DRAFT

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Rev 1

Industry Paper on the Commission's Proposed Initiative for Improving Nuclear Safety and Regulatory Efficiency – Phase 2, Addressing Cumulative Impact through Generic Prioritization and Plant-Level Integrated Schedules

Executive Summary

Power reactors and fuel cycle facilities have seen substantial regulatory workload expansion and inspection in recent years despite improvement in industry's compliance and safety record. This expansion has increased the importance for management and resources to be focused on safety significant actions. Specifically, industry sees a growing need for the development of processes such that:

- Regulatory and plant-identified actions are assessed, prioritized and scheduled commensurate with safety significance and cost effectiveness
- Plant and worker safety take precedence over administrative tasks.

In recognition of these needs, industry formed a senior working group to address cumulative impact of industry and regulatory actions. The working group recommended the development of processes for the prioritization of existing and new generic issues and the implementation of integrated plant-specific schedules.

The purpose of this paper is to describe industry's plan to develop an approach to prioritize regulatory and plant-identified actions and schedule plant improvements at licensee facilities consistent with safety significance. The initial activities will focus on power reactors. Fuel cycle facilities and material licensees will monitor and adjust the process, as necessary, based on lessons learned from the power reactor activities and the unique circumstances applicable to non-power reactor licensees.

Industry has systematically reviewed potential alternatives and is proposing a process for prioritization of regulatory and plant-identified actions and another process for integrated implementation scheduling (IIS). These processes build upon the best features of the Integrated Safety Assessment Program (ISAP) [1], the process details for scheduling in NSAC-90 [2], and the 1992 Commission policy statement on integrated scheduling [3]. The industry approach is generally consistent with SECY-12-0137 [4], "Implementation of the Cumulative Effects of Regulation Process Changes," as directed in the accompanying staff requirements memorandum, as well as COMGEA-12-0001/COMWDM-12-0002 [5], "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency." In addition, numerous other programs and processes were considered.

Industry's approach would support generic and plant-specific prioritization that focuses on items of greatest safety importance and cost effectiveness. Industry is proposing a *phased approach*. Adoption of a phased approach to implementing the proposed initiative has the potential for incentivizing industry to develop more complete probabilistic risk assessment (PRA) models. Phase 1 is existing risk-informed activities that have been completed or are in progress.

Examples are seismic PRAs and the implementation of 10 CFR 50.48(c) NFPA 805, Alternate Fire Protection Rule. Phase 2 uses existing information and processes, adapted as appropriate, for the prioritization of issues in an efficient and effective manner. Phase 2 is the prioritization process outlined in this paper. Phase 3 would include a broader scope of Level 1 and Level 2 PRA models that would enable the NRC and industry to seek additional safety benefits. However, the phases are not disconnected. If new PRA models or refinements in existing PRA models are appropriate to support prioritization of specific issues, such new or refined models would support a transition to Phase 3 prioritization of regulatory actions. In either case prioritizing issues/actions provides an opportunity to improve the understanding of the issue and further exercise the PRA models. Such activity provides additional opportunities to identify risk insights and react accordingly.

The prioritization process would consist of a similar set of *attributes* as considered in the ISAP program [6, 7], namely:

- Public safety (e.g., radiological and non-radiological hazards)
- Plant personnel safety (e.g., industrial and radiological)
- Plant economic performance (e.g., plant availability and efficiency)
- Personnel productivity
- External impacts (e.g., regulatory).

The approach would be *risk-informed*, not risk-based. Thus, it would make use to the extent practicable of risk insights from existing information and processes, such as the Regulatory Oversight Process (ROP), and existing plant PRAs, along with considerations of defense in depth (DID) and margin of safety. The process would be flexible and adaptable to address the variability in items to be prioritized. It would make use of a front-end generic regulatory action ranking and prioritization, as well as a back-end plant-specific assessment. The prioritization process includes a reassessment, review and reconciliation module for issues that are outstanding for more than three outages or when circumstances change. The concept of a multi-disciplinary *Expert Panel* review akin to those employed by the Maintenance Rule (10 CFR 50.65) and 10 CFR 50.69 would be integrated into the process. An industry-sponsored guidance document endorsed by the NRC would be the vehicle for implementation.

There are two major elements to the overall prioritization process. These are:

1. Improvements to the existing regulatory process to better characterize the issue definition, success criteria, significance and priority of new regulatory activities as they are contemplated and developed. This process would include a periodic monitoring and feedback loop, such that new interpretations or issues that develop in the process of implementation are identified and treated with respect to the original problem statement, and, as appropriate, a new issue is identified. The intent of this process is to improve predictability, stability and timeliness of regulatory activities, and to ensure their significance, resource impacts, and schedules are within reasonable proximity to the original regulatory analysis. Figure 1 depicts this overall proposed process.

2. The review of existing regulatory activities by an expert team to determine their generic safety nexus, risk significance, degree of completion, costs, and other factors. This information would be used by plants to inform their plant specific analysis of priority, factoring in plant specific risk insights, external hazards, etc. A plant specific integrated schedule would be developed accordingly and implemented through a regulatory action, the nature of which is still under discussion. Figure 2 depicts this proposed process, and how it would integrate with the overall process described in Figure 1.

To be most effective, the prioritization process should address the full scope of outstanding regulatory actions. These include, for example:

- Fukushima regulatory response
- Current and future generic safety issues
- Rules and orders
- License conditions
- Generic communications
- 10 CFR 50.54(f) letters
- Regulatory Issue Summary (RIS)
- Implementation documents (regulatory guides, interim staff guidance)
- Plant modifications (regulatory and non-regulatory).

Additionally, changes to or issuance of other regulatory mechanisms can have large impacts, and the following vehicles are also recommended for evaluation:

- Proposed additions of scope to license amendment requests
- NRC "positions" expressed in meeting summaries and correspondence

The features of a process for the prioritization of actions and integrated implementation scheduling are discussed in this paper and will be addressed in developing guidance and piloting. At the basic level, the most desirable characteristics are:

- A structured, robust process
- Transparency
- Simplicity while remaining structured and robust

The process must be transparent and simple to understand, and cannot be excessively burdensome. *Transparency* means that the process to be used by each licensee, and the outcome of the prioritization, are openly available to all stakeholders, subject to security, proprietary and commercial constraints. The regulatory approval process for prioritization and plant-specific integrated schedules is being developed.

The level of detail in the assessment and the robustness of the results are key aspects of issue prioritization. A *progressive process* similar to NRC's phased approach to significance determination under the reactor oversight process (ROP) is under consideration. Checklists with supporting guidance are used to qualitatively assess the issue, although a more detailed qualitative or semi-quantitative evaluation also could be performed, as appropriate. If necessary, the assessment might consist of a number of quantitative analyses. The level of PRA model development that has been attained at most facilities is appropriate for the broad categorization of safety benefit and sequencing of activities. If necessary, additional or refined analyses can be conducted for specific issues.

Industry currently envisions the development of guidance documents and piloting beginning in the second half of calendar year 2013. The pilots are expected to be completed in 2014 with development of the final guidance documents for NRC endorsement by the end of 2014. Effective piloting of the process is essential for efficient industrywide implementation. As-you-go refinements to the process are an effective way to quickly capture the lessons learned. Effective communication between all stakeholders is crucial to the program's success and acceptance.

The remainder of this paper discusses:

- Background (previous and recent initiatives and activity on prioritization and scheduling)
- Existing or adapted processes which could be used to address prioritization
- Key characteristics of a successful process
- Industry proposal
- Challenges which must be addressed
- Concluding remarks and path forward

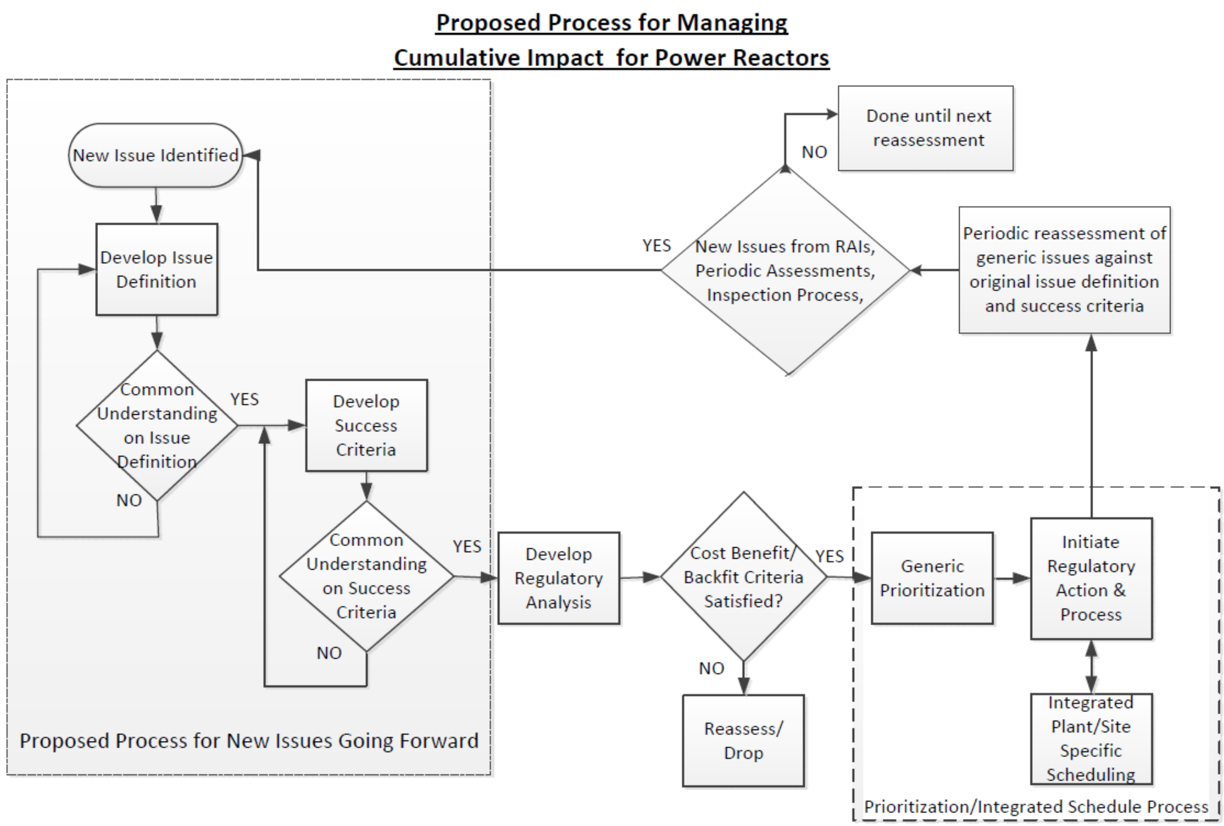

Figure 1 Industry's Proposed Process for Regulatory Issue Prioritization

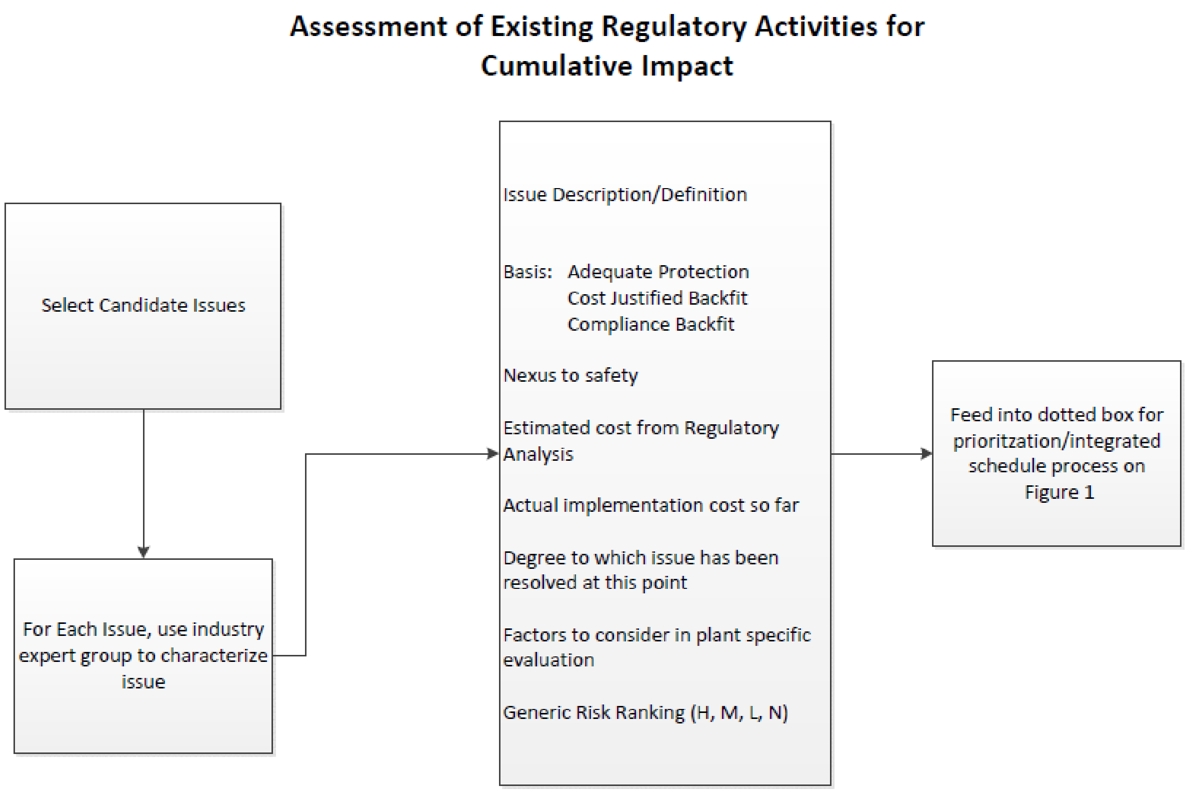

Figure 2 Assessment of Existing Regulatory Activities

1.0 Background

1.1 Early NRC and Industry Initiatives

In SECY-84-133, the NRC staff proposed, and the Commission approved with some conditions (July 16, 1984), a new program called the Integrated Safety Assessment Program (ISAP). The program was proposed to be undertaken in lieu of the previously proposed continuation of the Systematic Evaluation Program (SEP) and the conduct of the National Reliability Evaluation Program (NREP). ISAP was intended to provide improved effectiveness and efficiency to the implementation and resolution of licensing requirements for operating nuclear power plants. As noted in the Commission paper,

> "The benefits of conducting ISAP would be sound regulatory management of the licensing requirements for operating reactors on a plant-specific basis, assurance that the greatest measure of safety is accomplished in the near-term, and the most efficient use of both staff and licensee resources."

As envisioned by the staff, ISAP would:

- Improve safety
- Eliminate backlog
- Improve understanding of the plant
- Develop a living/integrated schedule
- Provide a framework for future decisions.

The staff had originally proposed that ISAP would be implemented as a trial program consisting of four plants, which would be conducted over a two-year period.

ISAP consisted of an integrated assessment of outstanding issues on a given plant, as shown schematically in Figure 3. At the time, these issues included:

a. All previously issued, unimplemented licensing actions for the (NUREG-0748) particular plant
b. All previously issued Three Mile Island (TMI) (NUREG-0737 and Supplement1) requirements for the particular plant yet to be implemented
c. The implementation of all resolved generic issues
d. The significant safety lessons-learned topics from SEP II
e. Unresolved Safety Issues and Generic Safety Issues, to the extent practical.

The issues to be evaluated in ISAP were to consider utility-sponsored plant improvements. The review process would ensure that the plant improvements would be considered as competing demands for outage time and resources in setting implementation priorities. This aspect was considered important by the staff because the licensees had often argued that their plant enhancements had equal or greater safety significance than some pending NRC requirements at the time.

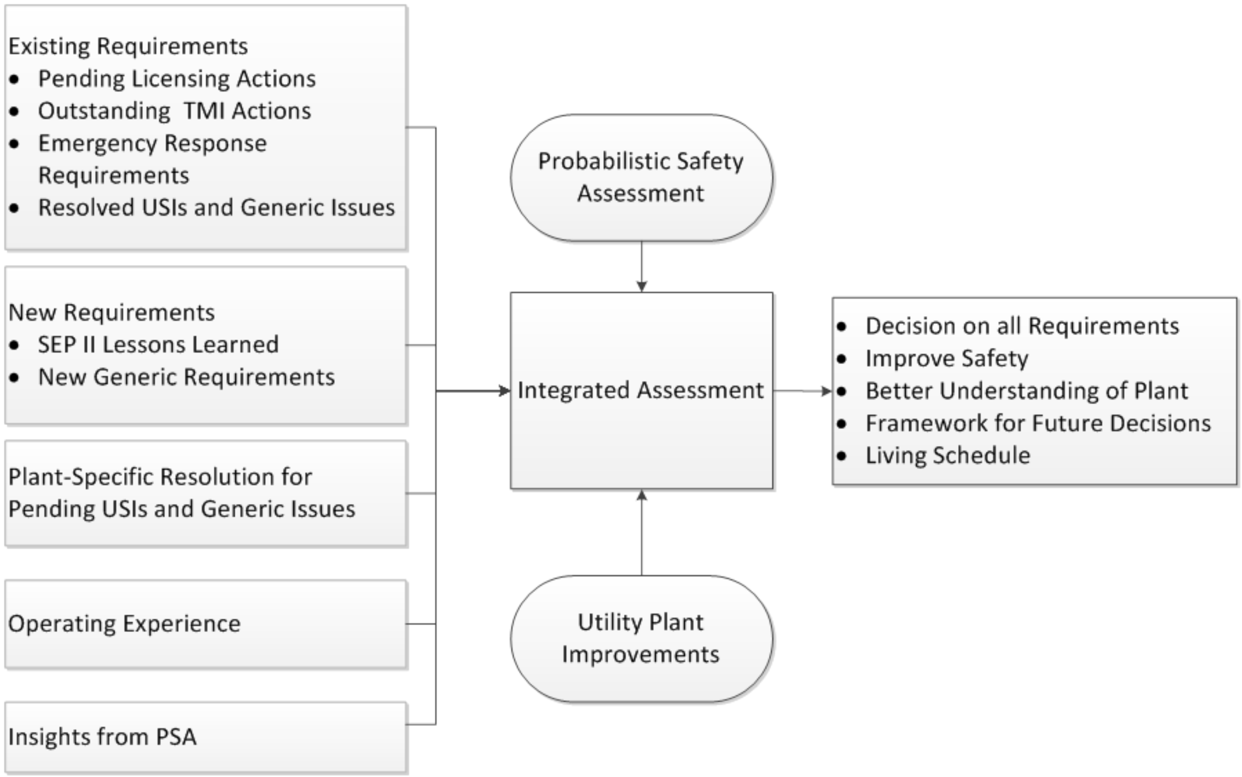

Figure 3 Integrated Safety Assessment Program [1]

An important aspect of the program was that prior to the start of an ISAP review, each licensee would have an opportunity to request deferral of specific, existing requirements as part of a screening review to establish the initial scope. During the conduct of the program, it would be appropriate to similarly defer implementation of certain new requirements to be addressed in the program. SECY-84-133 acknowledged that ISAP would likely cause some of the deferred NRC requirements to be modified or deleted on a plant-specific basis.

The integrated assessment would consider both deterministic findings and insights from a plant-specific probabilistic safety analysis (PSA), i.e., probabilistic risk assessment (PRA). The output of the program would be a plant-specific "living schedule." The terminology has since evolved to become better-known as Integrated Implementation Scheduling (IIS).

The staff implemented ISAP via the issuance of Generic Letter (GL) 85-07, "Implementation of Integrated Schedules for Plant Modifications," [8]. The original two pilots consisted of Millstone Unit 1 and the Haddam Neck Plant, as documented in draft NUREG-1184 and NUREG -1185, respectively [9, 10]. The publically available (non-proprietary) summaries of the ISAP methodology used in the two pilots are described in the licensee final report submittals [6, 7]. The five attributes considered in the project evaluations included:

- Public safety (e.g., radiological and non-radiological hazards)
- Plant personnel safety (e.g., industrial and radiological)

- Plant economic performance (e.g., plant availability and efficiency)
- Personnel productivity
- External impacts (e.g., regulatory)

The costs of proposed projects as well as the consideration of alternatives were important inputs into the evaluations.

About this time, the Electric Power Research Institute (EPRI) issued NSAC-90 [2] and NSAC-102 [11]. NSAC-90 identified procedures and techniques needed to carry out integrated scheduling programs, assessed programs available at the time, and identified enhancements to the process. The seven key process elements for implementing integrated scheduling that were identified include:

1. Attribute Definition: What is important to the utility management and owners in terms of plant design and operation?

2. Issue Management: What aspects of the design or operation raise concerns, and are the concerns of sufficient importance to define specific modifications to the plant?

3. Project Identification: How should the plant be modified to address previously stated concerns? What are the best alternatives?

4. Project Prioritization: What is most important to the plant owners/operators to achieve in terms of plant improvement?

5. Planning and Scheduling: When should (or can) the project be implemented?

6. Implementation: whereby the actual modifications to plant design or operation are carried out and documented.

7. Monitoring: whereby the actual impact of the project is tracked and relevant information is fed back to the integrated decision-making process.

The final policy statement on integrated schedules was published on September 23, 1992, and made effective on November 23, 1992 [3, 12]. The major elements of the policy statement include:

- A systematic process to identify activities
- A process for prioritization and a process for scheduling
- A plan for maintaining and updating schedules
- A provision for NRC to be informed of process and schedule information at periodic intervals
- A process for requesting schedular relief
- A process for evaluating licensee's maintenance of schedules.

The policy statement notes that the process for prioritization should account for factors such as safety, plant availability, radiation exposure, procurement requirements, and costs.

As described in the policy statement, licensees who volunteer are to develop an integrated schedule covering rules, orders, license conditions, Technical Specifications and amendments, licensee commitments of NRC actions, including generic communications (generic letters and bulletins). There would be a provision for a 90-day review by the NRC staff (negative consent by the NRC). For licensee and industry initiatives and licensee event report follow-up actions there would be no formal NRC review. According to the 1992 policy statement, if the schedule cannot be agreed upon by both parties and if the staff believes that a significant safety concern exists, the staff at any time could issue an order to implement such items. The staff can take this action whether or not a licensee has an integrated schedule. The licensee could request relief from implementing specific NRC items in level 2 that have not been implemented over a number of years because of their low safety significance. The licensee would need to obtain specific NRC approval for removal of these licensee commitments. The 90-day negative consent process would not apply.

1.2 More Recent Policy-Related Documents

In SECY-11-0032, the staff informed the Commission of plans to make enhancements to the NRC rulemaking process to enable explicit consideration of "cumulative effects of regulation" (CER) [13]. In the associated SRM, the Commission approved the staff's plan with several process changes, and the following two noteworthy actions:

1. The staff should consider whether the revised process should apply risk insights to prioritize regulatory actions and whether such a prioritization is practical and if so, how it might be pursued. The staff's review of this issue should be reflected in its cumulative effects of regulation strategy.

2. The staff's implementation of the cumulative effects of regulation should consider other regulatory instruments. The staff's office-specific procedures should be revised to include provisions to account for other regulatory actions (e.g. orders, generic communications, license amendment requests, and inspection findings of a generic nature) that may influence implementation dates for new rule requirements.

In COMGEA-12-0001/COMWDM-12-0002, the Commission approved an initiative to further explore the idea of enhancing safety by applying PRA to determine the risk significance of current and emerging reactor issues in an integrated manner and on a plant-specific basis [5]. Key aspects of the COM's proposal include the following substantive provisions:

- Allowing licensees to propose to the NRC a prioritization of the implementation of regulatory actions as an integrated set and in a way that reflects their risk significance on a plant-specific basis
- Requiring site-specific Level 1 and 2 PRAs, including natural hazards and plant modes as supported by NRC endorsed consensus standards
- Not impacting the schedules on Recommendation 1 of the Fukushima Near-Term Task Force and the Risk Management Task Force recommendations

- Exploring the use of a backstop to ensure that issues will be resolved and regulations implemented in a timely manner; licensee's implementation should not be perpetually deferred
- Prioritizing in a risk-informed manner, not risk-based. Other considerations, such as the need for sufficient defense in depth, should be a factor in any prioritization process, particularly for issues where probabilistic methods have not been sufficiently developed (e.g., for external flooding hazards).

In SECY-12-0137, the staff requested Commission approval on the staff actions to implement the Commission direction related to the CER process [4]. The paper built upon the staff's earlier proposals in SECY-11-0032. Specifically, SECY-12-0137 describes interactions with stakeholders throughout all stages of the rulemaking process, guidance publication, the common prioritization of rulemaking (CPR), the staff's consideration of applying risk insights to prioritize regulatory actions, the impact of CER implementation on other regulatory actions, and the staff's consideration of the need to quantify cumulative impacts of regulation. In addition, the paper addresses feedback from external stakeholders received at the May 2012 public meeting on CER.

The staff developed the following definition of CER:

> Cumulative Effects of Regulation describes the challenges that licensees, or other impacted entities (such as State partners), face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic letters, backfits, inspections). Cumulative Effects of Regulation is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a number of complex regulatory positions, programs or requirements within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). Cumulative Effects of Regulation can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security.

SECY-12-0137 stated that CER will not apply to administrative rules, direct final rules, interim final rules, design certification rules, consensus standards rules, and other similar types of rulemakings that will be identified in a pending revision to Management Directive (MD) 6.3, "The Rulemaking Process." While the staff does not routinely apply the CER process to other regulatory actions such as orders, generic communications, and inspections, it does apply the overall concepts of CER (e.g. providing early communication of guidance, conducting meetings with stakeholders, and coordinating schedule implementation). After some experience with CER in the rulemaking process, the staff could reevaluate CER for applications other than the rulemaking process.

In the associated SRM to SECY-12-0137 [4], the Commission approved the staff's proposed actions to implement the CER process enhancements as described in the Commission paper, subject to a number of comments. Of particular note are the following comments:

- Consider the broader context of COMGEA-12-0001/COMWDM-12-0002

- Implement outreach tools to consider overall impacts of multiple rules, orders, generic communications, advisories, and other regulatory actions; and to focus effectively on items of greatest safety import
- Obtain input from both reactor and non-reactor licensees; encourage Agreement State engagement
- Provide status report on lessons-learned within 2 years
- Seek volunteer facilities for “case studies.”

2.0 Consideration of Existing or Adapted Processes to Address Prioritization of Regulatory and Plant-Identified Actions

2.1 ISAP-like Process

In the ISAP-like methodology, a process for prioritization and a process for integrated implementation scheduling would be adapted from SECY-84-133 and NSAC-90. The prioritization process would consist of a similar set of attributes as considered in the original ISAP program [6, 7], namely:

- Public safety (e.g., radiological and non-radiological hazards)
- Plant personnel safety (e.g., industrial and radiological)
- Plant economic performance (e.g., plant availability and efficiency)
- Personnel productivity
- External impacts (e.g., regulatory)

The above set of attributes is not unique. Some would argue that these considerations have been factored implicitly or explicitly into scheduling of plant improvements at nuclear power plant sites for decades. What the original ISAP provided, however, was a structured process for ranking and prioritization, and a formal regulatory review and approval process.

Some aspects of the historic ISAP may or may not be applicable to the ISAP-like process that would be implemented under this option. For example, subjective weighting of each attribute used in the original ISAP adds complexity since it might involve a methodical process to solicit input from a significant number of decision-makers at the nuclear operating company. Moreover, such weightings reflect company-specific and even site-specific culture and values, and as such, there is the potential to have a wide range of variability in the program across the nuclear fleet. Likewise, the scoring of each attribute on a -10 to +10 scale, with some attributes rated linearly and other attributes rated logarithmically, adds modeling complexity. Careful considerations of these aspects would need to be evaluated before proceeding with this option.

Converting the scoring scale for each attribute to monetary values such as dollars per person-rem averted or the value of a saved workday of skilled crafts labor can be accomplished by simply updating readily available economic data. Again, more than 25 years after the implementation of ISAP, the use of objective conversion factors such as $2000 per person-rem averted (now under review by the NRC) is rather common place, e.g. severe accident mitigation alternatives (SAMA) for license renewals. Benefit-cost ratio or value-impact evaluations are common in almost any business enterprise, and are not unique to the nuclear utility or to ISAP. Likewise, the key elements of integrated scheduling can be easily adapted from ISAP, NSAC-90, or any of a number of similar processes.

2.2 Maintenance Rule-like Approach

The Maintenance Rule, 10 CFR 50.65, is a risk-informed and performance-based regulation applicable to commercially operating nuclear power reactors in the U.S. The NRC published 10 CFR 50.65 on July 10, 1991. As discussed in the Statements of Consideration for this rule, there is a clear link between effective maintenance and safety as it relates to such factors as the number of transients and challenges to safety systems and the associated need for operability, availability, and reliability of safety equipment. In addition, good maintenance is also important in ensuring that failure of other than safety-related structures, systems and components (SSCs) that could initiate or adversely affect a transient or accident is minimized. Minimizing challenges to safety systems is consistent with the NRC's defense-in-depth philosophy. Maintenance is also important to ensure that design assumptions and margins in the design basis are maintained and are not unacceptably degraded. Therefore, nuclear power plant maintenance is important to protecting public health and safety. Guidance is provided in Regulatory Guide (RG) 1.160 [14] and NUMARC 93-01 [15].

The Maintenance Rule and associated guidance were not developed for the purpose of prioritization of the broad range of regulatory actions considered in this paper. But there are several aspects within the guidance documents such as NUMARC 93-01 that provide a structured process for decision-making that are worthy of note. Establishing risk significance criteria by utilizing a multi-disciplinary panel of individuals experienced with the plant PRA and with operations and maintenance provides a structured framework that could be emulated. As noted in NUMARC 93-01,

> The use of an expert panel would compensate for the limitations of PRA implementation approaches resulting from the PRA structure (e.g., model assumptions, treatment of support systems, level of definition of cut sets, cut set truncation, shadowing effect of very large (high frequency) cut sets, and inclusion of repair or restoration of failed equipment) and limitations in the meanings of the [risk] importance measures.

While this feature of an expert panel is probably not sufficient by itself to meet all of the objectives for the prioritization of a broad set of regulatory actions, elements of this decision-making process could be factored into the framework and processes that are ultimately implemented.

2.3 Risk-informed SSC Categorization and Special Treatment-like Approach

10 CFR 50.69, or 50.69 for short, provides an alternative regulatory framework with respect to "special treatment," where special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that SSCs perform their design-basis functions. Under this framework, licensees using a risk-informed process for categorizing SSCs according to their safety significance can remove SSCs of low safety significance from the scope of certain

identified special treatment requirements. In addition the treatment of non-safety SSCs with high safety significance is considered. Industry guidance is provided in NEI 00-04 [16].

Similar to the above discussion on 50.65, the 50.69 framework was not developed with prioritization of the broad range of regulatory actions considered in this paper. But two aspects of the approach merit discussion:

- Defense-in-depth (DID) assessment
- Integrated Decision-making Panel

DID characterization is an integral part of the 50.69 rule. 50.69(c)(1)(iii) requires the SSC categorization process to maintain DID. In cases where the component is safety-related and found to be of low risk significance, it remains important to confirm that DID is preserved. The DID assessment includes consideration of the events mitigated, the functions performed, the other systems that support those functions and the complement of other plant capabilities that can be relied upon to prevent core damage and large, early release. The assessment of the adequacy of DID may be qualitative or quantitative in nature, and may use the concepts of diverse and redundant trains and systems in evaluating the level of DID.

The second important consideration regarding the 50.69 process is the regulatory requirement for the Integrated Decision-making Panel (IDP). The IDP is a multi-discipline panel of experts that reviews the results of the initial categorization and finalizes the categorization of the SSCs/functions. The IDP is required to be staffed with expert, plant- knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering. The purpose of the IDP is to ensure that the appropriate considerations from plant design and operating practices and experience are reflected in the categorization input. The IDP considers the safety significance of the SSCs based on:

- The PRA assessments and sensitivity studies,
- A defense-in-depth assessment from an operational perspective,
- Insights from other risk informed programs (e.g. risk-informed in-service inspection of piping), and
- Operational and maintenance experience.

Again, while these two features of maintaining DID and for the IDP review are not sufficient by themselves to meet all of the objectives for the prioritization of regulatory actions, elements of DID and this IDP review process could be factored into the framework that is ultimately implemented.

2.4 Backfit Rule and Regulatory Analysis

Though a “regulatory analysis” and “backfit analysis” are distinct processes, there is substantial overlap between the two, particularly with respect to how the benefits and costs of proposed regulatory actions that are believed to result in a substantial increase in overall safety (as opposed to those that are determined to be necessary for the adequate protection of the public health and safety) are estimated.

The Backfit Rule, or 10 CFR 50.109, sets forth the backfit-related regulatory requirements established by the NRC. Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after certain time frames. NUREG-1409 [17] provides guidance on implementation of the backfitting rule, with a particular focus on the identification of backfits. More detailed guidance on the performance of the cost-justified, substantial increase analysis required for backfits that are not imposed pursuant to one of the exceptions provided in Section 50.109 is found in NUREG/BR-0058, which is discussed below. The NRC uses these documents to guide its decisions on whether to issue new or revised regulatory requirements, generic correspondence, regulatory guidance, and staff positions to nuclear power reactor licensees.

Separate from, but related to NUREG-1409, NUREG/BR-0058 [18] provides guidance to NRC staff in conducting regulatory analyses of proposed regulatory actions that affect reactor and materials licensees. The guidance aids the staff and the Commission in determining whether the proposed actions are needed, in providing adequate justification for proposed actions, and in documenting the basis for recommending the proposed actions. The guidelines also provide guidance on estimating the quantitative and qualitative costs and benefits of a proposed regulatory action, and determining whether a proposed action will result in a substantial increase in the overall protection of the public health and safety or the common defense and security. In the event that the action being evaluated meets the definition of a backfit and is not covered by one of the exceptions to the backfit rule, the agency's regulatory analysis process is used to determine whether the action can meet the "cost-justified, substantial increase" test provided in section 50.109(a)(3). More generally, the guidelines in NUREG/BR-0058 establish a framework for (1) identifying the problem and associated objectives, (2) identifying alternatives for meeting the objectives, (3) analyzing the consequences of available alternatives, (4) selecting a preferred alternative, and (5) documenting the analysis in an organized and understandable format.

Value-impact evaluations are an integral part of backfitting and regulatory analysis. For example, the list of attributes considered in NUREG/BR-0058 includes:

- Reductions in public and occupational radiation exposure
- Enhancements to health, safety, or the natural environment
- Averted onsite impacts
- Averted offsite property damage
- Savings to licensees
- Savings to the NRC
- Savings to State, local, or tribal governments
- Improved plant availability
- Promotion of the efficient functioning of the economy
- Reductions in safeguards risks.

There are many aspects of both NUREG/BR-0058 and NUREG-1409 that could be incorporated into the prioritization framework to prioritize and implement potential changes addressed in this document.

2.5 Generic Safety Issue Prioritization

A generic issue (GI) is (1) a well-defined, discrete, technical or security issue, (2) the risk or safety significance of which can be adequately determined, and that (3) applies to two or more facilities or licensees and certificate holders or holders of other regulatory approvals (including design certification rules), (4) affects public health and safety, the common defense and security, or the environment, (5) is not already being processed under an existing program or process, (6) cannot be readily addressed through other regulatory programs and processes, existing regulations, policies, guidance, or voluntary industry initiatives, and (7) can be resolved by new or revised regulation, policy, or guidance or by voluntary industry initiatives. NRC staff or members of the public may propose a GI when issues are identified that indicate or suggest there might be weaknesses in NRC rules and regulations to ensure public health and safety and security for nuclear matters.

Under the Generic Issues Program (GIP), the resolution of these GIs is documented and tracked in NUREG-0933 [19]. In addition, the GIP tracks and reports the GI status and resolutions to Congress and the public. The resolution of these issues may involve new or revised rules, new or revised guidance, or revised interpretation of rules or guidance that affect nuclear power plant licensees, nuclear material certificate holders, or holders of other regulatory approvals. Congress requires that the NRC maintain this program.

After issuance of the Policy Statement on the resolution of generic issues in 1978, the NRC program to resolve generic issues underwent many reviews and changes. As a result, the Commission concluded in April 1989 that the 1978 Policy Statement no longer reflected the NRC's generic issues program and withdrew it from the public record. From 1983 to 1999, the generic issues program consisted of six separate and distinct steps: identification, prioritization, resolution, imposition, implementation, and verification. Although historic, it is interesting to note that the prioritization step assigned one of four priority rankings: HIGH, MEDIUM, LOW, and DROP. They were intended for use in guiding allocation of NRC resources and scheduling of efforts to resolve the various issues, in conjunction with other pertinent factors. The method of assigning priority rank involved two primary elements: (i) the estimated safety importance of the issue; and (ii) the estimated cost of developing and implementing a resolution. To the extent reasonably possible, quantitative estimates were made of the possible solutions to a generic safety issue (GSI) by calculating an Impact/Value Ratio that reflected the relation between the risk reduction value expected to be achieved and the associated cost impact. The total cost included both the cost of developing the generic solution, typically NRC cost, and the cost of implementing the possible solution at all affected plants, typically industry cost, including design, equipment, installation, test, operation, and maintenance. The priority ratio had the units of dollars per person-rem. While a full discussion of the historic GSI priority ranking scheme is beyond the scope of this paper, it is interesting to note by way of a reference point that for a reduction in core damage frequency (ΔCDF) greater than 10^{-4} per reactor-year, a HIGH priority was assigned on the basis of safety importance alone, regardless of other considerations, such as an initially estimated high cost, which might result in a low priority score.

2.6 SAMA/SAMDA

For license renewal, the provisions of 10 CFR 51.53(c)(3)(ii)(L) require that license renewal applicants consider alternatives to mitigate severe accidents if the staff has not previously evaluated SAMAs or severe accident mitigation design alternatives (SAMDAs) for the applicant's plant in an environmental impact statement (EIS) or related supplement or in an environmental assessment. The purpose of a SAMA/SAMDA is to ensure that plant changes with the potential for improving severe accident performance (i.e., reducing the risk or probability-weighted consequences) are identified and evaluated. SAMAs include SAMDAs, which are addressed for design certifications, but SAMAs also include changes in operating procedures and training. Section 5.4 of NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," provides background information on the genesis of the SAMA regulatory requirement [20]. The severe accident analysis for license renewal is prepared as a site-specific environmental impact statement supplement to NUREG-1437.

Potential benefits of a SAMDA/SAMA include averted public exposure; averted offsite property damage; averted onsite occupational exposure; and averted onsite costs, such as decontamination and replacement power. The costs and benefits of the SAMDA/SAMAs are compared to see whether any SAMDA/SAMA is cost beneficial. The NRC staff evaluates the applicant's benefit-cost comparison to determine whether it is consistent with the benefit-cost balance criteria and methodology given in, for example, NUREG/BR-0058.

2.7 Regulatory Oversight Process

The regulatory framework for reactor oversight, the ROP, is a risk-informed, tiered approach. There are three key strategic performance areas: reactor safety, radiation safety, and safeguards. A key part of this oversight is the Significance Determination Process (SDP) for inspection findings. This process is progressive, in that the process includes screening and qualitative evaluations as well as quantitative evaluations, if a quantitative evaluation is deemed appropriate. The quantitative evaluations can range from bounding to best estimate depending on the nature of the issue and the initial results of conservative evaluations.

Such a process is considered in this paper, as the assessment of significance is a key part of prioritization, and as a result of the considerable NRC and Industry ROP-SDP experience base.

3.0 Key Characteristics of a Process

From the experience base in Section 1 above and the discussion in Section 2, the desirable features of a process for the prioritization of regulatory actions and integrated implementation scheduling can be ascertained. At a high level, the most desirable characteristics are:

- A structured, robust process

- Transparency
- Simplicity while remaining structured and robust

A *structured, robust process* means that the steps needed to arrive at the desired goals, a prioritized ranking of regulatory actions and the schedule for implementation, are adequately described and effective. Each step in the process has a purpose and the necessary actions to be taken are defined. Guidance documents with templates, worked examples, and other tools are provided. The framework does not imply a one-size-fits-all procedure, since site-specific administrative procedures will vary across the reactor fleet. But the process should lend itself to effective use by experienced plant and regulator staffs, and build upon existing risk-informed processes such as the Maintenance Rule. The actions to be taken by licensees and regulator at each step along the way are provided. The who, what, when, where, and how of each step are described explicitly. A robust process also means that the guidance is sufficiently detailed to lead to substantially the same prioritization outcome if performed by different, capable personnel.

Transparency means that the process to be used by each licensee, and the outcome of the prioritization, are openly available to all stakeholders. As appropriate, the technical bases for the ranking results are on the docket in the public domain and can be readily downloaded from the NRC web site. It is acknowledged that in this era of open market competition between electrical generators, some aspects of the integrated scheduling may need to be kept proprietary. Otherwise, information on future outages, the length of the outages, perhaps outage schedule risk, and other commercial information would place the nuclear plant owners and operators at a competitive disadvantage. A second consideration would be with regard to plant security matters. These aspects will need to be further evaluated before proceeding with implementation of the IIS.

The desire for *simplicity* of the processes must be balanced with the need for effective evaluations (whereby ranking conclusions are robust). At one end of the spectrum, a licensee might convene a multi-disciplinary team who reviews the various regulatory and plant-initiated projects, ranks them, schedules each action, and provides the results for NRC review. A *negative consent* process would be simplest and most efficient, but not necessarily consistent with the objectives of *structure* and *transparency*. At the other extreme is a complex and resource-intensive prioritization and scheduling scheme, requiring multiple layers of review by both the licensee and regulator. Detailed PRA modeling and quantification, formal documentation of the basis for each ranking, and a detailed report by both the licensee and the regulator akin to those used in the original ISAP [6, 7] would demand large resources on the part of licensee and regulator. Multiply the resources for one plant by tens of participants in the program and such a complex process might not be beneficial or sustainable. Furthermore, such larger resources are not necessary given the nature of the risk-informed application – the prioritization of issues.

There are important considerations in addition to the key characteristics described above. Any issue, whether plant-initiated or regulatory-initiated, has a life cycle. The issue may initially be generic in nature, get ranked and prioritized, then progress to the nuclear plant level where ultimately the issue gets addressed and implemented by technical evaluations, a hardware modification, or changes to operating and administrative procedures. Implementation of the issue may not be a simple matter such as the one-time installation of an SSC.

The level of detail in the assessment and the robustness of the results are key aspects of issue prioritization. How much analysis is needed when a particular issue is ranked? Are checklists and templates sufficient? A progressive process similar to NRC's phased approach to significance determination under the reactor oversight process (ROP) would be most desirable. Checklists are first used to qualitatively screen the issue. If necessary, a more detailed qualitative or semi-quantitative evaluation using pre-quantified templates could be performed. Finally, the assessment might consist of quantitative analysis using the plant-specific PRA. The complexity of the issue will determine which approach is appropriate.

A process that uses or adapts existing approaches such as those described in Sections 1 and 2 would appear to be the most efficient path to implementation, and with the greatest likelihood of success. Rather than establishing a new prioritization process, supplementing or enhancing existing regulatory and industry programs that have proved successful appears to be the most rational way to proceed. There are over 25 years of experience using risk understanding for project prioritization and integrated scheduling in the industry to build upon.

Effective piloting of the process is essential. The upfront testing of the processes and guidance documents will have a many-fold return on the time and resources invested. As-you-go refinements to the process are an effective way to quickly capture the lessons learned. Effective communication between all stakeholders is crucial to the program's success and acceptance.

Consideration should be given to cumulative effect of the regulatory action on classes of licensees. Is the issue relatively narrow in scope, such as those plants impacted by particular natural hazards? Or is the issue truly generic in nature, affecting the entire nuclear fleet? How can the issue be addressed most effectively at both a generic level and then at a plant-specific level? The prioritization process should be flexible enough to address both the generic and plant-specific impacts of the potential or proposed regulatory action.

Performance monitoring and feedback are essential elements of a program. How does one ascertain if the processes for prioritization and integrated scheduling have been successful? Periodic assessment by the licensees and regulator should be built into the process that is adopted. This can follow the workings of existing industry and NRC groups and steering committees. The ROP may serve as a model in this regard.

The optimal approach to be used would include a process for prioritization of regulatory actions and a process for integrated implementation scheduling. The process would place primary emphasis on public safety impact, but would also address other attributes such as personnel safety, personnel productivity, and plant production. Cost considerations in the assessments would include not only installation cost, but forward looking recurring cost such as operations and maintenance.

The approach would be risk-informed, not risk-based. Thus, it would make use to the extent practicable of risk insights from the existing PRAs, along with qualitative considerations of DID.

The process would be flexible and adaptable. It would make use of a front-end generic regulatory action ranking and prioritization, as well as a back-end plant-specific assessment. The concept of a multi-disciplinary Expert, Integrated Decision-making Panel review akin to those employed by the Maintenance Rule and 50.69 would be integrated into the process. An industry-sponsored guidance document, endorsed by the NRC, would be the vehicle for implementation.

4.0 Industry's Proposed Approach

4.1 Overview

Industry proposes an ISAP-like approach [1], with a process for the prioritization of regulatory actions including plant-initiated projects, and a process for integrated implementation scheduling. ISAP was successfully implemented at several plants during the 1980s in that, through the prioritization process, improvements in plant safety were achieved while eliminating unnecessary plant projects and deferring projects with low safety significance [21, 22, 23]. The NRC 1992 Policy Statement on Integrated Schedules [3] contains all of the essential elements for the identification of activities, maintenance and update of schedules, and regulatory review. Consideration should be given to expanding the scope of regulatory actions (and activities) subject to this policy. NSAC-90 offers additional integrated scheduling process details that are useful to the industry approach [2].

A key element of industry's proposed approach is the provision for a formal multi-disciplinary plant expert panel review of the issue prioritization. The processes that are developed would be piloted prior to full implementation. Industry believes that the most efficient mechanism for implementation of both the prioritization process and the integrated implementation scheduling process would be via NRC-endorsed industry developed guidance.

4.2 Improved Risk Understanding and Modeling Support ISAP-like Process

There are a number of reasons industry proposes a prioritization approach built upon the ISAP. For one, there have been significant improvements in risk understanding and modeling over the past 25 to 30 years. Some of the programs and processes that have led to this enhancement of the understanding of risk and address potential severe accidents include:

- IPE and IPEEE
- ASME/ANS PRA standards
- Risk-informed regulation (e.g., RG 1.174)
- Improved EOPs, development and implementation of SAMGs
- Maintenance Rule implementation
- ROP
- Fire PRAs developed for NFPA 805 and other applications
- SAMAs as part of license renewal
- B.5.b – 10 CFR 50.54 (hh)(2)
- Post-Fukushima Actions (FLEX and others including seismic and external flooding)

GL 88-20, Individual Plant Examination (IPE) for Severe Accident Vulnerabilities, and the associated Supplement 4 for external events (IPEEE), provided significant plant-specific risk insights and industry-wide perspectives [24, 25]. All operating nuclear power plants now have Level 1 PRAs, including consideration of large early release frequency (LERF), for internal events at power. Many PRAs include fire and external events. Through the auspices of the ASME and American Nuclear Society, consensus standards for PRA applications [26] have been developed for at-power.

Second, a more risk-informed approach to regulation has been a long sought goal, with risk-related regulations such as the anticipated transient without scram (ATWS) rule (10 CFR 50.62) and the Station Blackout Rule (10 CFR 50.63) having been implemented. In August 1995, the NRC issued a policy to expand the use of PRA [27]. The following summarize the key elements of the policy:

a. Increase use of PRA to the extent supported by the state-of-the-art and in a way that complements traditional engineering approaches
b. Use PRA both to reduce unnecessary conservatism in current requirements and to support proposals for additional regulatory requirements
c. Be as realistic as practicable
d. Consider uncertainties appropriately when using the Commission's safety goals and subsidiary numerical objectives.

RG 1.174 [28] and associated guidance documents provide the NRC staff's recommendations for using risk information in support of licensee-initiated licensing basis changes to a nuclear power plant that require such review and approval. This guidance forms the foundation for numerous risk-informed initiatives including risk-managed Technical Specifications, risk-informed in-service inspection of piping, and other applications.

Over the past few decades, using insights from PRAs, the industry has continued to improve upon symptom-based emergency operating procedures (EOPs). EOP programs are frequently re-assessed/self-assessed by licensees. Additionally, in response to Supplement 2 of GL 88-20, the owners groups sponsored and developed severe accident management strategies. These have since been implemented at all reactor sites and are now in the process of being improved to reflect lessons learned from Fukushima and other improvements.

As discussed above in Section 2.2, the Maintenance Rule has been an effective means of enhancing plant systems reliability and overall safety performance for over two decades. Objective performance data, such as those tabulated in NUREG/CR-6928 [29], clearly indicate that the overall frequency of plant transients has decreased considerably in this time frame. Current equipment performance as illustrated by decreasing failure rates and system train unavailabilities is significantly better, in most cases, than during the period of the late 1980s and early 1990s just prior to Maintenance Rule implementation.

Third, the initial implementation of the ROP began on April 2, 2000. Some of the key tenets of the ROP and the drivers in its development were (1) to improve the objectivity of the oversight processes so that subjective decisionmaking is minimized, (2) to improve the scrutability and predictability of NRC actions so that regulatory response has a clear tie to licensee performance, and (3) to risk-inform the processes so that NRC and licensee resources are focused on performance issues with the greatest impact on safe plant operation. Consistent with RG 1.174, the ROP's risk-informed processes, such as the mitigating systems performance index (MSPI) and the SDP, integrate risk insights with more traditional deterministic factors (such as defense in depth and maintaining safety margins) to guide regulatory decisionmaking.

Fourth, published in February 2001, NFPA 805 [30] describes a methodology for existing light-water nuclear power plants to apply risk-informed, performance-based requirements and fundamental fire protection design elements to establish fire protection systems and features required for all modes of reactor operation. In addition, it presents a methodology for establishing fire protection procedures, systems, and features for nuclear power plants that are decommissioning and permanently shut down. Currently it is expected that 46 reactor units will be transitioning to NFPA 805.

Fifth, as discussed above in Section 2.6, license renewal applicants must consider alternatives to mitigate severe accidents. SAMA identifies and evaluates changes with the potential for improving severe accident performance (i.e., reducing the risk or probability-weighted consequences). Nearly all of the currently operating reactors have either completed the license renewal process, or the application is currently undergoing NRC review, or an application is expected within the next few years.

Finally, enhanced capability to cope with events and accidents through the implementation of the so-called B.5.b measures under 10 CFR 50.54(hh)(2) and the industry's initiative on Post-Fukushima (FLEX) continues [31]. For example, under 50.54(hh)(2), each licensee must develop and implement guidance and strategies intended to maintain or restore core cooling, containment, and spent fuel pool cooling capabilities under the circumstances associated with loss of large areas of the plant due to explosions or fire. FLEX is a major step in addressing the critical problems encountered at Fukushima Daiichi: loss of electrical power and cooling capability. It provides an additional layer of backup capability after an extreme event by stationing additional equipment—generators, battery packs, pumps, air compressors and battery chargers—in multiple locations. Implementing FLEX will help maintain cooling if normal systems and other backup systems fail by stationing additional equipment in multiple locations.

In summary, risk assessment understanding and modeling have seen significant evolution since ISAP was first initiated. A risk-informed regulatory framework has been developed and exercised. Standards describe *what* needs to be included in PRA models. Numerous industry guidance documents and NRC reports illustrate *how* to perform risk analyses in specific applications such as risk-managed technical specifications or fire PRA. Operating experience data have improved in terms of both the quantity of the information and the quality. Processes and programs have been implemented that exercise the risk models on essentially a daily basis (e.g., Maintenance Rule). This improvement in risk modeling ensures that the foundation for the risk-informed decisionmaking process under an ISAP-like process is sound. The PRA models which could be used for issue prioritization, if needed, are developed to standards, and undergo rigorous internal and external reviews. Improved personnel training and qualification in PRA, plant-specific risk insights, the sharing of best practices through risk management forums and conferences, and the widespread publication of both industry and NRC reports has greatly expanded the experience base of those who would assess and prioritize issues in an ISAP-like program.

4.3 High-Level Discussion of Proposed Processes

4.3.1 Process for Prioritization

Industry's proposed process for the prioritization of regulatory actions is shown schematically in Figures 1 and 2. Both new and existing issues would be prioritized by this process. The approach has many of the elements of ISAP and NSAC-90 in that there is a process for prioritization and a process for implementation. As illustrated in Figure 1, there would be improvements to the existing regulatory process to better characterize the issue definition, success criteria, significance and priority of new regulatory activities as they are contemplated and developed. This process would include a periodic monitoring and feedback loop, such that new interpretations or issues that develop in the process of implementation are identified and treated with respect to the original problem statement, and, as appropriate, a new issue is identified. The intent of this process is to improve predictability, stability and timeliness of regulatory activities, and to ensure their significance, resource impacts, and schedules are within reasonable proximity to the original regulatory analysis.

A key difference with ISAP is the inclusion of an upfront generic prioritization. An expert team would review existing regulatory activities to determine their generic safety nexus, risk significance, degree of completion, costs, and other factors. This information would be used by plants to inform their plant specific analysis of priority, factoring in plant specific risk insights, external hazards, etc. A plant specific integrated schedule would be developed accordingly and implemented through a regulatory action, the nature of which is still under discussion. Figure 2 depicts this proposed process, and how it would integrate with the overall process described in Figure 1.

To illustrate the 2-step prioritization process, assume a regulatory action regarding external flooding mitigation was assigned a *medium* priority ranking based on generic (reactor fleet-wide) considerations. At a particular plant site, the issue might be elevated to *high* based, in part, on insights from site-specific external flooding considerations. At other sites, the ranking might be adjusted lower, again based on site-specific or plant-specific considerations. Based on this site-specific adjustment to the issue ranking, the site-specific integrated implementation schedule would be revised commensurate with the site-specific prioritization results.

The initial generic prioritization using qualitative considerations will be based on addressing a series of risk-related screening questions. The screening questions will be drawn from a number of existing sources including risk-informed guidance documents and plant-specific procedures for 50.59 and 50.69, Maintenance Rule, risk-informed in-service inspection of piping, and so forth. NRC's Inspection Manual Chapter (IMC) 0609 Appendix A [32] also provides a potential list of questions. The screening questions are currently under development and will be refined as implementation guidance is developed and the program is piloted. A 4-tier designation for screening is proposed: High, Medium, Low and Very Low priority.

Once the proposed prioritization process is adopted, guidance including examples will be provided. This guidance will be piloted. Depending on the outcome of such pilots, quantitative guidelines may be developed as well.

Each regulatory issue that is prioritized generically would then be subjected to a plant-specific assessment. Depending on the issue, and the scope of models in the plant-specific PRA, the assessment may be qualitative or quantitative in nature. Consistent with the earlier ISAP approach, key attributes of the plant-specific prioritization include:

- Public safety
- Plant personnel safety
- Plant economic performance
- Personnel productivity enhancements
- Regulatory and external impacts
- Implementation costs

The *public safety* attribute considers radiological as well as non-radiological hazards (e.g., large stores of hazardous chemicals). While routine discharges may be considered in the risk model, studies have shown that the greatest risk is associated with potential accidental releases. The assessment is similar to that used in SAMA evaluations:

- The potential impact of the regulatory activity on SSCs is assessed
- Changes in initiating event frequencies and SSC performance during accidents is evaluated
- The impact on core damage frequency and the frequency of various release categories are evaluated if needed
- Public consequences are evaluated, usually expressed in terms of person-rem per year if needed
- The dose is converted to an economic impact using dollars per person-rem conversion factors if needed.

Non-radiological hazards may be assessed using a similar method or more subjective approaches.

Plant personnel safety accounts for both radiological exposure and industrial safety. Conversion factors translate the person-rem exposure or lost workday into dollar values.

Plant economic performance addresses the potential impact of the regulatory action on plant availability, plant efficiency, electrical output, and other characteristics.

Personnel productivity addresses the potential impact of the regulatory issue on the performance of plant staff, equipment, and the work environment.

Regulatory and external impacts require a more subjective assessment regarding NRC actions, actions of other federal agencies, as well as state and local governments.

Implementation cost addresses the impact of the regulatory action on initial costs, as well as recurring operations and maintenance costs.

The original ISAP used a number of adjustments to the attribute scoring of projects, as discussed in publically available documents [6, 7]. These included considerations of subjective weighting factors for each attribute, discount factors to address the time-value of cash flow, and linear versus non-linear attribute scoring scales. At this stage in the development of the framework for the prioritization of regulatory actions, no decisions have been made in this paper regarding such refinements to the model. In general, in keeping with one of the key characteristics identified in Section 3, the fewer such adjustments to the basic approach the simpler the process would be to implement. However, conversion of the various attributes to a common unit such as dollars or dollars per year is highly desirable although not absolutely necessary.

Alternatives to a quantitative assessment based on a set of conversion factors to dollars might include:

- Assignment of points depending on the impact of each attribute and subjective weighting
- A multi-dimensional matrix with implicit weighting of each attribute
- A process or flow diagram, which builds in a priority and weighting system

A detailed discussion of these options is beyond the scope of this paper at this stage in the development of the framework.

A key element of industry's proposed approach is the provision for a multi-disciplinary plant Expert Panel review of the issue prioritization results. The Expert Panel would be modeled after the use of expert panels for determining risk-significance in the Maintenance Rule, per NUMARC 93-01 guidance, or High/Low Safety Significance per 50.69, or as applied to Risk-Informed Technical Specification initiative 5b. In this regard, the use of the Expert Panel would address processes and/or procedures for training, qualification, composition of the panel by discipline, duties and responsibilities, and documentation of reviews.

Calibration of the approach against existing regulatory processes such as NUREG/BR-0058, and performance monitoring, are two additional mechanisms that would be given careful consideration during the development and piloting of the approach.

4.3.2 Process for Integrated Implementation Scheduling

There are a number of models that have been developed over the two plus decades since ISAP. All the approaches in one form or another address the flowing important considerations:

- Outage duration
- Resource availability
- Cost
- Other plant-specific and site-specific considerations

NSAC-90 describes the 7 basic interrelated categories for implementation scheduling:

1. Attribute Definition
2. Issue Management
3. Project Identification
4. Project Prioritization
5. Planning and Scheduling
6. Implementation
7. Monitoring

NRC's 1992 final policy statement on integrated scheduling [3] identified additional key attributes of an integrated scheduling process that are necessary to meet regulatory needs:

- A provision for NRC to be informed of process and schedule information at periodic intervals
- A process for requesting schedular relief
- A process for evaluating licensee's maintenance of schedules.

There is significant merit to the multi-level review and consent approach in the 1992 policy statement. A process that minimizes review for issues of low safety significance would make the best use of both NRC staff and industry resources. For example, the provision for a 90-day negative consent on relatively low safety significant issues deserves consideration.

4.4 Scope of Applicability

To be most effective, the prioritization process should address the full scope of outstanding regulatory actions. These include, for example:

- Fukushima regulatory response
- Fire protection
- Current and future generic safety issues
- Rules and orders
- License conditions
- Generic communications
- 10 CFR 50.54(f) letters
- Implementation documents (regulatory guides, interim staff guidance)
- Plant modifications (regulatory and non-regulatory).

Additionally, changes to or issuance of other regulatory mechanisms can have large impacts, and the following vehicles are also recommended for evaluation:

- Regulatory Issue Summary (RIS)
- Frequently Asked Questions
- Requests for additional information in context of license amendment requests
- Proposed additions of scope to license amendment requests
- NRC "positions" expressed in meeting materials and correspondence.

4.5 PRA Scope and Technical Adequacy Considerations

In the context of the prioritization of regulatory issues, technical adequacy is understood as being determined by the adequacy of the actual modeling and the reasonableness of the assumptions and approximations. A PRA used in regulatory issue prioritization should be performed in a manner that is consistent with accepted practices and commensurate with the scope and level of detail required, and appropriately represents the plant. The ASME/ANS PRA standard [26] provides technical supporting requirements in terms of three Capability Categories. In addition the standard provides for supplementary analyses in lieu of PRA analyses.

Virtually all reactor units have Level 1 and LERF internal events and internal flooding PRA models have been peer reviewed, most per the ASME/ANS Standard. For fire events at power, the majority of the reactor fleet has developed and implemented PRA models or development is underway. A number of plants are also developing external events at power while many of the remaining plants are sequencing the development of these models to support post-Fukushima activities. The existing activities to improve PRA scope and capability are proceeding to the extent allowed by the availability of subject matter experts and the need to prioritize resources towards tangible plant safety improvements. This constraint has been recognized in the establishment of a phased schedule for seismic PRA development.

Industry proposes to use a phased approach to address PRA scope. Phase 2 uses existing information and processes, adapted as appropriate, for the prioritization of issues in an efficient and effective manner. Phase 2 is the prioritization process described in this paper. Phase 3 would include a broader scope of Level 1 and Level 2 PRA models that would enable the NRC and industry to attain greater benefits. As noted some issues may benefit from further PRA model development or refinement and thus the scope of the plant-specific PRA would naturally progress towards the scope of Phase 3.

4.6 Challenges

Implementation of industry's proposed process for the prioritization of regulatory issues, and the integrated implementation scheduling thereof, has challenges. First, industry participants, the NRC, and other stakeholders need to attain a common understanding of the processes for prioritization and integrated scheduling. What information must be prepared by whom, and in what time frame, with what level of level of documentation subject to what constraints on scope of issues need to be ascertained? The process that is adopted should build upon earlier successful scheduling initiatives, as well as the 1992 policy statement on integrated schedules.

The process should not be excessively burdensome. The level of PRA model development should be commensurate with its application, which is the broad categorization of safety benefit and sequencing of activities. The process should incentivize PRA development and use by the licensees.

This initiative should interface with other ongoing regulatory initiatives including the Cumulative Effects of Regulation [4], Recommendation 1 of NRC's Near-Term Task Force on the Fukushima Dai-Ichi Accident [33], and the proposed risk-informed regulatory framework in NUREG-2150 [34].

Finally, the processes that are implemented must be as transparent as possible while addressing the challenges posed by the discussion of competitive and security issues in the public domain.

5.0 Concluding Remarks and Path Forward

This paper describes industry's proposed approach to prioritize regulatory and plant actions and schedule work at licensee facilities consistent with safety significance. The policy issue is of great importance to the industry, regulatory bodies including the NRC, and stakeholders. Industry has systematically reviewed potential options and is proposing a process for prioritization of regulatory actions and another for integrated implementation scheduling. This proposal builds upon the best features of the 1980s era ISAP, NSAC-90, and the 1992 Commission policy statement on integrated scheduling. The approach is generally consistent with SECY-12-0137, as directed in the accompanying staff requirements memorandum, as well as COMGEA-12-0001/COMWDM-12-0002. Industry's approach would provide generic and plant-specific prioritization that focus on items of greatest safety import. Adoption of industry's phased approach would incentivize industry to develop more complete PRA models.

Industry currently envisions the development of guidance documents and piloting beginning in the second half of 2013. The goal is to complete the pilots and update the implementing guidance documents for NRC endorsement towards the end of 2014.

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