems and components (SSCs) have increased. Additionally, plant performance has dramatically improved, as indicated by key performance indicators.

Nuclear power plant operational excellence and efficiency are hallmarks of the U.S. industry. New technologies create opportunities not only to modernize the nuclear power industry and regulatory oversight, but also to improve safety. These technologies include digital instrumentation and controls (I&C), accident tolerant fuel (ATF), drones, sensors, artificial intelligence, advanced reactors and many more.

Licensees and others in the nuclear industry have been working aggressively to apply each of these technologies. The NRC, however, is not moving at the same pace. The NRC's inability to efficiently regulate when it comes to the use of innovative technologies is a key barrier to implementation, and slows efforts to improve safety. The failure to implement widespread digital I&C in nuclear power plants exemplifies how regulatory stagnation creates a barrier in applying modern technology that would otherwise enhance safety and improve performance.

Additionally, the implementation of the NRC Reactor Oversight Process (ROP) is not functioning as intended. Licensees are expending considerable resources to address

findings that have very low significance, or none at all. Potential findings that approach ROP-significance thresholds trigger expensive debates over small numbers, rather than drive improved performance. The application of licensee resources to support the ROP is out of sync with the intended outcomes to drive performance improvement, and the associated costs draw resources and attention away from more safety-significant aspects of operation. If the U.S. is to continue as a leader in nuclear energy, the ROP must become more adaptable and more safety-benefit-focused.

The rigidity and unpredictability of the existing regulatory framework is driving the next generation of nuclear entrepreneurs to set its sights abroad to build new nuclear reactors. The U.S. stands to lose more valuable infrastructure and energy security assets, and our role as the global leader in nuclear energy is being threatened.

There is an urgent need for change and this change cannot happen without transforming the regulatory framework and initiating the necessary changes in both NRC and industry behavior. Transformation is an opportunity to increase the effectiveness of the NRC as a regulator, enable modernization of the industry, increase overall levels of safety, and achieve those outcomes more efficiently for both the NRC and licensees.

This transformation should aim to achieve an organizational culture change throughout the NRC, and as a result a regulatory framework that is:

- **Risk-Informed** – Identification and prioritization of all work and the decisions on what work is performed are driven by risk and significance considerations. Once a decision is made to perform work, the acceptance criteria and needed rigor for assessing reasonable assurance of adequate protection are informed by the associated risks, uncertainties and margins.
- **Agile** – Achieving high levels of performance drive the NRC's regulatory focus. Regulatory behaviors and processes adapt to align with the needs and priorities of a changing landscape.
- **Innovative** – The inherent safety benefit of innovation is embraced to ensure the best available technology is implemented.
- **Predictable** – Schedule and budget estimates are reasonable and adhered to while ensuring decisions are safe, effective and consistent.
- **Anticipatory** – Research and preparation are performed in advance to ensure that regulatory framework changes – whether driven by technology or process – are appropriately anticipated.
- **Results Driven** – Achieving desired outcomes is the primary objective. Decision-making is timely, even where precedent may be unclear. Novelty does

not impede problem-solving or prevent improvement. The regulatory framework enables licensees to improve their performance and safety margins.

It is critical for the NRC leadership to fully support the timely implementation of transformation. This support should include a policy statement supporting the program goals, applying the needed prioritization, and providing the appropriate resources. The policy statement should re-emphasize the Principles of Good Regulation and clearly describe the desired complementary elements of a transformed organization.

3 VISION OF A TRANSFORMED NRC AND REGULATORY FRAMEWORK

The current regulatory framework was established decades ago, long before modern technologies were envisioned. The U.S. nuclear industry, including the NRC, now has more than 50 calendar years (and more than 3,000 reactor-years) of operating and regulatory experience. This experience forms the foundation of improved understanding of the risks, challenges, and strengths of existing nuclear power plant operation under NRC oversight. Recent experience also highlights the areas where the regulatory framework should be transformed to improve effectiveness.

Although the current framework may have been effective in maintaining safety, today it is cumbersome and exceeds the original regulatory mandate. As a result, the framework is not suited for the current industry challenges nor does it capture the opportunities available to improve operational excellence and regulatory excellence, and achieve even greater levels of safety.

To fully embrace the benefits of a new framework, transformation of the NRC must be wide and deep. The transformation will need to touch all aspects of its regulatory oversight approaches and processes. This vision of a transformed NRC regulatory framework incorporates an enhanced regulatory safety focus that recognizes and balances the accountability of both the NRC and licensees in regulatory decision-making.

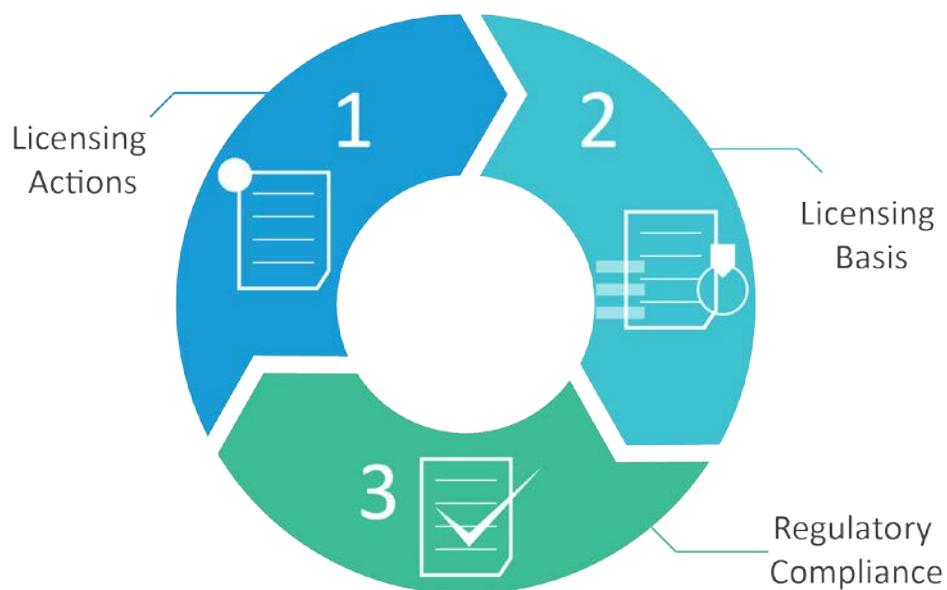


Figure 3-1: Continuum of Regulatory Oversight

A successful transformation will establish a regulatory framework that not only has the needed culture elements, but importantly provides the following features:

- **An Agile Licensing Process** – New technology will require the NRC to become more agile, open to adapting processes to align with technology, focusing reviews and approvals on areas of true safety significance, as well as ensuring that the determination of reasonable assurance is commensurate with the inherent risks and margins, and makes use of all information to resolve areas of uncertainty.
- **Risk-Informed Compliance** – A paradigm shift is needed in how the NRC handles compliance. A refreshed ROP will focus NRC and licensee resources on risk-significant issues. Items with little to no safety significance will be dispositioned routinely without draining NRC and licensee resources or distracting from higher-safety value activities. The inspection program needs to reflect the benefits of new technology, efficiently focus resources on risk-significant issues, and be adaptable to new and smaller reactor sites. The responsibility to operate safely will be clearly on the licensee with NRC oversight rather than NRC direct engagement.
- **Path to Modernizing Plant Licensing Basis** – Adoption of new technology will challenge underlying assumptions of the original plant licensing basis. The regulatory framework will need to be more outcome-based, more flexible, and less prescriptive. Proper maintenance of the licensing basis will be the responsibility of the licensee with NRC oversight. NRC approval of changes will only be required for areas of high safety significance and clear instances of introducing new threats with potentially high safety significance. This increased agility in modernizing the licensing basis is critical to adopting new and advanced technology and embracing its benefits.

4 ACHIEVING TRANSFORMATION

The previous section describes the vision for a transformed NRC and regulatory framework. Achieving this transformation will only occur through the disciplined application of tools coupled with engaged and effective leadership. Specific and actionable objectives are critical to facilitate and guide the change process as well as to create a force that sustains the change effort.

The following sections describe four recommended primary objectives, along with initial actions for each objective. When properly implemented and realized, these objectives should drive and empower transformational change at the NRC.

- **Objective 1:** Early use of risk insights in regulatory decision-making processes, related regulatory changes, and reviews to focus the scope, level of detail of reviews, and resources.
- **Objective 2:** Development of a results-driven, efficient, and predictable framework to determine reasonable assurance of adequate protection in the context of the current understanding of safety margin. This framework should leverage operating experience, accept capabilities of external organizations, and allow pathways to licensing that enhance regulatory certainty along the way.
- **Objective 3:** A transformed ROP program that better focuses resources on issues with risk and safety significance, leading to timelier decision-making that evaluates available and relevant information.
- **Objective 4:** Flexibility in the regulatory framework to allow alternative ways to achieve safety goals, and embracing new approaches, methods, and technologies that help meet safety regulations.

Pursuing these objectives provides parallel benefits of improving and strengthening NRC processes and regulatory framework, as well as serving as tools to facilitate the needed change in NRC culture. Together, these benefits will enable a modernized approach to safety and enhanced licensee performance.

While most of the specific recommendations provided for each of these four objectives relate to reactor safety, this framework for transformation is equally applicable to other nuclear activities regulated by the NRC. By applying the same philosophies used to develop a graded regulatory approach – one that considers the inherently lower risks associated with these activities – the NRC can achieve equally significant improvements with respect to materials facilities, used fuel, and in other areas.

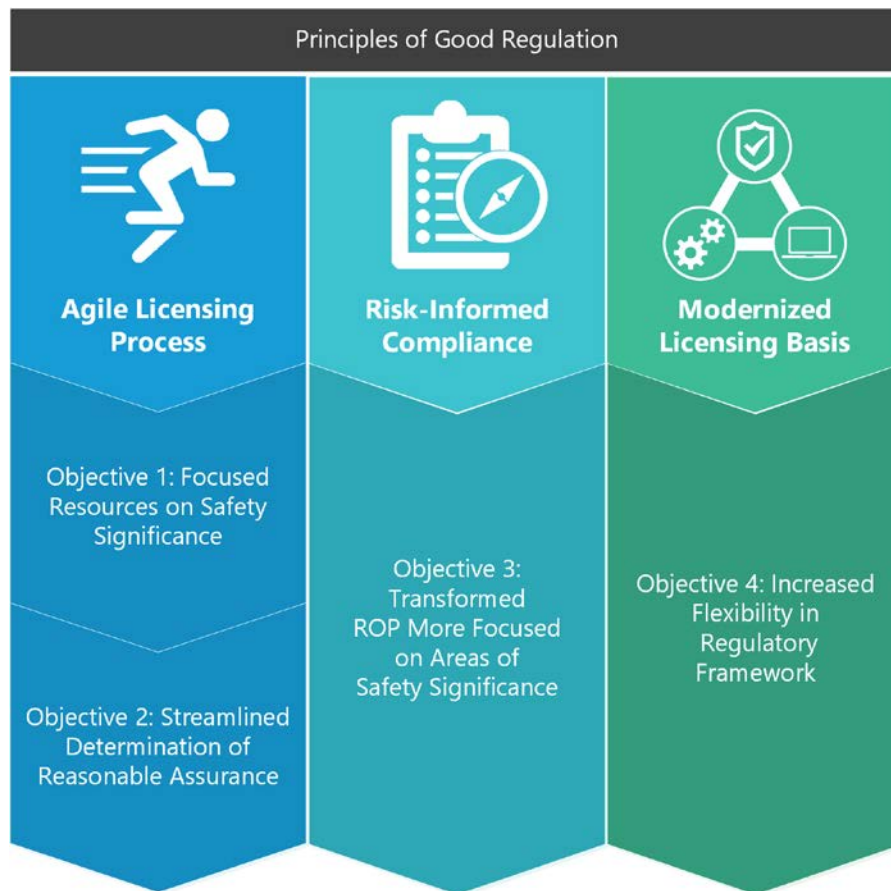


Figure 4-1: Framework for Regulatory Transformation

4.1 OBJECTIVE 1: RESOURCES FOCUSED ON AREAS OF SAFETY SIGNIFICANCE

The NRC’s Principles of Good Regulation seek to drive efficiency and clarity, stating that regulatory activities should be “consistent with the degree of risk reduction they achieve” and utilize options “which minimize the use of resources.” This value of efficiency should be ingrained using streamlined decision-making processes for licensing actions that integrate the best information available for the decision being sought. Therefore, all NRC decision-making processes related to licensing actions should be modified to incorporate steps early in the process to characterize and determine the significance of the safety issue being addressed. Minimal resources should be expended on issues that cannot be characterized as having an impact on safety or those determined to be of low risk significance.

Furthermore, NRC review resources should be applied commensurate with the safety significance of the elements and actions contained in a license amendment or application. Requests for Additional Information (RAIs) should be developed using the

same framework. Safety significance can be determined qualitatively or quantitatively incorporating appropriate risk insights. Regulators should also consider improvements in safety and risk that the licensing action would bring. This will result in more efficient scope for NRC reviews and an improved graded approach to the review process based on safety.

A risk-informed, safety-focused process should be employed early in all decision-making to allocate resources commensurate with the significance of the issue. In any process, the safety significance of the decision being evaluated should be characterized to determine the best path for addressing the issue. Whether risk insights are derived quantitatively through Probabilistic Risk Assessment (PRA) models or through qualitative approaches, decisions related to low safety-significant areas should be streamlined and resolved quickly.

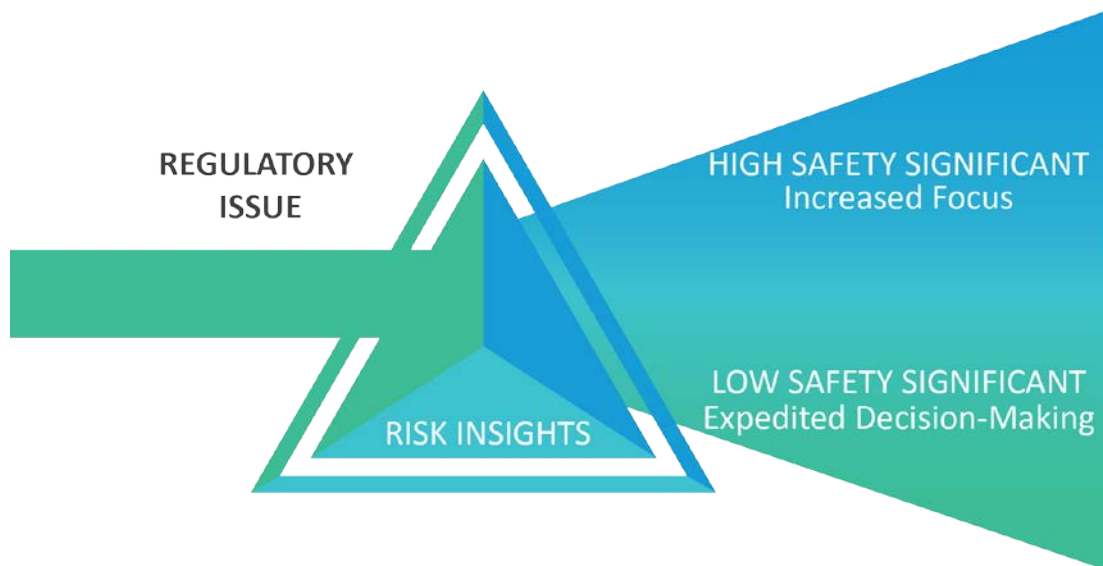


Figure 4-2: Use of Risk Insights to Improve Safety Focus

The existing Action Plan for Risk-Informed Decision Making and SECY-17-0112 “Plans for Increasing Staff Capabilities to Use Risk Information in Decision-making Activities” espouse many of the elements needed to transition toward a risk-informed, safety-focused process. Development of an enhanced framework and tools to implement this philosophy would help accelerate the transition across the entire NRC organization.

Below are some specific areas that the agency should address on a priority basis.

- **Risk-Informed Decision Making Tool or Process** – The development of a tool that incorporates key design, operation, and application insights to determine the appropriate level of review would help provide consistency and transparency. Existing fleet regulatory change and review processes should use this tool to follow a risk-informed and safety-focused framework. For example, the review of new fuel concepts should be based on the risk associated with the proposed concept. The overall safety significance of the issue should be determined early. Low safety significance changes should follow a streamlined process. Review resources, audits, and RAIs should also be applied consistent with the safety significance of each element of the application. The amount of time the NRC deliberates should be commensurate with the safety significance of a decision. The industry should also use this tool to ensure that the proper level of information is provided to the NRC for any regulatory decision.
- **Regulatory Certainty in 10 CFR 50.59 for Digital Upgrades** – The 10 CFR 50.59 process is one vehicle that can support this objective by determining what changes are required for review by the NRC. However, the current process is not applied consistently and changes such as digital I&C upgrades of systems with low safety significance are being subjected to excessively detailed reviews. The NRC should reevaluate the implementation of this process and clarify what is required. The 50.59 process should require NRC approval only for changes of high safety significance, such as the complete replacement of an analog Reactor Protection System (RPS) or Engineered Safety Features Actuation System (ESFAS) with digital platforms. No other changes, including digital-to-digital upgrades of RPS and ESFAS, should require NRC review.
- **Adaptable Review Process for New Reactor Designs** – For SMRs and advanced reactors, the Standard Review Plan (SRP) is applied to guide the NRC approval of applications such as the design certification. However, the SRP was designed for large light water reactors and many portions do not apply to SMRs and Advanced Reactors. Additionally, the Design-Specific Review Standard (DSRS) is also not a process that is working effectively. Therefore, the SRP should be replaced with high-level guiding principles for conducting safety reviews that are technology neutral. This new approach should identify key aspects of the design based on safety that should be included in the new reactor application prior to the submittal. Areas of the design that do not contribute significantly to a safety function need not be described or reviewed in detail. A more structured approach to pre-application activities should be developed to reduce regulatory uncertainty by providing more formal feedback to designers of the acceptability of their approaches. New reactor application reviews should consistently apply a safety focused approach where the level of detail, resources, audits and RAIs, are utilized to tailor the review based on safety significance.

- **Modernize Conflict Resolution Processes** – The NRC’s differing professional opinion (DPO) and non-concurrence processes are important to ensure staff safety concerns are raised and addressed appropriately. However, these concerns are not always addressed efficiently and licensing decisions are either significantly delayed or the desire to avoid DPOs drive decision-making. The NRC should look to address issues in the context of the safety significance of the issue being challenged and determine a more streamlined path of addressing issues of low safety significance.

4.2 OBJECTIVE 2: STREAMLINED DETERMINATION OF REASONABLE ASSURANCE

A consistent agency-wide understanding is needed of reasonable assurance of adequate protection established in the context of the current understanding of safety margins. This would underscore the efficiency aspects of the Principles of Good Regulation to drive results. NRC's own analyses have shown that the margin to the NRC's Quantitative Health Objectives (QHOs) is much greater than it was when the QHOs were established. The NRC should use this understanding of substantial existing margin to the QHOs in determining reasonable assurance of adequate protection. Specifically, the NRC should analyze reasonable assurance of adequate protection at a functional level, rather than at the issue or component level. Additionally, the level of detail and confidence required in licensing approvals should reflect the existence of this safety margin.

In addition to efficiency and clarity, the Principles of Good Regulation emphasize the importance of open lines of communication, fair and prompt decision-making, and independence. However, it clearly states that independence does not imply isolation. The agency should use relevant nuclear and non-nuclear operating experience to speed the adoption of advanced technologies. The NRC should also establish confidence in qualified external organizations in order to credit their capabilities, research, and any codes and standards. Using this approach will limit detailed reviews in determining reasonable assurance thereby reducing the amount it relies on NRC developed research.

This objective should be applied across the NRC organization. Below are specific areas that the agency should address.

- **Recognize External Standards and Operating Experience** – The use of digital components is not unique to the nuclear industry. Airlines, hospitals and the military have used digital for over 20 years in critical applications, yet the NRC is very prescriptive in regulating this technology. There is great safety benefit to be gained: digitalization can aid diagnostics, eliminate testing, and reduce maintenance needs. NRC reviews of digital upgrades should credit the digital operating experience of both non-nuclear industries and the international nuclear industry. The industry should be able to adopt consensus codes and standards to establish reasonable assurance without the need for detailed NRC reviews. Instead of prescriptive requirements, higher-level criteria should be established for the use of digital technology. These criteria would allow added flexibility for licensees to adopt more advanced technology without the need to go through an unnecessary detailed review. The current state of NRC digital regulation is delaying the application of digital technologies in the operating fleet thereby preventing improvements in safety and efficiency.

- **Leverage Capabilities of Other Research Organizations** – The Department of Energy (DOE) has many modeling and simulation (M&S) capabilities that can provide the necessary NRC confidence in the industry analysis in support of NRC reviews. In the area of Accident Tolerant Fuel (ATF), the NRC should rely on these DOE M&S capabilities to review the proposed ATF designs instead of developing those M&S capabilities within the agency. The improved reliability of these advanced capabilities can also reduce the dependence on time-consuming physical testing to validate results. This will reduce redundant efforts as well as shorten the time to approve the ATF designs.
- **Reduce the time required for NRC environmental licensing reviews** – The NRC staff should take steps to ensure that draft and final Environmental Assessments and Environmental Impact Statements prepared by NRC staff or NRC contractors are completed in less time with no adverse effects on the National Environmental Policy Act (NEPA) process. Also, discontinue the detailed adjudication of NEPA-based and other environmental contentions in NRC licensing hearings.
- **Revise Burnup and Enrichment Limits** – Revision of burnup and enrichment limits should be considered to maximize the efficiency of the nuclear fuel and flexibility in cycle planning. This would enable increased innovation in fuel technologies. The benefits support advanced reactor development and are complementary to ATF's benefits.
- **Establish Confidence in PRA Consensus Methods** – Decisions that require the use of Probabilistic Risk Assessment (PRA) benefit from the insights of realistic models. The NRC should rely on consensus methods, per existing regulatory guidance, and eliminate duplicative prescriptive requirements or detailed reviews of methods. Increased reliance on the NRC-endorsed industry peer review process to provide an independent assessment and review to the NRC-endorsed PRA Standard should be established to streamline the use of PRA information or insights in regulatory decision-making.

4.3 OBJECTIVE 3: TRANSFORMED REACTOR OVERSIGHT PROCESS

Introduction of new technology into nuclear power plant operations will influence how licensees and the NRC approach compliance. The reactor oversight process will need to evolve and become more efficient in utilizing new technology to collect operating data. A more effective inspection program will allow the NRC to better focus resources and understand safety improvements provided by new technology and advanced designs. Consistent with the current understanding of the margin of safety discussed above, the NRC should restructure the inspection and ROP to better focus on safety-significant issues and integrate additional data provided by the use of digital equipment as well as remote monitoring programs. Setting the ROP on a foundation better focused on risk

and safety significance will support the program to be more adaptable and scalable for future nuclear facilities with substantially different designs. In the long-term, the ROP must be commensurate with the safety significance of the attributes of specific reactor designs including the size of reactor modules.

This philosophy should be applied across the NRC. Below are specific areas that the agency should address.

- **Eliminate White Findings** – Findings should be focused on risk significant issues. For example, the white ROP threshold should be eliminated so that only green, yellow and red findings are issued. This will eliminate a very large amount of low-value work by the NRC and the licensees in evaluating low-risk white issues. A common unintended consequence of a white finding is the significant expenditure of NRC and industry resources that do not result in a corresponding safety benefit.
- **Development of a Risk-Informed Compliance Process** – The NRC inspection program should become more fully risk-informed so that inspections are focused on risk significant licensee activities. Compliance issues can be evaluated using a licensed risk tool or process such that low risk issues may be simply corrected without additional regulatory burden and accepted into the licensing bases of the plant without need for further consideration as a “delta” from the regulatory basis. A similar approach is being pursued to address tornado missile compliance issues. As the industry implements 10 CFR 50.69, the risk-informed safety class of SSCs should also be integrated into this framework to reduce inspection resources on components determined to be of low safety significance.
- **Eliminate the Use of SPAR Models** – The NRC should rely on more realistic licensee models to determine the significance of any deficiencies. The Standardized Plant Analysis Risk (SPAR) models should be phased out. Instead, assumptions associated with the representation of a performance deficiency should be determined and discussed with the licensee prior to conducting the analysis.

4.4 OBJECTIVE 4: FLEXIBILITY IN REGULATORY FRAMEWORK

Transformative technologies must be fully integrated into the overall approach to determining reasonable assurance of adequate protection. Transformative technology could come in the form of new reactor designs and new fuel technologies that further increase safety margin and mitigate the impacts from a wide range of events. The regulatory framework should provide reasonable assurance against unacceptable consequences while achieving real reductions in regulatory burden through recognition of the capabilities of these technologies.

The licensing bases for existing plants were developed considering the technology of the time. Though modified often, they were never truly modernized. Fully embracing the advantages of new technology into nuclear operations and the regulatory framework will require added flexibility in the licensing basis. These advancements will require shifts in currently accepted methods of meeting regulations and safety goals. In some cases these shifts will require changes to the regulatory requirements or policy; however many hurdles may be resolved through guidance or general acceptance by the staff.

Technologies such as Accident Tolerant Fuels (ATF) and advanced non-LWRs will affect large portions of the licensing basis, including security, and emergency preparedness (EP). Traditional systems, such as safety-related electrical systems may not be needed. Progress is being made in some of these areas for advanced and small modular reactors, however less progress is being made for the existing fleet. Flexibility in security and EP is necessary to implement and credit advancements such as measures incorporating drone technology and remote weapons.

NRC's current cybersecurity approach will impede increased use of digital components because it is not risk-informed and does not distinguish the safety significance of components.

This objective should be applied across the NRC organization. Below are specific areas that the agency should address.

- **Expedite Security and EP Rulemaking for New Reactors** – Security and EP regulations for transformative technologies should be changed to be consequence-oriented, technology-inclusive, and performance-based. The associated guidance should allow applicants and licensees to use technology-specific risk-informed insights to identify means for meeting regulatory requirements. The NRC has adopted this approach to update EP regulations for transformative technologies (see the “Regulatory Basis for Rulemaking for Emergency Preparedness for Small Modular Reactors and Other New Technologies” (NRC-2015-0225)) and a similar effort to modernize security-related regulations for new reactors should be expedited.
- **Shift Security Basis to Prevention of Large Early Release** – For the current fleet of reactors, there are additional opportunities to transform security regulations including basing the design of physical protection programs on the prevention of large early releases instead of core damage.
- **Enable States to Work Directly with the NRC on EP Plans** – Allow states to certify directly to the NRC that offsite emergency plans will direct adequate protective measures, can be implemented by the relevant agencies, and were developed in coordination with the nuclear power plant licensee.

- **Integration of New Technology into Compliance** – Greater NRC acceptance of new technologies to achieve regulatory compliance with existing requirements is needed. For example, a licensee should be able to use a Firearms Training Simulator to meet some shooting range training requirements or use remote operated weapons to protect the facility.
- **Modernize Surveillance and Code Requirements with Technology** – Plants are collecting and analyzing data in the same way that other industries (such as airlines) have done, to anticipate equipment issues and allow repairs before the problems become consequential. Regulations and licensing bases should be modified to allow these more advanced approaches to replace older deterministic regulations.
- **Risk-Informed Cybersecurity** – Cybersecurity regulations and guidance should be more risk-informed and focus on the safety significance of the component when determining if it is a critical digital asset (CDA), and how to protect it.
- **Improving Safety by Risk-Informing Shutdown Actions** – A risk-informed approach is needed to address Shutdown Action Statements. The current approach could force one or more nuclear units on a site to prematurely shut down when not warranted by the safety significance, creating the potential for unintended consequences. An increased window of opportunity to evaluate or correct conditions may improve safety.

5 CONCLUSION

The nuclear industry is in a state of transition between what has worked in the past and what will be needed for the industry to move forward. Successful innovative industries are never frozen or isolated. They absorb and incorporate new materials, techniques and discoveries from the world around them. Therefore, the regulations that govern the U.S. nuclear industry should adapt at a rate that allows for technological advances.

The status quo is not acceptable and many outdated regulatory methods need to be updated, as they impede industry advancement. The NRC has recognized this in their initiation of innovative and transformative efforts, but the outcome and the timing are what matter most. Nuclear power is an important industry, and whether it continues to supply the majority of emissions-free electricity, and provides clean, safe, secure and economic energy to the American people, or instead fades into a distant memory, depends in large part on the industry's ability to re-invent itself, and modernize equipment, materials and processes.

NEI looks forward to working with the NRC on the changes discussed in this report that will allow the U.S. nuclear industry to benefit from technologies that advance both efficiency and safety.



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