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Nuclear Energy Institute

GUIDELINES FOR PRIORITIZATION AND SCHEDULING IMPLEMENTATION

Pre-Draft 1 – September 30, 2013

[Note: Real Examples, matrix and checklists will be developed during piloting.]

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ACKNOWLEDGMENTS

NOTICE

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FOREWORD

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 saw 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 working group to address cumulative impact of industry and regulatory actions. The working group recommended the development of processes for the characterization of existing and new generic issues and the implementation of integrated plant-specific schedules. The overall outcome of the process is risk beneficial in that plants will be made safer in a timelier manner.

The purpose of this document is to describe industry's guidance for characterizing and prioritizing regulatory and plant-identified actions and scheduling plant improvements at licensee facilities consistent with safety significance. This guidance focuses 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.

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

The approach supports generic characterization and plant-specific prioritization that focuses on items of greatest safety importance and cost and resource use effectiveness. The guidance is consistent with a three phase approach for incentivizing industry to develop a more complete suite of probabilistic risk assessment (PRA) models. Phase 1 is in progress and involves successful implementation of existing risk-informed activities. Examples are seismic PRAs to address Fukushima Tier 1 and 10 CFR 50.48(c) NFPA 805, Alternate Fire Protection Rule. Phase 1 is not addressed by this guidance, but is important to the goal of incentivizing full scope PRA development. Phase 2 is the prioritization process contained in this guidance that uses existing information, PRA models, and processes, adapted as appropriate, for the prioritization and scheduling of plant activities in an efficient and effective manner. 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.

These phases are interconnected and can provide a success path to the goal of broader scope PRAs. If new PRA models or refinements in existing PRA models are appropriate to support Phase 1 or Phase 2, such new or refined models would support a transition to Phase 3 whereby other potential issues for action could be identified and prioritized. In addition, prioritizing issues/actions provides an opportunity to improve the understanding of the risk significance of activities and further exercise the PRA models. Such activity provides additional opportunities to identify risk insights and react accordingly.

The prioritization process consists of a set of *attributes*, namely:

- Public safety (e.g., radiological and non-radiological hazards); and includes security
- Plant personnel safety (e.g., industrial and radiological)
- External impacts (e.g., regulatory).

The approach is *risk-informed*, not risk-based. Thus, the process makes use, to the extent practicable, of risk insights from existing information and processes, such as the Regulatory Oversight Process (ROP), risk-informed licensing applications, and existing plant PRAs, along with considerations of defense in depth (DID) and margin of safety. The process is flexible and adaptable to address the variability in items to be addressed. It makes use of a front-end generic regulatory action characterization, as well as a back-end plant-specific assessment and prioritization. The characterization and prioritization processes include 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 is integrated into the process.

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

1. An improved NRC process for characterization of regulatory activities going forward, including enhanced definition of the issues, establishing clear success criteria for issue closure, and prioritizing the activities based on their significance 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 issue definition and success criteria, 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 characterization, degree of completion, costs, and other factors. This information is 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.

NRC regulatory requirements are defined as rules, orders, and license conditions. Other regulatory vehicles are guidelines or informational in nature, although it should be noted that these guidance documents tend to be treated by industry as requirements as alternative approaches to the guidance are typically difficult to justify.

NRC requirements may be promulgated through several different mechanisms depending on their nature:

1. Requirements deemed necessary by the Commission for adequate protection of public health or safety and common defense and security. This standard is at the discretion of the Commission but is not intended to achieve zero risk.
2. Requirements that represent a substantial increase in safety and are cost justified through the regulatory analysis process and 10 CFR 50.109.
3. New actions to address an existing requirement that represent a "compliance backfit" in that they are deemed necessary for compliance with the regulation as interpreted.
4. "Voluntary" requirements that may be implemented by the licensee either as an improvement or an alternative to existing regulation. Examples include 10 CFR 50.69, or 10 CFR 50.48(c). It should be noted that "voluntary approaches" may sometimes be effectively mandatory as no other

practical compliance alternative may be available to address a new regulatory interpretation (as in the case of 10 CFR 50.48(c).

Items 1 and 3 above do not require cost benefit analysis and are expected to be implemented irrespective of cost or impact on other activities. Item 4 may or may not include a regulatory analysis estimating cost and benefit. The potential risk significance of regulatory actions is not necessarily related to their basis, and a pure safety focused process should not be expected to differentiate the above in terms of prioritization. However, there may be other factors that warrant their consideration in the process.

The prioritization and scheduling processes proposes to address the full scope of outstanding regulatory actions, regardless of their origin above. Industry believes the best approach to address these actions is on an issue basis. Examples of issues include:

- Fukushima regulatory response
- Current and future generic safety issues
- GSI-191
- NFPA-805

Examples of regulatory processes to implement issue resolution include:

- 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 addressed:

- 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 guidance. At the basic level, the following characteristics are addressed:

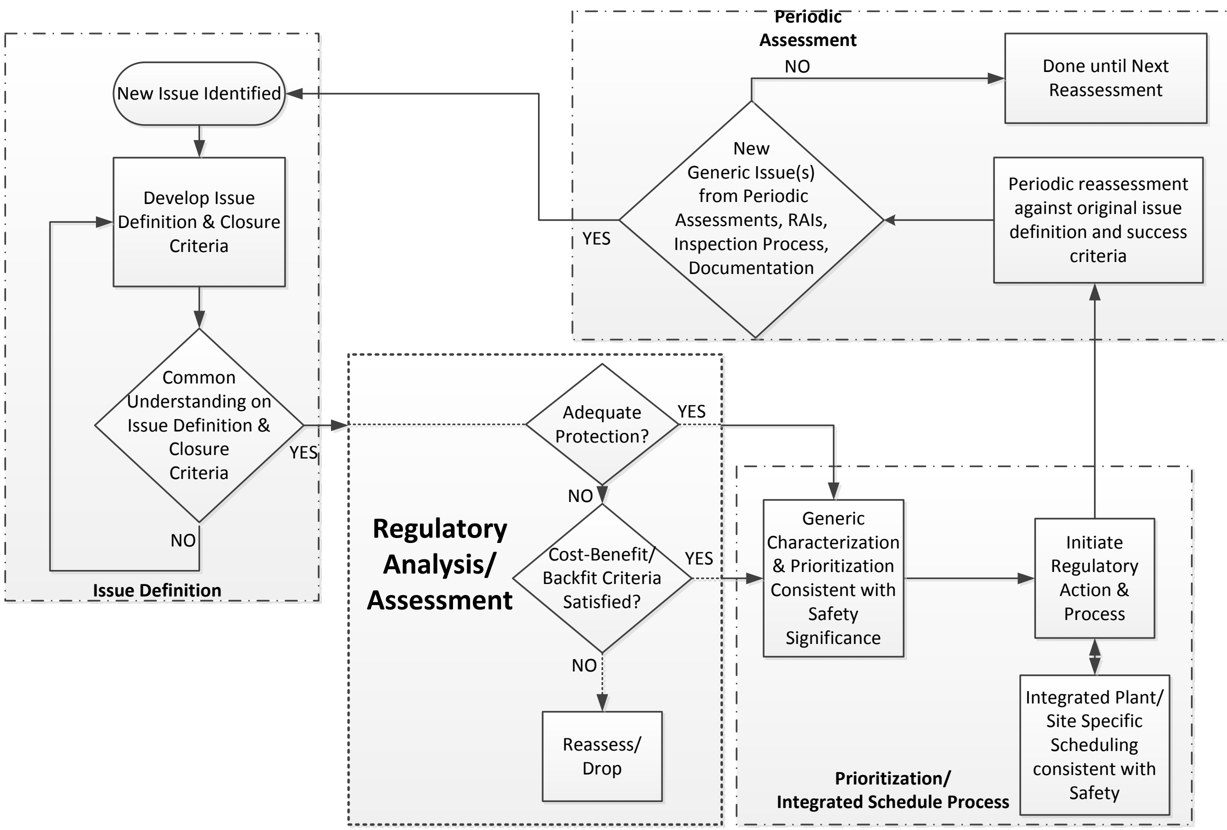
- A structured, robust process
- Transparency

- Straightforward while remaining structured and robust

The process is intended to be transparent and straightforward to understand, and is not excessively burdensome. *Transparency* means that the process to be used by each licensee, and the outcome of the prioritization, are publically documented, subject to security, proprietary and commercial constraints.

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) has been developed. Checklists with supporting guidance are used to qualitatively assess issues, although a more detailed qualitative or semi-quantitative evaluation also can be performed, as appropriate. If necessary, the assessment can 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.

Figure 1 Industry's Process for Managing Cumulative Impact -- Regulatory Issue Characterization and Prioritization



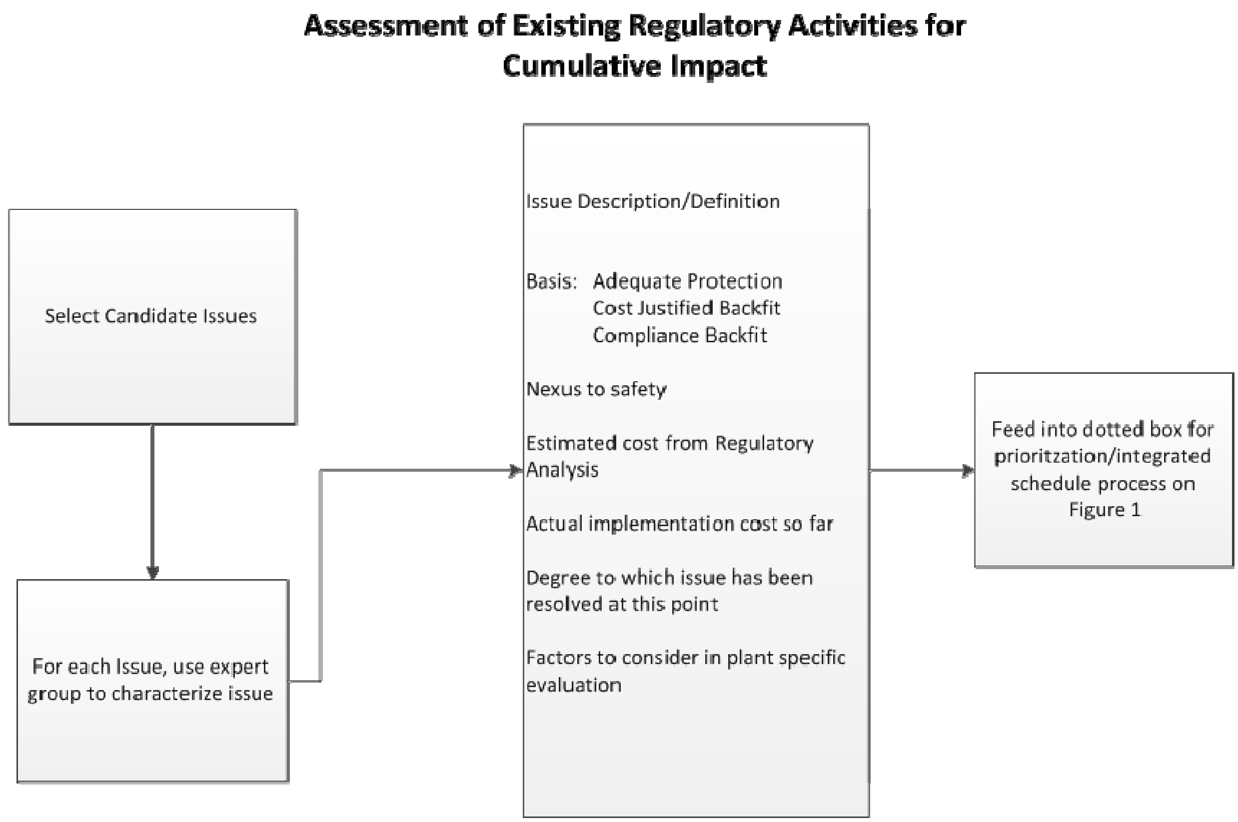


Figure 2 Assessments of Existing Regulatory Activities

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1 INTRODUCTION

1.1 PURPOSE

The purpose of this document is to describe industry's guidance for characterizing and prioritizing regulatory and plant-identified actions and scheduling plant improvements at licensee facilities consistent with safety significance. This guidance focuses 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.

1.2 CONTENT OF THIS GUIDANCE DOCUMENT

Section 2 presents definitions and a discussion of key terms used in this guideline.

Section 3 discusses the key characteristics of the process, including the basic approach, philosophy, and quantitative guidelines from the SDP.

Section 4 provides guidance on implementing and documenting evaluations. Decision attributes (safety, security, plant personnel safety, external impacts, and costs) are addressed in this section.

Section 5 discusses the implementation of integrated scheduling.

Section 6 discusses reassessment, review and reconciliation.

Section 7 provides documentation guidance.

Section 8 is a list of references.

Appendices A through E provide the background on the process as well as additional examples and details.

2 DEFINITIONS AND APPLICABILITY OF TERMS

Will be developed through the pilot process.

3 PROCESS CONSIDERATIONS

3.1 KEY CHARACTERISTICS OF THE PROCESS

In developing the process key characteristics and principles were established. Below are the key characteristics. Key principles are addressed in a subsequent section.

The desirable characteristics of a process for the characterization and prioritization of issues, associated actions, and integrated implementation scheduling are:

- Structured and robust
- Transparent
- Straightforward while remaining structured and robust
- Lifecycle, from issue conception to implementation of an action that addresses the issue or a determination that an action is not needed
- Piloting
- Generic, plant type (e.g., BWR or PWR) and Plant-specific Implementation
- Performance monitoring and feedback
- Risk Informed versus Risk Based

A *structured, robust process* means that the steps needed to arrive at the desired goals, a characterization and prioritized ranking of regulatory and plant-identified actions and the schedule for implementation, are adequately described and effective. Each step in the process has a specific purpose and the necessary actions to be taken are defined. Guidance with templates, worked examples and other tools are needed. Note that 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 does lend itself to effective use by experienced plant and regulator staffs, and builds upon existing risk-informed processes such as the Maintenance Rule. The actions to be taken each step are provided. The guidance needs to be sufficiently detailed to lead to substantially the same characterization and prioritization outcomes if performed by different, capable personnel. In addition, the level of detail appropriate to support robustness and efficient development of results are key aspects of characterization and prioritization.

Transparency means that the process to be used and the outcome of the characterization and prioritization are publically documented. As appropriate, the technical bases for the results will be on the docket in the public domain. It is acknowledged that in this era of open market competition between electrical generators, some aspects of the integrated scheduling will need to be kept proprietary. Otherwise, information on future outages, the length of the outages, perhaps outage schedule risk, and other commercial information will place the nuclear plant owners and operators at a competitive disadvantage. A second consideration regards plant security matters.

The desire to be straightforward must be balanced with the need for effective evaluations (whereby characterization and ranking conclusions are robust). Consider that at one end of the spectrum, a multi-disciplinary team could review the various regulatory and plant-initiated projects, characterize and rank them, schedule each action, and is either subject to auditing by the NRC or provides the results for NRC review. A *negative consent* process could be used. At the other end of the spectrum is a complex and resource-intensive characterization, prioritization and scheduling approach, requiring multiple layers of review by both the licensee and regulator. Detailed PRA modeling and quantification, and a detailed report by both the licensee and the regulator, would require large resources on the part of licensees and regulator. Such a complex process would not be beneficial or sustainable on a broad scale, and would itself induce burden that offsets resources better applied to other activities. The level of rigor necessary to characterize, prioritize and focus activities does not compel the need for such an approach. The overall outcome of the process is risk beneficial in that plants will be made safer in a timelier manner. A reasonable and timely process will more readily achieve this result.

Rather than establishing a new process, the process builds on existing regulatory and industry programs that have been successfully implemented. There are over 25 years of industry experience using risk understanding for project characterization, prioritization, integrated scheduling, and decision making to build upon.

The process starts with a generic characterization of issues and is followed by a plant-specific prioritization basis. The concept for level of detail used to develop the guidance is:

- Use a *progressive process* similar to NRC's phased approach to significance determination under the reactor oversight process (ROP).
- Use checklists with supporting guidance to qualitatively assess the issue, although a more detailed qualitative or semi-quantitative evaluation also can be performed, as appropriate.
- If necessary, the assessment can consist of quantitative analyses, for example, using PRA or reliability models.
- 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, refined, or focused scope analyses can be conducted for specific issues.

- Available, relevant information are used (NRC evaluations, Industry evaluations, severe accident mitigation alternative (SAMA) results, etc., as appropriate to the issue)

On lifecycle, any issue, whether plant-initiated or regulatory-initiated, has a life cycle. The issue may initially be generic in nature, become characterized and prioritized, then progress to implementation. At the implementation stage the issue is addressed and implemented by technical evaluations, a hardware modification, or changes to operating and administrative procedures, or is determined to not require a change. It is then subject to inspection/audit, plant control processes, and possible re-interpretations. Implementation of the issue may not be a simple matter such as the one-time installation of a structure, system or component (SSC). This is addressed in this guidance document.

On classes of plants/generic/plant-specific, consideration is given to cumulative effect of the regulatory action on classes of licensees, either by plant design or hazard contributors. Is the issue relatively narrow in scope, such as those plants potentially impacted by particular natural hazards? Or is the issue 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 characterization and prioritization process is sufficiently flexible 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. This addresses ascertaining if the processes for prioritization and integrated scheduling have been successful. Periodic assessment by the licensees and regulator is included in the process.

On risk informed, the approach is not risk-based. Consistent with the philosophy and integrated decision process of Regulatory Guide 1.174, it uses to the extent practicable risk insights qualitatively and from existing PRAs, along with qualitative considerations of defense in depth (DID) and safety margins. The concept of a multi-disciplinary Expert, Integrated Decision-making Panel review akin to those employed by the Maintenance Rule (10 CFR 50.65) and 10 CFR 50.69 are integrated into the process.

3.2 Basic Approach to Prioritization

The prioritization of potential actions at plant-specific level uses a straightforward benefit-cost (B-C) evaluation. The evaluation includes:

- Identification of benefits and dis-benefits for each evaluation attribute (public health and safety, personnel safety, plant performance)

- Aggregation of all benefits and dis-benefits
- Aggregation of all costs (capital, O&M, etc.)
- Establishment of a B-C relationship in the form or a ratio of aggregated benefits to aggregated costs

Note: The approach to aggregation is under development. To be robust the approach should be anchored using a reference point such as NRC regulatory analysis guidelines and/or SAMA analyses. For example:

- For safety, change in risk approximations can be converted to either person-rem averted (converted to $s) and economic costs (plant, offsite, replacement power costs, land contamination, etc.) averted, such as used in SAMA and NRC regulatory analysis guidelines, or a more straightforward approach could be used based on past practices such as the following (example values are used; actual values will need a technical basis):
  - Delta CDF and Delta LERF of 1E-7/1E-8 per year respectively equals $AB thousand lifetime (Drop)
  - Delta CDF and Delta LERF of 1E-6/1E-7 per year respectively equals $ABC thousand lifetime (VL to L transition point)
  - Delta CDF and Delta LERF of 1E-5/1E-6 per year respectively equals $A million lifetime (L to M transition point)
  - Delta CDF and Delta LERF of 1E-4/1E-5 per year respectively equals $AB million lifetime (M to H transition point)
  - Delta CDF and Delta LERF of >1E-4/1E-5 per year respectively equals (H) is greater than $AB million lifetime with the appropriate value to be determined on a case by case basis, as such an outcome is highly unlikely, as other processes would address such H outcomes
- For security………………[to be developed later after piloting of safety]
- For personal safety, use ALARA at ~$2K per person rem times 10 years or $20K per person rem if a recurring increase or decrease

The approach will be determined as the guidance document is further developed and piloted.

Note: The evaluation considers making use of any existing NRC cost-benefit or generic safety impact analyses if available. If NRC has developed a "generic" or plant-type cost-benefit or prioritization analysis, then one option involves using the NRC analyses by refining on a generic or plant-specific basis and including full implementation costs.

Note: Development of anchor points based on existing cost-benefit analyses is under consideration. The anchor points would be placed into categories (high, medium, low and very low/minimal). Then a comparison of a specific issue's characteristics to these anchor points could be conducted. As noted the most appropriate approach will depend on the issue and the availability of information. SAMA evaluation techniques are potentially amenable to the establishment of anchor points.

3.3 PHILOSOPHY

The philosophy used to develop this process is based on the following considerations:

- Review of Existing Practices
- Lessons Learned from Risk Informed (RI) applications

Existing Practices: Industry and NRC have several relevant practices for ranking. These include NRC C-B analyses used to support backfit determinations, the significance determination process (SDP), severe accident mitigation alternatives (SAMA) analyses, risk informed in-service inspection (RI ISI), and 10CFR50.69 guidance. In addition, although focused on the design basis, 10 CFR50.59 aims to address the safety and licensing implications, if any, of potential plant changes through qualitative and as appropriate quantitative guidance. Relevant lessons learned are summarized below.

Lessons Learned: Successful risk informed applications have “blended” risk insights/analyses and traditional measures such as defense in depth and safety margin. Examples of successful risk informed applications to date (Note: Identification of key lessons learned, etc. for other applications is under consideration) are:

- Maintenance Rule (MR)
- Risk informed inservice inspection (RI ISI)
- NRC Significance Determination Process (SDP)
- Technical Specifications surveillance frequency initiative

RI ISI: The RI ISI approach implemented by most of the licensees uses broad groups based on relative frequency and prevention-mitigation capability which could be based on qualitative measures, relative availability and reliability of prevention-mitigation capability, or using PRA results directly. Importantly, the qualitative measures are calibrated to risk. Broad groups address uncertainty, repeatability and reduce the potential for changes in conclusions if new information becomes available. As a Regulatory Guide 1.174 application, defense in depth, safety margin, monitoring and other risk informed applications considerations are addressed.

SDP: A key feature of the SDP approach is the use of reasonably broad ranges, using a factor of 10 on frequency, and the use of a progressive approach using a combination of qualitative and quantitative measures. Further NRC uses

Appendix M, "Significance Determination Process Using Qualitative Criteria" where the scope is excerpted as follows:

> "This Appendix provides deterministic guidance for assessing the significance of inspection findings, identified through the cornerstones of Reactor Safety and Radiation Safety in the Reactor Oversight Program (ROP), when the probabilistic risk assessment (PRA) methods and tools, including the existing significance determination process (SDP) appendices, cannot adequately address the finding's complexity or provide a reasonable estimate of the significance due to modeling and other uncertainties within the established SDP timeliness goal of 90 days or less. Appendix M should not be used by decision makers when the results of another SDP appendix do not appear to be appropriate (i.e., the significance is too high or too low). In these cases, the appropriate SDP should be used and a deviation from the Reactor Oversight Process (ROP) Action Matrix should be pursued in accordance with Inspection Manual Chapter 0305, "Operating Reactor Assessment Program."

The process described in this guidance addresses each of the key features in NRC's Appendix M.

In addition the licensee can provide an alternate view on significance and /or additional plant-specific information which could impact the NRC assessment.

Other Lessons Learned: NEI's 50.59 guidance (NEI 96-07) has been successfully implemented and addresses significance with respect to potential changes to the design and licensing basis. The approach is progressive, and includes discussion of minimal, with examples which can be adapted for use in this guidance. (Note: Questions for streamlined RI ISI, 50.69, TS initiative 4b, TS initiative 5b, etc. will be considered as the guidance is further developed.)

Features for Success of RI ISI and SDP: Both of these applications use a combination of qualitative, semi-quantitative and quantitative approaches to assessing risk significance to support decision making. Important features are:

- Qualitative aspects are founded on relative risk significance; i.e. they are calibrated, if even informally.
- A binning or range approach is used
- In the case of SDP, licensee input can be considered by NRC to change the evaluation outcome as the licensee can provide additional information or refined analyses.

The differences in impact relative to RI ISI/SDP and prioritization are significant, however, given that for characterization and prioritization:

- A change to the licensing basis is not being proposed by the licensee, or otherwise Reg. Guide 1.174 or NRC requirements would be used
- A Regulatory response to an operational or design issue identified as a part of the ROP is not being determined
- The objective is constrained to characterizing and prioritizing potential actions to achieve more timely safety benefit

Using the lessons learned associated with the RI ISI and SDP, in consideration of the characterization and ranking desired, supports development of a process which meets the success attributes. Key elements include having wide ranking categories, and a robust basis for assigning potential changes to categories.

Calibration: The qualitative aspects of the process need to be calibrated, and the following questions are therefore addressed:

- What to use for calibration?
- What process is appropriate to effectively use the calibrated bins of VL (minimal), L, M, and H?

This is addressed below.

Establishing Significance: The significance of an issue/potential action is established based on two considerations:

- The current risk associated with the issue being addressed by the potential action
- The effectiveness of the potential action (i.e., how much would risk be reduced?) This includes:
    - Direct effects associated with addressing the issue
    - Other effects where the potential action could reduce/increase risk which are not directly associated with addressing the specific issue

Note: If a cost-benefit, or ranking, analysis has been conducted on a generic or plant-type basis, then these factors should have been addressed, albeit with the limitations associated with any generic or plant-type evaluation. A plant-specific evaluation could change the benefit and/or cost, perhaps significantly. Further a more effective, "smarter", approach to addressing the underlying issue might be identified on a plant-specific basis.

Use of SDP Concept: The philosophy used here is based on the SDP approach whereby risk significance is determined on the basis of current risk minus the risk if the potential action is taken. In SDP this delta risk is associated with the increase in risk due to degraded licensee performance, but the philosophy is the same; simply the inverse.

Qualitative and Quantitative: The relative impact among potential actions needs some "robust" basis, whether developed using qualitative and/or quantitative evaluation (s). This is addressed herein by using a logical approach founded in determining the potential impacts of a potential action on the key elements which impact risk. These include consideration of initiating events, system performance, human performance and other typically used risk considerations.

Generic Assessment Expert Team (GAET): The generic assessment uses an expert team to assess issues and develop the generic characterization of potential actions. The GAET is comprised of Industry technical leaders supported by subject matter experts (SMEs), as needed. The GAET uses available NRC and Industry information which is supportive of determining issue and potential action significance. This information could include an objective assessment conducted by others within the Industry, as discussed below.

The GAET uses the process provided herein in the framework of a Generic Integrated Decision Making Panel (GIDP). The output of the GAET deliberations is a document of issue and significance characterization, cost-benefit, and associated bases, including identification of plant-specific (P-S) considerations which could influence the significance on a P-S basis. Note: The actual structure, format, team makeup, etc. is to be determined. Depending on Industry decisions, either the GAET would work completely independently to develop the noted outcomes or could reach out to others who would provide an objective assessment. The objective assessment would be intended to provide the information needed by the GAET. The use of a separate assessment is based on the specific characteristics of an issue, e.g. complexity and desire for refining any NRC developed C-B or ranking results.

P-S Integrated Decision Making Panel (P-S IDP): An P-S IDP is used to support final rankings on a plant-specific basis. The IDP would not establish prioritization; instead they should conduct a "peer" check. For example, in addition to reviewing the rankings developed by plant subject matter experts (SMEs) and the outcome of the GAET, the P-S IDP could conduct a pairwise comparison. If the P-S IDP conducts the actual rankings, the benefits of a peer check would not be achieved. (Note: The P-S IDP process will be adapted from existing P-S IDP approaches.) This approach is consistent with other applications which use a P-S IDP.

3.4 Qualitative and Quantitative Guidance including SDP

The initial approach to prioritization should begin with characterization of the issues and qualitative considerations. For example, the impact of the regulatory issue or plant-identified action on initiators, mitigating systems, and defense in depth could be evaluated through the use of generic and/or plant-specific risk insights. After a large database of characterized and prioritized issues has been established, pair-wise comparisons of the issue at-hand with previous prioritizations can be performed.

As with the NRC significance determination process, a phased qualitative to quantitative approach is employed. Should qualitative assessment of priority prove insufficient, quantitative assessments similar to those performed in SDP guidance would be considered. The SDP quantitative guidelines are inverted as follows. Instead of being used to determine the risk significance of an inspection finding they establish the relative characterization and ranking for addressing a potential action aimed at reducing the current risk associated with a specific issue. In order to consider central tendencies (mid-range) and lower and upper bounds for each priority (H, M, L, VL) these values have been added as needed to the SDP guidelines. A geometric mean has been used to develop mid-range values. The purpose of using a mid-range is to emphasis that the range used in SDP is reasonably high and that, depending on the evaluation, the estimated impact could be considerably lower than the upper bound value of the range.

<u>High Priority/Red:</u> Taking into consideration the fleet of operating reactors in the aggregate, the following would merit **High** priority:

- Reduction per unit in average core damage frequency (CDF) by greater than 10^{-4} /year, or
- Reduction per unit in average large early release frequency (LERF) by greater than 10^{-5} /year

The above values are lower bound (LB). For mid-range (MR) and upper bound (UB) the guidance assumes

- Mid-range of 3E-4/3E-5 per year for CDF and LERF, respectively
- Upper bound of 1E-3/1E-4 per year for CDF and LERF, respectively (higher values would most likely be treated under adequate protection or expedited NRC and Industry processes)

<u>Medium Priority/Yellow:</u> Taking into consideration the fleet of operating reactors in the aggregate, the following would merit **Medium** priority:

- Reduction per unit in average CDF of between 10^{-5} /year (LB) and 10^{-4} /year (UB), or
- Reduction per unit in average LERF of between 10^{-6} /year (LB) and 10^{-5} /year (UB)

For mid-range use 3E-5/3E-6 per year for CDF and LERF, respectively

<u>Low Priority/White:</u> Taking into consideration the fleet of operating reactors in the aggregate, the following would merit **Low** priority:

- Reduction per unit in average CDF of between 10^{-6} /year (LB) and 10^{-5} /year (UB), or
- Reduction per unit in average LERF of between 10^{-7} /year (LB)and 10^{-6} /year (UB)

For mid-range use 3E-6/3E-7 per year for CDF and LERF, respectively.

Very Low Priority/Green: Taking into consideration the fleet of operating reactors in the aggregate, the following would merit **Very Low** priority:

- Reduction per unit in average CDF of less than 10^{-6} /year (UB), and
- Reduction per unit in average LERF of less than 10^{-7} /year (UB)

These values are upper bound (UB). To establish a range for use in ranking, for mid-range (MR) and lower bound (LB) assume

- Mid-range of 3E-7/3E-8 per year for CDF and LERF, respectively
- Lower bound of 1E-7/1E-8 per year for CDF and LERF, respectively (Issues with lower values should never enter the process, i.e. they either have no impact or much less than minimal impact on public safety)

4 IMPLEMENTATION GUIDANCE

The overall approach addresses the generic characterization and plant-specific prioritization of regulatory and plant-identified actions. The following decision attributes are addressed:

- Safety
- Security
- Plant personnel safety
- External impacts
- Costs

Then aggregation to establish benefit to cost relationship is addressed.

4.1 Safety

The screening and prioritization process is progressive and includes the following three basic steps:
Step 1: Screening on any Safety Impact based on a qualitative assessment, using an approach in consonance with NEI 96-07 (50.59 guidance)

Step 2: Screening on Less than Minimal Safety Impact based on a qualitative assessment, using an approach in consonance with NEI 96-07

Step 3: Ranking/Binning into High (H), Medium (M), Low (L), and Very Low (VL)/Minimal Safety Impact based on either a qualitative assessment, or a combination of qualitative and quantitative assessments. Table 4-1 provides the categorization, with the basis discussed in Appendix D.

Figures 4-1 and 4-2, described below, provide the generic and plant-specific processes, respectively.

Figure 4-3 provides screening questions for the first Step, any safety impact; in

Figures 4-1 and 4-2 (See Appendix B for guidance).

Figure 4-4 provides screening questions for the second step, less than minimal safety impact, in Figures 4-1 and 4-2 (See Appendix C for guidance).

Figure 4-5 provides questions to support identification of any adverse impacts, which are addressed in each step as appropriate.

Figure 4-1

Progressive Screening and Evaluation
- Safety Ranking (Generic) –
(Similar Logic for Other Attributes)

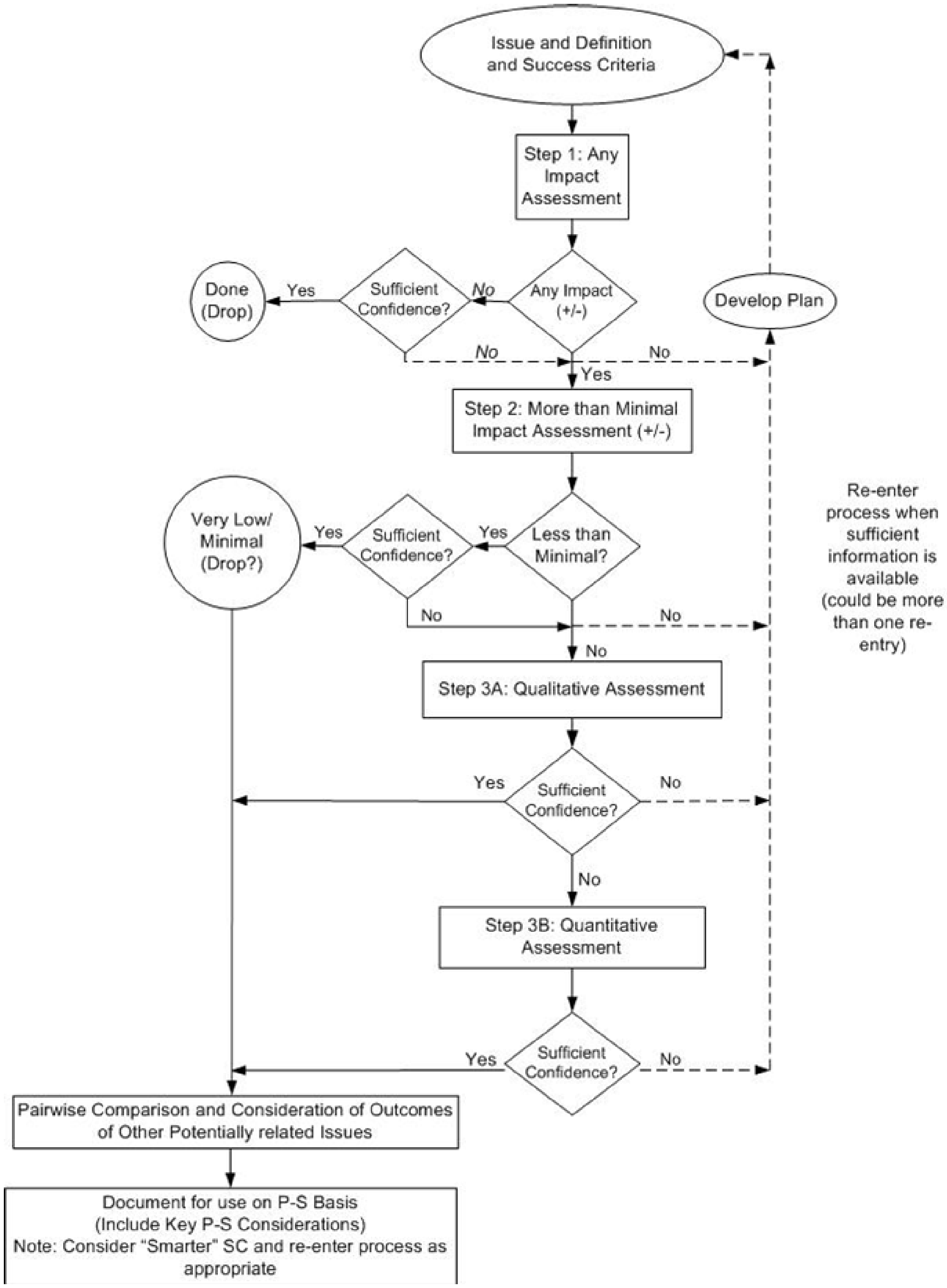

Figure 4-2

Progressive Screening and Evaluation
– Safety Ranking (P-S) –
(Similar Logic for Other Attributes)

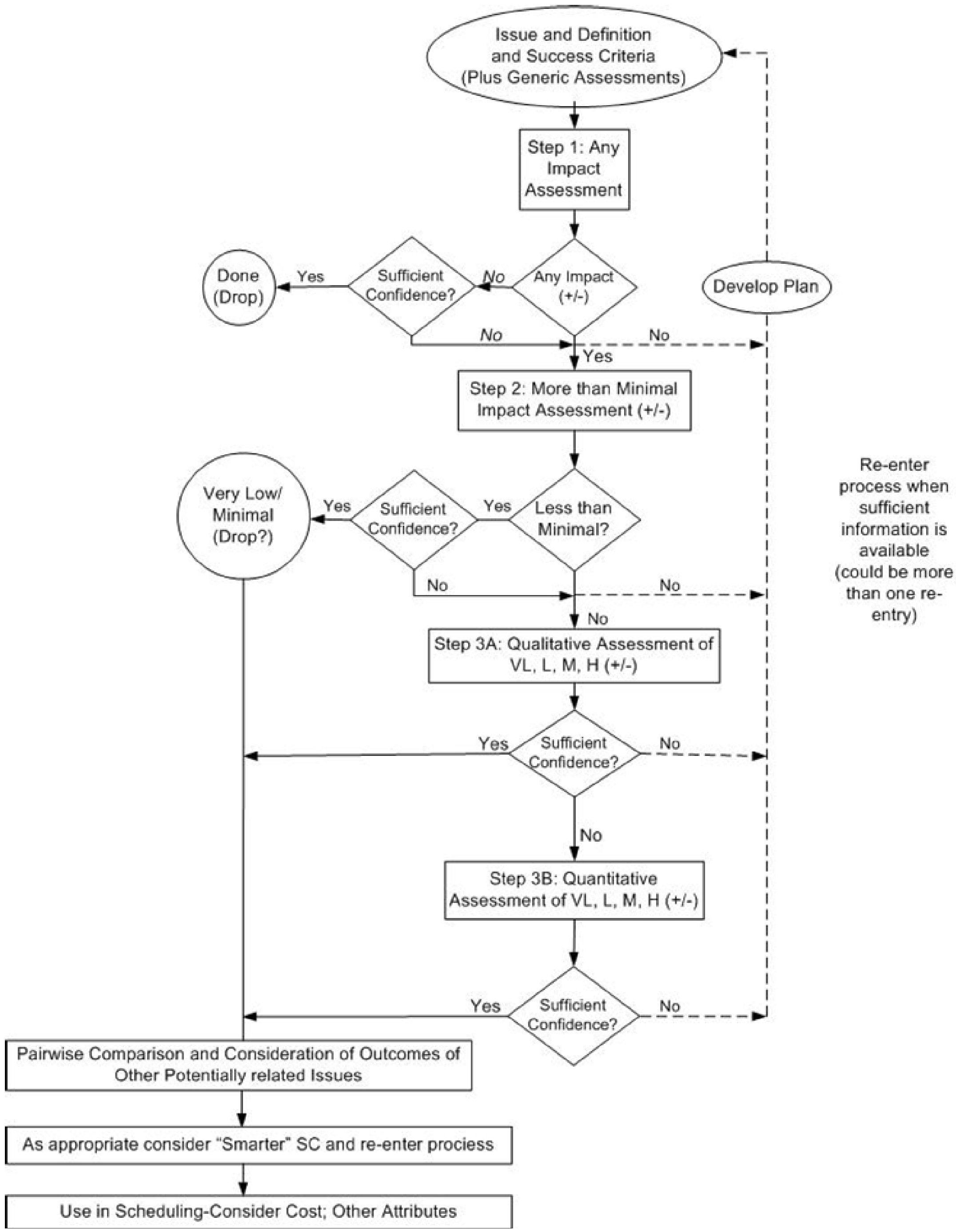

Figure 4-3 (Step 1 Safety Screening Questions)

Step 1: Screening on No Impact (See Appendix B)
Does the proposed activity or issue:

1. ☐ YES ☐ NO Result in an impact on the frequency of occurrence of a risk significant accident initiator?

Justification:

2. ☐ YES ☐ NO Result in an impact in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

Justification:

3. ☐ YES ☐ NO Result in an impact in the consequences of a risk significant accident sequence?

Justification:

4. ☐ YES ☐ NO Result in an improvement in the capability of a fission product barrier?

Justification:

5. ☐ YES ☐ NO Result in an improvement in defense-in-depth capability? Examples include:
   a. Strengthen balance of accident prevention and mitigation
   b. Reduce reliance on programmatic activities
   c. Reduce probability of common-cause failures

Justification:

If ALL the responses are NO, AND Confidence is sufficient, issue or activity has NO IMPACT and screens out (**DROP**). **STOP.**

If ANY response is YES, continue on to Step 2 or develop a plan.

Figure 4-4 (Step 2 Safety Evaluation Questions)

Step 2: Screening on Minimal Impact (See Appendix C)

Does the proposed activity or issue:

1. ☐ YES ☐ NO Result in more than a minimal decrease in frequency of occurrence of a risk significant accident initiator?

Justification:

2. ☐ YES ☐ NO Result in more than a minimal improvement in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

Justification:

3. ☐ YES ☐ NO Result in more than a minimal decrease in the consequences of a risk significant accident sequence?

Justification:

4. ☐ YES ☐ NO Result in more than a minimal improvement in the capability of a fission product barrier?

Justification:

5. ☐ YES ☐ NO Result in more than a minimal improvement in defense-in-depth capability? Examples include:
   a. Strengthen balance of accident prevention and mitigation
   b. Reduce reliance on programmatic activities
   c. Reduce probability of common-cause failures

Justification:

If ALL the responses are NO, AND Confidence is Sufficient, issue or activity screens to Very Low priority. **STOP.**

If ANY response is YES, continue on to Step 3 or develop a plan.

Figure 4-5 (Safety Adverse Impact Considerations)

Does the proposed activity or issue:

1. ☐ YES ☐ NO Result in an adverse impact on reactor safety? Examples include:
   a. Increase in frequency of occurrence of a risk significant accident initiator
   b. Decrease in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?
   c. Increase in the consequences of a risk significant accident sequence?
   d. Decrease in the capability of a fission product barrier
   e. Increase in CDF of greater than 10^{-6}/year or LERF greater than 10^{-7}/year?

Justification:

Initial guidance for Step 3A is provided in Appendix E.

[Step 3B is under development but most likely will be a SAMA-like assessment.]

Figure 4-6 is a visual aid for viewing impacts and costs, as follows:

- Quadrant I addresses potential changes with an improvement in safety but with associated costs and would be subject to cost/benefit evaluation, preferably with some screening
- Quadrant II addresses potential changes with net savings and an improvement in safety
- Quadrant III has net savings (e.g., burden reduction) but may have some increase in risk. Here guidelines such as RG 1.174 would be used for such cases.
- Quadrant IV addresses potential changes with net costs and increase in risk, which should not be implemented, so an alternative should be identified or the issue dropped

The expectation is that the process used herein will focus on Quadrant I.

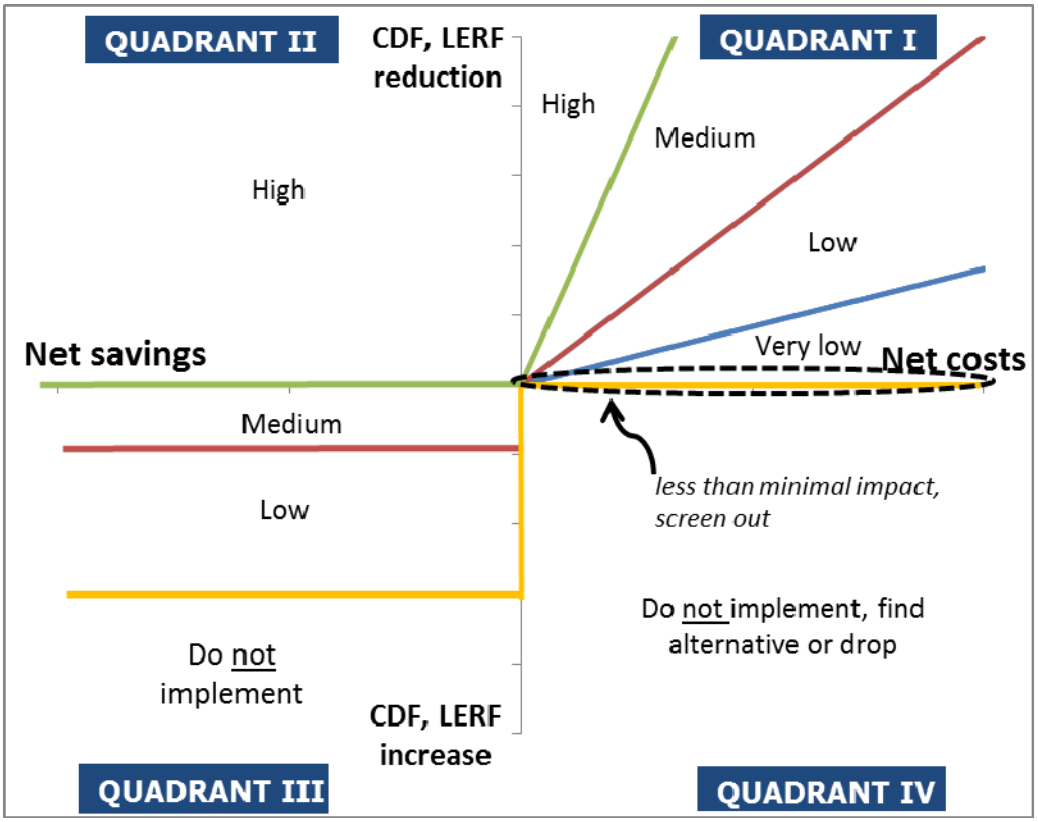

Figure 4-6: Cost and Impact

4.1.1 Important Notes on Safety Significance Determination Process

Note: Incomplete draft questions are provided in the main body and appendices to this pre-draft guidance.

Note: If there is a more than a minimal impact, a matrix similar to Table 4-1 is used to develop a safety significance ranking. The basis for the matrix is provided in Appendix D to this document. [The matrix will be the subject of table top exercises.]

Note: Placement of a potential action into the matrix if more than minimal is based on either the response to logical questions or "SAMA-like" results as appropriate to the potential action. (See below section for "types of models".)

Note: If NRC and/or Industry have developed a "generic" or plant-type cost-benefit analysis, or ranking, then one option involves adapting these analyses instead of using the guidance contained herein.

Note: An alternative which will be explored is to develop anchor points based on existing cost-benefit analyses. The anchor points would be placed into categories (high, medium, low and very low/minimal). Then a comparison of a specific issue's characteristics to these anchor points could be conducted. As noted the most appropriate approach will depend on the issue and the availability of information.

Note: On a plant-specific basis the P-S IDP will review the results. The P-S IDP process is in consonance with existing P-S IDPs, such as for Maintenance Rule (10 CFR 50.65) and 10 CFR 50.69.

Note: The GAET process is not yet developed or included. The expectation is the GAET process will be consistent with a Generic IDP process, with the following differences:

- The GAET will be establishing characterizations rather than rankings
- The GAET may or may not consider attributes other than public health and safety

4.1.2 Safety Progressive Screening and Evaluation Steps

A 3-step process is used. Section 4.1.3 provides common elements which should be considered for each step.

- Table 4-1 provides a matrix used in Step 3, and perhaps Step 2 (Appendix D provides the basis for the Table 4-1 Matrix.)
- Figure 4-3 provides screening questions for Step 1 (Appendix B provides guidance for Step 1)
- Figure 4-4 provides screening questions for Step 2 (Appendix C provides guidance for Step 2)

- Figure 4-5 provides questions for assessing potential adverse impacts, and can be used in any of the 3 steps
- Initial guidance for Step 3A is provided in Appendix E.

4.1.2.1 Generic Safety Assessment

The generic safety assessment starts with a specific issue (either current or future) and associated issue definition and success criteria. This is a precondition for starting the evaluation. In addition, available information is collected, including NRC and Industry information. Available cost-benefit analyses and SAMA-like analyses are also collected, as available.

There are two ways to use the process as follows:

- Direct use by the GAET
- Use by a separate team which would follow the process and develop an objective assessment which the GAET would then use to implement Figure 4-1.

The characteristics of the issue will determine the most efficient way. Considerations include complexity of an issue (s) and the potential desire to have refined analyses in advance of the GAET deliberations.

Note: The success criteria (SC) for a specific issue can range from a potential plant change (e.g. hardware, procedure change, training, staffing) to the conduct of an evaluation.

- For a potential plant change treat the assessment as if the plant change could impact safety/risk (This could include a change aimed at reducing risk (e.g. FLEX) or a change aimed at preventing or minimizing a potential increase in risk due to a future increase in hazard level or frequency (e.g. Cyber Attacks)
- For the conduct of an evaluation treat the assessment as if the evaluation could identify plant changes, which if implemented, could impact safety/risk (In the cost evaluation note that both evaluation costs and potential implementation costs will need to be estimated.)

Note: Although the expectation is that an issue and associated definition entering this process is intended to reduce risk/improve safety (noted as "+" in the figure), there is a potential for the SC to be adverse (noted as "-" in the figure) to safety/risk. The process addresses this possibility. If an adverse to safety impact is identified, there are alternative paths:

- Continue using the process and address in the overall assessment of benefit and cost (This may invoke guidance such as Regulatory Guide 1.174 and require a license amendment request. This is unlikely on a generic basis but is captured here as a precautionary measure.)

- Develop and implement a plan for interacting with the NRC whether the SC was established by NRC or Industry. A "plan" here means the approach to communicating with the NRC including, as appropriate, a recommended course of action.

Note: At any step in the process, except Step 3B, the GAET can continue to the next step if there is insufficient confidence in the assessment or develop a plan to gain the information needed to have sufficient confidence. The plan could include interaction with NRC, conduct of analyses, etc. This note applies on a plant-specific basis also.

Step 1: Does the potential action have any beneficial (reduction, "+") or adverse (increase, "-") effects on risk? (This is consistent with the 50.59 process – See Figures 4-3 and 4-5 and Appendix B.)

- If the answer is no beneficial effect on risk, then no further action is needed if there is sufficient confidence
- If there is an adverse effect on risk, then the evaluation process has two alternatives
  - Continue to Step 2 to refine the assessment OR
  - Provide feedback to NRC if the issue and success criteria were developed by NRC (If the SC was developed by Industry then the adverse impact can be assessed pursuant to a Regulatory Guide 1.174-type process or other relevant process.)
- If the answer is yes continue to Step 2

Note: This step is intended to screen issues which have no safety/risk benefit; but provide assurance that any beneficial or adverse effects are identified, if they exist. Implementation of this step could vary from extremely straightforward to transferring to the questions associated with Step 2 or transferring to either Step 3A or 3B.

Step 2: Does the potential action have more than a minimal effect on risk? (This is consistent with the 50.59 process, but adapted to address risk rather than being applied to the design and licensing basis safety analyses. – See Figures 4-4 and 4-5 and Appendix C)

- If the answer is no, and there is sufficient confidence,
  - Then the issue can be dropped (e.g., by an exemption request), if the impact is not adverse, OR
  - The issue can be assigned to the "minimal/very low" category, and its beneficial or adverse impacts noted, OR
  - The success criteria may be revisited to search for a smarter success criteria, i.e. an alternative (This outcome is included for potentially "risk significant" issues where the potential action (i.e. SC) is ineffective.)

- If the answer is yes, continue to Step 3A OR
- Develop a plan if confidence is insufficient

Step 3A: What is the risk significance of the issue being addressed and the potential benefits and adverse impacts as determined using a detailed breakdown of questions which focus on the relative risk of the issue being addressed and the relative impact of the potential action? Questions to address include:

What is the relative decrease in frequency of occurrence of a risk significant accident initiator?

What is the relative improvement in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

What is the relative decrease in the consequences of a risk significant accident sequence?

What is the relative improvement in the capability of a fission product barrier?

What is the relative improvement in defense-in-depth capability?

Examples include:

a. Strengthen balance of accident prevention and mitigation
b. Reduce reliance on programmatic activities
c. Reduce probability of common-cause failures

[Questions and guidance will be further developed during the piloting]
The outcomes are:

- High, Medium, Low, Very Low/Minimal ranking OR
- Continue to Step 3B OR
- Develop a plan

- If the outcome has high uncertainty, or confidence is insufficient, then there are alternatives
  - Alternative 1: Raise ranking 1 level
  - Alternative 2: Continue to Step 3B
  - Alternative 3: Develop a plan to obtain additional information needed to adequately evaluate the issue and potential change. This could include interactions with NRC.
- If the issue and/or potential action are not amenable to adequate assessment using qualitative means, then
  - Develop initial responses to all questions so as to support a more detailed assessment, AND
  - Continue to Step 3B

Based on Table 4-1, the following approximate, initial approach for adding impacts is established.

- Any high is a high
- 3 mediums is a high (3* (3E-5/3E-6) which is ~1E-4/1E-5): Based the range of medium to mid-range.
- 3 lows is a medium (3* (3E-6/3E-7)): See above
- 3 very lows is a low (3* (3E-7/3E-8)): See above
- 2 M plus 3L is a high (2*(3E-5/3E-6) + (3* (3E-6/3E-7)): See above

[The means of adding impacts will be determined during piloting.]

Step 3B: Using existing information ("SAMA-like") and new information/analyses (e.g. focused scope analyses), as needed, determine if outcome is H, M, L, VL/Minimal.

- Outcomes are:
    - High, Medium, Low, Very Low/Minimal ranking OR
    - Develop a plan, as discussed above

Note: Any existing cost-benefit analyses or anchor points could be used as input to this step in the prioritization process, if available. A process for use of such existing data, as well as database, could be developed to serve as reference points for generic characterization and plant-specific characterization.

4.1.2.2 Common Elements for Each Step

For each step above, common elements should be considered in the assessment. Note: These will be converted to a "checklist" to be used in documenting the evaluation. These common elements are the following:

1. Ensuring the issue and success criteria are well defined.

   Although the goal of the overall Industry process is to have clearly defined issues and success criteria, the actual assessment may indicate that additional definition is appropriate. In addition, if the assessment progresses to Steps 2 and 3, the actual conduct of the assessment may identify additional considerations not identified in the initial definition (s).

2. Being realistic where appropriate so as to not bias the rankings.

   The level of realism and level of analyses will vary depending on the issue. A pairwise comparison, GAET, P-S IDP and a matrix with wide ranges are included in the process to limit the potential impact of uncertainty, as noted next. Note that if the risk impact is exceedingly small or clearly large a bounding evaluation may suffice.

3. Considering Uncertainty and Sensitivity

   Although the characterization and prioritization matrix in Table 4-1 does not require quantitative risk measures, the matrix is based on relative risk and is consistent with the SDP process of Green, White, Yellow and Red. Thus each of the entries on current risk differs by about a factor of 10. This should address most concerns on uncertainty.

   As needed, uncertainty should be addressed by more refined analyses and sensitivity evaluations. The need for any such uncertainty analyses, or sensitivity analyses, will depend on the characteristics of an issue and proposed success criteria, as well as the potential change in ranking results.

4. Considering the Need for Additional Information

   There is the potential for the assessment of some issues that additional information will be needed, for example external flooding at some sites. For such issues existing NRC-Industry practices, including public meetings and interactions between Industry and NRC SMEs, should be used to enable the development of additional information. This may be a phased approach similar to that used for addressing Post-Fukushima external flooding and seismic NRC requests.

5. Using caution in identifying how, and how much, a potential action impacts risk

   Direct and indirect effects should be considered (e.g. FLEX and B.5.b affect more than external hazards and loss of large areas, respectively).
   Beneficial and adverse effects should be considered (e.g., replacing a small pump with a large pump could reduce the available margin of an emergency diesel generator (EDG); e.g., closing and depowering pressurizer power/pilot operated relief valves (PORV) block valves to prevent spurious operation could reduce effectiveness of feed and bleed).

6. Identifying commonalities with other issues

   The resolution of other issues could have a beneficial or adverse impact on the ranking of an issue. A pairwise comparison is included to support both a peer check on issue rankings as well as for support in identifying any commonalities. For example, implementation of FLEX impacts the potential benefits of future changes to the station blackout rule.

7. Considering the effectiveness of existing or planned programs and processes to address the underlying issue (e.g. Regulatory Oversight Program (ROP), Mitigating System Performance Index (MSPI) program, Maintenance Rule, Fire Protection Programs, etc.)

   Industry and NRC have many, sometimes overlapping, programs and processes which either could directly, or with modest changes, address the underlying issue versus development of a new program or the conduct of new analyses. To be effective such programs and processes would be expected to provide the information and actions needed to address the underlying issue. Such programs and processes could be applied to issues such as fitness for duty and cyber security, as well as other potential issues aimed at equipment availability/reliability and human and organizational performance.

8. Considering effectiveness of potential action

   An alternate, smarter action may be identified during the evaluation such that either the cost would be reduced and/or the risk further reduced compared to using the offered success criteria (potential action). This has been common in NFPA 805 projects.

4.1.2.3 Types of Models and Evaluation Tools

The models and evaluation tools available or achievable are extensive. The appropriate model/tool will depend on the issue. Models include:

1. Qualitative checklist (See Steps 1, 2 and 3A above)
2. Comparison to a previously ranked issue (s) –which is addressed by using a pairwise comparison
3. Review of Previous Studies (e.g. SAMA and Issue-specific cost-benefit evaluations)
4. Direct use of an existing PRA model
5. Adaptation of an existing PRA model
6. Development of a new PRA model (e.g. a focused scope assessment)
7. Direct, adaptive or new deterministic model, such as to characterize margin in system capability

4.1.3 Generic Safety Impact Examples

Examples are provided below to illustrate the approach to be used when the regulatory issue has generic safety implications across the industry. [In the final guidance document examples will address each step and the common elements discussed above. The actual examples will be established during piloting. Here shorter summary level examples are provided.]

Example 1 (Fitness for Duty (FFD)): Here, as examples, Step 1 "No impact" and Step 2 "More than Minimal" approaches are used. In addition, Step 3A is explored. [Note: This example may be completed as a part of the piloting process.]

Issue: NRC has an issue with current FFD requirements and is exploring changing requirements to reduce the potential risk associated with potential FFD issues.

NRC Success Criteria: The changes would require additional FFD testing and documentation.

Industry Costs and Reference Risk Level: Assume Industry has assessed the cost at ~$200K per year per plant, so for 10 years a total cost of $2M per plant. This implies the risk would need to be reduced by ~ 1E-5/1E-6 to 1E-6/1E-7 per year for CDF and LERF respectively and to be of Low (L) priority. (Note: Values are for illustration only.)

Existing Practices and Experience: Industry has extensive programs in place, and to date there is no evidence that safety has been adversely impacted as a result of FFD issues.

Step 1 (No Impact Assessment): This step screens for both beneficial and adverse effects as noted in Figures 4-3 and 4-5. For this example, assume there are no adverse safety impacts. Recall that the Step 1 screening process is not concerned with the magnitude of adverse/beneficial effects that are identified. Any change that adversely or beneficially affects risk is screened in. The magnitude of the effect (e.g., is the minimal increase standard met?) is considered in the evaluation in Step 2. Screening determinations are made based on the engineering/technical information supporting the potential action. The screening focus on basic functions, etc., ensures the essential distinction between no impact, minimal impact and more than minimal impact are addressed in Steps 2 and 3. Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse/beneficial effect on functions, methods of performing or controlling functions, or evaluations that demonstrate that intended functions will be accomplished may be used as basis for screening out the potential change.

The guidance and examples in Appendix B can be used to support this screening. As provided in Figure 4-3, the screening on no impact addresses the following (Note that example results are provided):
Does the proposed activity or issue:

1. ☐ **YES** ☐ NO Result in an impact on the frequency of occurrence of a risk significant accident initiator?

Justification: The answer is uncertain as humans can cause an accident initiator, so assume **YES**

2. ☐ **YES** ☐ NO Result in an impact in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

Justification: The answer is uncertain as humans can affect SSCs and FFD could affect human performance, so assume **YES**

3. ☐ YES ☐ **NO** Result in an impact in the consequences of a risk significant accident sequence?

Justification: It is difficult to envision how a FFD issue could impact consequences (no discernible trend or impact) and **NO** is appropriate. Recall that any "Yes" results in continuing to Step 2.

4. ☐ YES ☐ **NO** Result in an improvement in the capability of a fission product barrier?

Justification: It is difficult to envision how a FFD issue could impact a fission product barrier (no discernible trend or impact) and NO is appropriate.

5. ☐ YES ☐ **NO** Result in no improvement in defense-in-depth capability? Examples include:
   a. Strengthen balance of accident prevention and mitigation
   b. Reduce reliance on programmatic activities
   c. Reduce probability of common-cause failures

Justification: Assume **NO** since there is no discernible trend from the proposed action which would impact defense-in-depth capability not already captured in the first 4 screening questions.

Thus the evaluation would continue to Step 2.

Step 2 (More than Minimal Assessment): This step addresses the same possible impacts as above but applies more than minimal as the basis for screening rather than no impact. Rather than repeating the above questions using more than minimal impact in place of no impact consider the following:

- To be more than minimal the effect of a proposed activity must be discernible and attributable to the proposed activity in order to exceed the more than minimal decrease standard.
- An impact of delta CDF and LERF of less than 1E-6/1E-7 per year respectively is not more than minimal
- Industry and NRC have comprehensive programs to monitor plant performance (Maintenance Rule, MSPI, ROP, accident precursor program, and others), and to date FFD issues have not been an issue. Further these programs are able to provide for corrective action before a safety significant trend could occur in the future

Given the above summary the GAET could conclude that there is no more than a minimal impact and that the proposed action has a ranking of VL. As an alternative, the GAET could continue to Step 3A and using Table 4-1 consider how much of an impact the proposed action would need to have in order to be ranked higher than VL. Consider for example:

- If the current risk associated with FFD is "Green", then any proposed action would be VL
- If the current risk associated with FFD is "White", then the highest priority would be L

Example 2 (Cyber Security): Here again Steps 1, 2 and 3A are examined

Issue: NRC has an issue with current cyber security requirements and is exploring changes to existing requirements and guidance to reduce the risk associated with potential cyber attacks.

NRC Success Criteria: The changes would require additional isolation devices, increased equipment diversity and so forth.

Industry Costs and Reference Risk Level: Assume Industry has assessed the 10-year total cost (plant changes, O&M, etc.) at $20M per plant. This implies the risk would need to be reduced by ~ 1E-4/1E-5 to 1E-5/1E-6 per year for CDF and LERF respectively and be of Medium (M) priority. (Note: Values are for illustration only.)

Existing practices and experience: Industry has extensive programs in place and to date there is no evidence that safety has been adversely impacted as a result of cyber security issues. Industry continues to address using Industry developed programs and practices.

Step 1 (No Impact Assessment): Assume for this example that there could be an impact. NRC and Industry concerns include digital I&C issues which could cause a plant accident initiator and/or impact the actuation and control of prevention and mitigation systems or operator actions. Assume the potential impacts are limited to plant transients, e.g. turbine trips, loss of feedwater, loss of offsite power. Potential passive failures would not be impacted, e.g. potential loss of primary, secondary or containment integrity.

Step 2 (More than Minimal Impact Assessment): Assume for this example that demonstrating less than minimal impact is not possible without using Step 3A and Table 4-1.

Step 3A: Here consider that transients including loss of offsite power (LOOP) on a generic basis contribute ~1E-5/1E-6 to 1E-6/1E-7 per year for CDF and LERF, respectively without considering future cyber attacks. Thus the current risk level from Table 4-1 is White (Low) to Green (VL). Consider that unmitigated cyber attacks could increase this risk by a factor of 3. This is a sample value, but for this example assume the value is based on the expert judgment and analyses of SMEs. So the future risk could be in the Yellow category (Medium) as an upper bound, or the White Category (L) as a lower bound. Further consider that Industry plans would be effective in preventing this increase and be less costly than NRC identified generic requirements. Given this belief the NRC potential action would be ranked as VL or L. This is an example of a "smarter" solution. Clearly for issues such as cyber attacks subject matter experts (SMEs) must be able to work with safety experts to determine the potential for risk changes, on an approximate basis.

Example 3 (Proposed Changes to ISI)
Issue: NRC has proposed changes to requirements for ISI which Industry experts have determined will have no discernible impact.
NRC Success Criteria: The change is to require use of a revised ASME Standard which has been adopted by new plants.
Industry Costs and Reference Risk Level: Industry costs are estimated at $5M in total per plant. The risk associated with current practices is insignificant based on Industry analyses. In addition there is no identified quantitative basis for concluding risk would be discernibly impacted.
Assessment of More than Minimal Impact on accident initiator frequency: The proposed activity has a negligible effect on the frequency of occurrence of a risk significant accident initiator. A negligible effect on the frequency of occurrence exists because the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e., there is no clear trend toward decreasing the frequency).
Assessment of More than Minimal impact on other screening questions: Assume the same outcome and rational as above.
Example 4 (FLEX)

Issue: Industry and NRC have reached agreement on developing and installing FLEX equipment and processes both onsite and at two central locations. This decision was reached on the basis of lessons learned from Fukushima and involved NRC and Industry experts.

Success Criteria: Implement FLEX per agreed upon NEI guidance

Generic Assessment: The issue and potential actions should be assumed to have more than minimal risk significance on a generic basis and perhaps on a plant-specific basis. The reason for this outcome is the extensive interactions between Industry and NRC experts. FLEX addresses the following key safety functions:

extended loss of offsite and onsite power; loss of the ultimate heat sink; and primary system and containment integrity for these potential challenges. The FLEX approach has three phases: an early phase where installed equipment, possibly enhanced, is used to provide core cooling; an intermediate phase where onsite portable equipment could be used to provide core cooling; and a longer term phase where equipment stored offsite could be used to provide for core cooling. FLEX thus can address potential dependent failures caused by an external hazard. In addition FLEX improves upon the ability to respond to other challenges. Further defense in depth is improved for what have referred to as the "unknown unknowns and the known possible challenges".

Plant-Specific Assessment: Step 3 can address a ranking which can be plant-specific on the basis of plant design and location, including:

- Hazard level
- Design capability and margin
- Diversity and redundancy of mitigation systems
- Operator performance

Simplified examples are provided below and candidate rankings are provided. The actual evaluation is more involved but follows these fundamental elements.

Plant X evaluation: This plant is an advanced light water reactor (ALWR) with passive cooling systems and "investment protection" active systems. Passive systems can maintain a safe condition for up to 72 hours and the design has connection points, which could be used if needed to add water, provide charging to batteries, etc. The plants under construction are in low seismicity areas and the design meets all recent requirements for external hazards.

Assessment for Key Elements is as follows:

- Hazard level: Low especially compared to the design basis of the plant
- Design capability and margin: Very high and considerable margin as design basis addressed sites with higher hazard levels
- Diversity and redundancy of mitigation systems: Combination of passive and active systems, whereby active systems are not needed for at least 72 hours
- Operator performance: Passive systems do not require operator actions

Outcome: For this plant type and location the ranking was determined to be very low and already addressed the first two phases and most of the third phase of the Industry FLEX approach. Consistent with Industry FLEX initiative this plant type will provide for phase 3 use of offsite portable equipment.

Plant Y evaluation: This plant has three safety trains and includes B.5.b capability. The cooling systems are active. The plant is in a low seismicity area and the design meets the intent of all recent requirements for external hazards. In addition low leakage reactor coolant pumps (RCP) seals have been installed.

Assessment for Key Elements is as follows:

- Hazard level: Low especially compared to the design basis of the plant as the original plant design basis addressed higher seismicity sites
- Design capability and margin: Very high and considerable margin as design basis addressed sites with higher hazard levels
- Diversity and redundancy of mitigation systems: One more train than a typical operating plant and with low leakage RCP seals.
- Operator performance: Given the design basis local manual actions are not needed for addressing design basis external hazards.

Outcome: For this plant type and location the ranking was determined to be low. Consistent with Industry FLEX initiative this plant type will, however, address all 3 phases.

Plant Z evaluation: This plant has two safety trains and includes B.5.b capability. The cooling systems are active. The plant is in a moderate seismicity area, where the uncertainty is not low. The design basis for external hazards is lower than would be required to meet the intent of all recent requirements. In addition low leakage reactor coolant pumps (RCP) seals have not been installed.

Assessment for Key Elements is as follows:

- Hazard level: Moderate compared to the above examples, with less margin to address uncertainties
- Design capability and margin: Margin to the current design basis, but not extensive
- Diversity and redundancy of mitigation systems: Typical with less spatial separation than more recent plants
- Operator performance: Local manual actions are needed for addressing certain design basis external hazards, such as external flooding.

Outcome: For this plant type and location the ranking was determined to be medium. Consistent with Industry FLEX initiative this plant type will address all 3 phases.

Example 5 (SBO Rulemaking)

Issue: NRC has initiated rulemaking to reassess station blackout (SBO) risk and to determine appropriate regulatory action.

Success Criteria: Cost effective changes or no changes on a plant-specific basis

Assessment Considerations: The risk attributable to SBO varies among plants on the basis of considerations of design, locations, etc. As the rulemaking is an "evaluation" rather than a potential plant change the potential risk significance can be bounded by considering the risk attributable to SBO sequences. This would need to include potential sequences other than grid initiated loss of offsite power (LOOP). These would include:

- Grid initiated
- Plant initiated (e.g. switchyard)
- Internal hazard induced (e.g. internal flooding and fire)
- External hazard induced

Depending on the plant and the availability of information determining that the risk is less than minimal could be challenging. This example is not developed further herein, as rulemaking has been initiated.

Example 6 (Any proposed change)
Issue: NRC is considering changes which are believed to reduce the frequency of risk significant initiating events. These changes include formal, logical assessment of potential causes of initiating events, quantification of associated frequencies and evaluation of alternate maintenance practices.

Success Criteria: Cost effective changes or no changes on a plant-specific basis

Evaluation: Based on operating experience and available risk information, the change in frequency of occurrence of an initiating event is calculated to support the evaluation of the proposed activity. If the proposed activity would not meet any (only one must be met) of the below criteria, the change is considered to involve more than a minimal decrease:

- The affected initiating events contribute less than 1E-6/year and 1E-7/year for CDF and LERF, respectively, OR
- The affected initiating events contribute less than 1% of total CDF/LERF (consistent with RG 1.174) OR
- The change would result in a less than 10% change in frequency

If the increase is more than minimal, Step 3 can be used to assign to a priority category.

4.1.4 Plant-Specific Assessment

The process used for plant-specific assessment and prioritization follows closely the assessment of generic issues. The key difference is that the plant design characteristics, site considerations, and plant-specific risk insights are considered. For example, the prioritization of station blackout related regulatory issues can be expected to vary from single unit sites to multi-unit sites with diesel-generator cross-tie and alternate AC power capability, all other considerations being equal. Likewise, there could be specific aspects of a plant design where certain proposed plant-initiated modifications would have greater impact than throughout the industry as a whole, for example, flooding mitigation enhancements at some sites.

4.2 Security

[To be developed following pilots on safety.]

4.3 Plant Personnel Safety

[To be developed following pilots on safety.]

4.4 External Impacts

[To be developed following pilots on safety.]

4.5Aggregating Rankings

[To be developed following pilots on safety.]

4.6 Benefit-Cost Assessment

[To be developed following pilots on safety.]

4.7 Generic Assessment Evaluation Team

[To be developed following pilots on safety.]

4.8 Integrated Decision Making Panel

[To be developed following pilots on safety.]

Table 4-1: Matrix by Current Risk and Potential Impact						
UB is upper bound of the risk range; Mid is "mid-range" (0.3 times UB); LB is factor of 10 lower than UB						
Current Risk associated with Issue *Note: Address the specific issue first; then assess impacts on other risk contributors potentially impacted*	**Potential Impact of Action (Reduction in Risk)**					
	None	Very Small/Minimal	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome Note: Quantitative values are delta CDF/LERF					
Green (VL) UB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	Maximum reduction is 1E-6/1E-7
Green (VL) Mid	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	No change from upper bound
Green (VL) LB	< VL/Green	< VL/Green	< VL/Green	< VL/Green	< VL/Green	No change from upper bound
White (L) UB	VL/Green	L/White	L/White	L/White	L/White	Maximum reduction is 1E-5/1E-6
White (L) Mid	VL/Green	*VL/Green*	L/White	L/White	L/White	Only change is 25% Category
White (L) LB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	All Green versus White above 25% category
Yellow (M) UB	VL/Green	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Maximum reduction is 1E-4/1E-5
Yellow (M) Mid	VL/Green	*L/White*	M/Yellow	M/Yellow	M/Yellow	Only change is 25% Category
Yellow (M) LB	VL/Green	L/White	L/White	L/White	L/White	All but 0% and 25% are near breakpoint of L (White) and M (Yellow)
Red (H) UB	?	H/Red	H/Red	H/Red	H/Red	
Red (H) Mid	?	H/Red	H/Red	H/Red	H/Red	No change
Red (H) LB	?	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Addressed by upper bound Yellow

5 INTEGRATED IMPLEMENTATION SCHEDULING

[To be developed following pilot.]

6 REASSESSMENT, REVIEW AND RECONCILIATION

[To be developed following pilot].

7 DOCUMENTATION

[To be developed following pilot.]

8 REFERENCES

1. NSAC-90, "Developing a Living Schedule, Fundamental Concepts," Final Report, Delian Corporation, August 1985.
2. 57 FR 43886, NRC Policy Statement on Integrated Schedules, published September 23, 1992.
3. SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," October 5, 2012, and associated SRM-12-0137, March 12, 2013.
4. COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency," February 6, 2013.

APPENDIX A BACKGROUND

1.0 Early NRC and Industry Initiatives

In the mid-1980s, the Electric Power Research Institute (EPRI) issued NSAC-90 [1] and NSAC-102 [2]. NSAC-90 identified procedures and techniques 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, 4]. 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 scheduler 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.

2.0 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) [5]. 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 [6]. 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 [7]. 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 [7], 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."

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

3.1 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 [8] and NUMARC 93-01 [9].

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 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 were factored into the framework and processes discussed in this guidance document.

3.2 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 [10].

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 have been factored into the guidance discussed in this document.

3.3 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 [11] 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 [12] 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.

NUREG/BR-0058 and NUREG-1409 were considered in this document.

3.4 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 [13]. 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 document, 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.

The GSI approach was considered in developing the guidance contained herein.

3.5 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 [14]. 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.

SAMA-like analyses are explicitly addressed in the guidance contained in this document.

3.6 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.

The SDP process was explicitly considered in developing the guidance, 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.

4. References for Attachment A

1. NSAC-90, "Developing a Living Schedule, Fundamental Concepts," Final Report, Delian Corporation, August 1985.

2. NSAC-102, "PRA Information Banks to Assist in Developing Living Schedules, Basic Considerations," Final Report, Delian Corporation, April 1986.

3. 57 FR 43886, NRC Policy Statement on Integrated Schedules, published September 23, 1992.

4. SECY-92-023, "Final Policy Statement on Integrated Schedules," dated January 21, 1992, and associated SRM-92-023, dated March 11, 1992.

5. SECY-11-0032, "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," March 2, 2011, and associated SRM-11-0032, October 11, 2011.

6. COMGEA-12-0001/COMWDM-12-0002, "Proposed Initiative to Improve Nuclear Safety and Regulatory Efficiency," February 6, 2013.

7. SECY-12-0137, "Implementation of the Cumulative Effects of Regulation Process Changes," October 5, 2012, and associated SRM-12-0137, March 12, 2013.

8. Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 3, US Nuclear Regulatory Commission, May 2012.

9. NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 4A, Nuclear Energy Institute, April 2011.

10. NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," Rev. 0, Nuclear Energy Institute, July 2005.

11. NUREG-1409, "Backfitting Guidelines," US Nuclear Regulatory Commission, July 1990.

12. NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, USNRC, September 2004.

13. NUREG-0933, "A Prioritization of Generic Safety Issues," Supplement 34, US Nuclear Regulatory Commission, December 2011.

14. NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," US Nuclear Regulatory Commission, May 1996.

APPENDIX B GUIDANCE FOR STEP 1 (SCREENING FOR BENEFICIAL OR ADVERSE EFFECTS)

The evaluation should screen for both beneficial and adverse effects as noted in Figures 4-3 and 4-5 in the main body of this document.

Thus a change that decreases/increases the reliability of a function whose failure could initiate an accident would be considered to adversely/beneficially affect risk. Similarly, changes that would introduce a new type of accident or malfunction, or eliminate a type of accident, would screen in.

If a change has both beneficial and adverse effects, the change should be screened in.

The Step 1 screening process is not concerned with the magnitude of adverse/beneficial effects that are identified. Any change that adversely or beneficially affects risk is screened in. The magnitude of the effect (e.g., is the minimal increase standard met?) is considered in the more detailed evaluation in Step 2.

Screening determinations are made based on the engineering/technical information supporting the potential action. The screening focus on functions, etc., ensures the essential distinction between no impact, minimal impact and more than minimal impact addressed in Steps 2 and 3. Technical/engineering information, e.g., design evaluations, etc., that demonstrates changes have no adverse/beneficial effect on functions, methods of performing or controlling functions, or evaluations that demonstrate that intended functions will be accomplished may be used as basis for screening out the potential change.

The guidance and examples here can be used to support this screening. As provided in Figure 4-3, the screening on no impact addresses the following:

Does the proposed activity or issue:

1. ☐ YES ☐ NO Result in an impact on the frequency of occurrence of a risk significant accident initiator?

Justification:

2. ☐ YES ☐ NO Result in an impact in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

Justification:

3. ☐ YES ☐ NO Result in an impact in the consequences of a risk significant accident sequence?

Justification:

4. ☐ YES ☐ NO Result in an improvement in the capability of a fission product barrier?

Justification:

5. ☐ YES ☐ NO Result in an improvement in defense-in-depth capability? Examples include:

    d. Strengthen balance of accident prevention and mitigation
    e. Reduce reliance on programmatic activities
    f. Reduce probability of common-cause failures

Justification:

APPENDIX C GUIDANCE FOR STEP 2 (MORE THAN MINIMAL)

Recall that the Step 2 Screening in Figure 4-4 of the main body of this document includes:

Does the proposed activity or issue:

1. ☐ YES ☐ NO Result in more than a minimal decrease in frequency of occurrence of a risk significant accident initiator?

Justification:

2. ☐ YES ☐ NO Result in more than a minimal improvement in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

Justification:

3. ☐ YES ☐ NO Result in more than a minimal decrease in the consequences of a risk significant accident sequence?

Justification:

4. ☐ YES ☐ NO Result in more than a minimal improvement in the capability of a fission product barrier?

Justification:

5. ☐ YES ☐ NO Result in more than a minimal improvement in defense-in-depth capability? Examples include:

   g. Strengthen balance of accident prevention and mitigation
   h. Reduce reliance on programmatic activities
   i. Reduce probability of common-cause failures

Justification:

If ALL the responses are NO, issue or activity screens to MINIMAL IMPACT.

If ANY response is YES, continue on to Step 3.

More than Minimal Effect on Risk Guidance

Note: In the final implementation guidance document we envision the following: A process flow diagram showing how we do these screenings; then for each block or question, guidance like we have here; then the actual checklist template; flowing from step 1 through the final step; so, we have them all in one appendix.

Question 1: Does the Activity Result in More Than a Minimal Decrease in the Frequency of a Risk Significant Accident Initiator?

In answering this question, the first step is to identify the risk significant accident initiators that have been evaluated that could be affected by the proposed activity.

For regulatory initiated actions, this should have been determined on a generic basis by NRC.

Then a determination should be made as to whether the frequency of these accident initiators occurring would be more than minimally decreased. Accidents initiators can be divided into categories, whether for at power or low power shutdown conditions, for example:

Accident Initiator Categories (Representative)	Risk Significant?	More than Minimal Decrease or Adverse?
Transients initiated by frontline systems		
Transients initiated by support systems		
Primary system integrity loss (e.g. SGTR, RCP seal LOCA, LOCA)		
Secondary system integrity loss		
Internal flooding		
Internal fires		
Earthquakes		
External flooding		
Tornados and High Winds		
Other External Hazards		

Risk Significance: Risk Significance should be based on:

- The definition used in the PRA Standard, OR
- Matrix benchmarks in Table 4-1, which are based on SDP risk significance, THUS, accident initiators that are not risk significant, i.e. minimal or less than minimal, are those:
    - Contributing less than 1E-6/year and 1E-7/year for CDF and LERF, respectively (Based on SDP) OR
    - Contributing less than 1% of total CDF/LERF (consistent with RG 1.174) OR
    - Contributing to a less than 10% change in frequency (as this is insignificant and consistent with 50.59 guidance)
    -

External Hazards: Practically, external hazard frequencies cannot be reduced or increased by a plant initiated or NRC initiated change. However, the frequency and/or severity might be changed for certain external hazards (such as external flooding) with changes beyond the nuclear power plant site. For example strengthening a dam could reduce the frequency/severity of an external flood which could affect the nuclear power plant site. Such changes can be considered in this process if under the control of the licensee. Otherwise changes related to external hazards will be considered in the second question.

Considerations for changes to accident initiator frequencies: The frequency of accident initiators can be changed in several ways, such as:

Considerations	Potential Action Effect?	More than Minimal or Adverse?
Changes in maintenance, training		
Changes in specific SSCs (e.g., installing a more reliable component)		
Changes in materials		
Equipment replacements to address age related degradation		
Changes in redundancy and diversity		
Additional of equipment		
Changes in operating practices		

Industry, NRC and each plant have programs and practices for managing accident initiator frequency. Existing programs and practices will support determination of changes in frequency (10 CFR 50.59, NFPA-805, age management programs, piping integrity programs, etc.).

Reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of a risk significant accident initiator would more than minimally decreased as a result of implementing a proposed activity. A large body of knowledge has been developed in the area of accident frequency and risk significant sequences through plant-specific and generic studies. This knowledge, where applicable, should be used in determining what constitutes more than a minimal decrease in the frequency of occurrence. The effect of a proposed activity on the frequency of a risk significant accident initiator must be discernible and attributable to the proposed activity in order to exceed the more than minimal decrease standard.

Examples: The following are examples where there is not more than a minimal decrease in the frequency of occurrence of a risk significant accident initiator.

Example 1

The proposed activity has a negligible effect on the frequency of occurrence of a risk significant accident initiator. A negligible effect on the frequency of occurrence exists when the change in frequency is so small or the uncertainties in determining whether a change in frequency has occurred are such that it cannot be reasonably concluded that the frequency has actually changed (i.e., there is no clear trend toward decreasing the frequency). An example could be a process change which cannot be demonstrated to have a positive impact, e.g. implementation of a new ASME code on ISI.

Example 2

The change in frequency of occurrence is calculated to support the evaluation of the proposed activity, and one of the following criteria is met:

- Those accident initiators contributing less than 1E-6/year and 1E-7/year for CDF and LERF, respectively, OR
- Those accident initiators contributing less than 1% of total CDF/LERF (consistent with RG 1.174) OR
- When the calculated change in frequency is less than 10%

If the proposed activity would not meet any of the above criteria, the change is considered to involve more than a minimal decrease.

Question 2: Does the Activity Result in more than a minimal improvement in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard?

This includes the reactivity control function, so anticipated transients without scram (ATWS) is addressed here, as ATWS is not an accident initiator but instead an accident sequence. In answering this question, the first step is to identify the risk significant SSCs and human actions that have been evaluated that could be affected by the proposed activity.

- For regulatory initiated actions, this may have been determined on a generic basis by NRC. If not guidance herein will develop this information.
- Then a determination should be made as to whether availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard would be more than minimally decreased.

Similar to accident initiators the availability, reliability, or capability of SSCs and personnel can be changed in several ways, such as:

Considerations	Potential Action Effect?	More than Minimal or Adverse?
Changes in maintenance, testing, training		
Changes in specific SSCs (e.g., installing a more reliable component)		
Changes in materials		
Equipment replacements to address age related degradation		
Changes in redundancy and diversity		
Additional of equipment		
Strengthening of equipment		
Moving equipment (to reduce the impacts of spatial events)		
Eliminating the need for recovery action (RA)		

Improving performance shaping factor related to human performance		
Changes in operating practices		

Industry, NRC and each plant have programs and practices for managing availability, reliability, capacity and human performance (A/R/C/H). Existing programs and practices will support determination of minor changes in A/R/C/H (10 CFR 50.59, NFPA-805, age management programs, piping integrity programs, etc.). Potentially major changes (such as changes in redundancy and diversity, additional equipment, strengthening equipment, moving equipment, eliminating RAs and improving performance shaping factors) will require more detailed evaluations.

Risk Significance: Risk Significance should be based on:

- The definition used in the PRA Standard OR
- Matrix benchmarks in Table 4-1, which are based on SDP risk significance
- THUS SSCs/Human actions that are not risk significant, i.e. minimal or less than minimal, are those:
    - Contributing less than 1E-6/year and 1E-7/year for CDF and LERF, respectively, *unless* the issue being addressed could increase risk above these values, OR
    - Contributing less than 1% of total CDF/LERF (consistent with RG 1.174), *unless* the issue being addressed could increase risk above these values, OR
    - The potential change would result in less than a 10% change in likelihood of failure (availability, reliability, capability, personnel performance), as such a change is insignificant and is consistent with 50.59 guidance

The term "risk significant" refers to the structures, systems and components (SSCs) performing risk significant functions, including nonsafety-related and safety-related SSCs, and human performance.

In determining whether there is more than a minimal decrease, the first step is to determine what SSCs and human actions are affected by the proposed activity. Next, the effects of the proposed activity should be determined. This evaluation should include both direct and indirect effects.

Direct effects are those where the proposed activity affects the issue (e.g., a motor change on a pump or changing the mounting of an electrical cabinet). Indirect effects are those where the proposed activity could affect other risk contributors.

After determining the effect of the proposed activity on the risk significant SSCs and human actions, a determination is made of whether the likelihood of failure has decreased more than minimally. Qualitative engineering judgment and/or an industry precedent is typically used in 10CFR50.59 evaluations and can be used here to determine if there is more than a minimal decrease in the failure probability could occur.

An appropriate calculation can be used to demonstrate the change in likelihood in a quantitative sense, if available and practical. The effect of a proposed activity on the failure probability must be discernible and attributable to the proposed activity in order to exceed the more than minimal decrease standard.

A proposed activity is considered to have a negligible effect on the likelihood of failure when a change in likelihood is so small or the uncertainties in determining whether a change in likelihood has occurred are such that it cannot be reasonably concluded that the likelihood has actually changed (i.e., there is no clear trend toward decreasing the likelihood). A proposed activity that has a negligible effect satisfies the minimal increase standard.

Potential SSC changes, such as increased structural capacity, to address earthquakes, tornadoes and other natural phenomena should also be treated as potentially affecting the likelihood of failure.

Examples: Examples below illustrate cases where there would/would not be more than a minimal increase in the likelihood of occurrence of a malfunction of a risk significant SSC/human action. [**Note:** The conclusions reached here may not be accurate as these examples are intended to illustrate the process.]

Example 1 (FLEX) – See main body of report

Example 2 (SBO Rulemaking) – See main body of report.

Question 3: Does the Activity Result in more than a minimal decrease in the consequences of a risk significant accident sequence?

In answering this question, the first step is to identify the risk significant sequences that have been evaluated that could be affected by the proposed activity.

- For regulatory initiated actions, this may be determined on a generic basis by NRC. If not this information will need to be developed.

- Then a determination should be made as to whether the consequences would be more than minimally decreased.

Risk Significance: Risk significance should be based on the matrix benchmarks, which are based on SDP risk significance, THUS, accident sequences, in total, that are not risk significant, i.e. minimal or less than minimal

- Are those contributing less than 1E-6/year and 1E-7/year for CDF and LERF, respectively OR
- Are those contributing less than 1% of total CDF/LERF (consistent with RG 1.174) OR
- Which the potential change results in less than 10% change in consequences

In determining if there is more than a minimal decrease in consequences, the first step is to determine which accidents may have their radiological consequences affected as a direct result of the proposed activity. Examples of questions that assist in this determination are:

(1) Will the proposed activity change, improve the effectiveness of an action?

(2) Will the proposed activity play a direct role in mitigating the radiological consequences?

In lieu of dose the following can be applied:

Containment Bypass

- Could the proposed action result in a more than minimal decrease in the frequency of an ISLOCA event?
- Could the proposed action provide a more than minimal improvement in the level of mitigation of an ISLOCA event?
- Could the action result in a more than minimal improvement in the ability isolate a faulted steam generator following a steam generator tube rupture event?

Containment Isolation and Capacity

- Could the proposed action result in a more than minimal improvement in containment isolation for containment penetrations that are:

• Directly connected to containment atmosphere, and
• > 2" in diameter, and
• Not locked closed or only locally operated?

- Could the proposed action result is a more than minimal improvement in containment isolation for containment penetrations that are:

• Part of the reactor coolant system pressure boundary, and
• > 3/8" in diameter, and
• Not locked closed or only locally operated?

Early Hydrogen Burns

- Could the proposed action result in a more than minimal improvement in operation of hydrogen igniters in ice condenser and Mark III containments?

Long-Term Containment Integrity
- Could the proposed action result in a more than minimal improvement in a system function that is not considered in CDF and LERF, but would be the only means for preserving long-term containment integrity post-core damage (e.g., containment heat removal)?

Emergency Planning effectiveness (to be developed)

Question 4: Does the Activity Result in more than a minimal improvement in the capability of a fission product barrier?

This evaluation focuses on the fission product barriers—fuel cladding, reactor coolant system boundary and containment. Guidance for applying this criterion is under development.

Question 5: Later

Question 6: Later

APPENDIX D BASIS FOR MATRIX

[NOTE: Will be completed during pilot activity. Below is working copy.]

Purpose, Scope and Intended Use of Appendix

Provide a summary of the basis for calibrating the prioritization of safety significance.

The calibration does not yet address defense in depth or safety margin.

Exercise in using SDP Baseline

An exercise was conducted to examine calibrating a "checklist" to probe its use and to address the impacts of a potential action on more than the direct objective of the potential action. First a very simple example based on EPRI RI ISI breakdown on event categories was used. Instead of number of trains available reduction in risk as measured by CDF and LERF was used. Then exercises were conducted for seismic and FLEX. Sample values for CDF and LERF were used.

Below are some simple quantitative table top examples.

- Table 1 is a base case to explore adapting the EPRI RI ISI process and examine relative ranking (There are notes and thoughts included in the table as a result of the exercise).
- Table 2 addresses seismic
- Table 3 addresses FLEX
- Table 4 applies the results of the exercises using the SDP concept explicitly.
- Thus Table 4 could be used to support a checklist and the associated lower level questions. Also if quantitative analyses are conducted then the results could be placed into the associated priority "bin", established by
    - "Current Risk"
    - "Delta Risk"

Percent changes could be replaced with a scale of 1 to X e.g., but 1 to X would still need some relative basis (factor or %).

Lessons and Considerations from Exercises

Lesson 1: The exercises provided in Tables 1-3 were useful in considering a blend of the EPRI RI ISI approach and relative change in risk, but is overly restrictive and requires some baseline risk by initiating event category. The factor/% change however is promising.

Lesson 2: Table 4 uses the SDP concept directly plus a few bins on relative impact of the potential action. It supports calibrating a checklist. Also, the impact of varying the values in the "SDP ranges" from high to middle to low is not significant. If the user decides the outcome of using the upper value of the range is not desirable then more refined analyses could be conducted.

A pairwise comparison could be conducted as an intermediate check, and then the IDP.

Consideration 1: The keys to robustness (while being progressive, straightforward, transparent, etc.) are:

- Understanding the baseline risk; and this could be addressed on a relative basis also (as baseline risk directly influences the ranking). Baseline risk is the risk of the current situation or future situation if an action is not taken.
- Impact of action on baseline risk (as the impact directly influences the ranking)

Robustness is intended to result in not only appropriate results but repeatability.

Consideration 2: Uncertainties must be considered for baseline risk and the impact of action.

The broad binning approach is intended to address uncertainty, and may introduce some conservatism. Conservatism can be addressed with further refinements as appropriate.

Consideration 3: The key uncertainty could be the baseline risk (e.g. external flooding, internal fire, etc.). NRC and Industry have considerable experience in judging the potential impact of an action. Consider the following simple examples:

- External Flooding: If the action is to meet the intent of the requirements used for ALWRs, external flooding risk is "negligible" for ALWRs; but what is the baseline for some operating plants, etc.?
- Seismic: Assume there is sufficient evidence (NRC, IPEEE, etc.) to support CDF/LERF < 1E-4/1E-5; so if the action is to strive for 1E-5/1E-6 (e.g. a

PGA twice the current 50-50 fragility PGA), then the maximum risk reduction is 9E-5/9E-6, which would be the high end of medium (essentially High)
  - But if the actual current CDF/LERF are 2E-5/2E-6, the risk reduction is 1E-5/1E-6 (Low)

Consideration 4: The calibration must be supported with a progressive approach which uses a process (questions, analyses, etc.) which allows for placement of an issue/potential actions into a bin with a robust basis.

Adding Impacts

Based on Table 1, the following approximate, initial approach at adding impacts is possible, but needs to be considered further:

- Any high is a high
- 3 mediums is a high (3* (3E-5/3E-6) ~1E-4/1E-5): Biased the range of medium to the lower range. Given uncertainty really should not matter.
- 3 lows is a medium (3* (3E-6/3E-7)): See above
- 3 very lows is a low (3* (3E-7/3E-8)): see above
- 2 M plus 3L is a H (2*(3E-5/3E-6) + (3* (3E-6/3E-7)): See above

These can be refined based on Table 4.

Summary

A progressive approach needs to be calibrated. A combination of the SDP concept and relative impact of a potential action can meet this need.

Table 5 provides the results of Table 4 without the numbers. Need to explore this further as a part of further guidance development, including:

- Structure (Words for Green, White, Yellow, Red) such as
  - Requires multiple failures or a hazard which is not credible (versus Green)
  - Need to think some more on this.
- Footnotes, etc.
- Actually discussing the progression process and use of all available information
  - NRC studies
  - Industry studies

- SAMAs
- Etc.

Table 1: Baseline Experimentation (Comment: Too many factors; see notes)									
Initiating event category (frequency range) (CDF-LERF Baseline)	Factor/% Change in IE Frequency-Prevention-Mitigation Availability/Reliability (Bounding)								
	F0	F1	F5	F6	F7	F8	F2	F3	F4
	Keep	Combine with F2 >0% <25%		Combine with F5 and F7 50% to 90%		Keep >90%		Combine with F4 25% to 50%	
	1 (0%)	1.1 (10%)	3 (67%)	10 (90%)	30 (97%)	100 (99%)	1.3 (23%)	1.6 (37%)	2 (50%)
	(Ranking/Delta)								
Anticipated (0.1 to 1) (2E-5/ 2E-6)	VL (no change)	L 1.8E-6 /1.8E-7	L-M 1.3E-5 /1.3E-6	L-M 1.8E-5 /1.8E-6	L-M 1.9E-5 /1.9E-6	L-M 2E-5 /2E-6	L 4.6E-6 /4.6E-7	L 7.5E-6 /7.5E-7	L 1E-5 /1E-6
Infrequent (0.01 to 0.1) (2E-5/ 2E-6)	VL (no change)	L 1.8E-6 /1.8E-7	L-M 1.3E-5 /1.3E-6	L-M 1.8E-5 /1.8E-6	L-M 1.9E-5 /1.9E-6	L-M 2E-5 /2E-6	L 4.6E-6 /4.6E-7	L 7.5E-6 /7.5E-7	L 1E-5 /1E-6
Unexpected (0.001 to 0.01) (2E-5/ 2E-6)	VL (no change)	L 1.8E-6 /1.8E-7	L-M 1.3E-5 /1.3E-6	L-M 1.8E-5 /1.8E-6	L-M 1.9E-5 /1.9E-6	L-M 2E-5 /2E-6	L 4.6E-6 /4.6E-7	L 7.5E-6 /7.5E-7	L 1E-5 /1E-6
Limiting Faults (< 0.001) (2E-5/2E-6)	VL (no change)	L 1.8E-6 /1.8E-7	L-M 1.3E-5 /1.3E-6	L-M 1.8E-5 /1.8E-6	L-M 1.9E-5 /1.9E-6	L-M 2E-5 /2E-6	L 4.6E-6 /4.6E-7	L 7.5E-6 /7.5E-7	L 1E-5 /1E-6
Total 8E-5/8E-6 Note: Delta to right assume proposed activity affects all IEs equally – bounding case	VL (no change)	L 7.2E-6 /7.2E-7	M 5.2E-5 /5.2E-6	M 7.2E-5 /7.2E-6	M 7.6E-5 /17.6E-6	M 8E-5 /8E-6	L-M 1.8E-5 /1.8E-6	M 3E-5 /3E-6	M 4E-5 /4E-6

Table 2: Seismic Enhancement Example ("Harden" a SSD Path to 2 time SSE)									
Initiating event category (frequency range) (CDF-LERF Baseline)	Factor/% Change in IE Frequency-Prevention-Mitigation Availability/Reliability								
	1 (0%)	1.1 (10%)	3 (67%)	10 (90%)	30 (93%)	100 (99%)	1.3 (23%)	1.6 (37%)	2 (50%)
	(Ranking/Delta)								
Anticipated (0.2 to 1) (2E-5/ 2E-6)	0 No change								
Infrequent (0.02 to 0.1) (2E-5/ 2E-6)	0 No change								
Unexpected (0.001 to 0.01) (2E-5/ 2E-6)	0 No change								
Limiting Faults (< 0.001) (2E-5/2E-6)			L-M 1.3E-5 /1.3E-6 Assume capability will be enhanced so as to address an event with a frequency 3 to 10 times lower	L-M 1.8E-5 /1.8E-6 Assume capabilit y will be enhanced so as to address an event with a frequency 3 to 10 times lower					
New Total 8E-5-1.3E-5 /8E-6-1.3E-6 Or 8E-5-1.8E-5 /8E-6-1.8E-6 Key issue is seismic hazard			L-M 1.3E-5 /1.3E-6	L-M 1.8E-5 /1.8E-6					

Table 3: FLEX Example									
Initiating event category (frequency range) (CDF-LERF Baseline)	Factor/% Change in IE Frequency-Prevention-Mitigation Availability/Reliability								
	1 (0%)	1.1 (10%)	3 (67%)	10 (90%)	30 (93%)	100 (99%)	1.3 (23%)	1.6 (37%)	2 (50%)
	(Ranking/Delta)								
Anticipated (0.3 to 1) (2E-5/2E-6)			L-M 1.3E-5 /1.3E-6	Assume a factor of 3 reduction					
Infrequent (0.03 to 0.1) (2E-5/2E-6)			L-M 1.3E-5 /1.3E-6	Assume a factor of 3 reduction					
Unexpected (0.001 to 0.01) (2E-5/2E-6)			L-M 1.3E-5 /1.3E-6	Assume a factor of 3 reduction					
Limiting Faults (< 0.001) (2E-5/2E-6)			L-M 1.3E-5 /1.3E-6	Assume a factor of 3 reduction Note: 1.8E-5 /1.8E-6 for factor of 10 reduction					
New Total 8E-5-5.2E-5 /8E-6-5.2E-6			M-H 5.2E-5 /5.2E-6						
Sensitivity Assume External Flooding dominate an achieve factor of 10 Key issue is "accuracy" of baseline				3.9E-5 + 1.8E-5 /3.9E-6 + 1.8E-6					

Table 4: Simple Matrix by Current Risk and Potential Impact						
Current Risk associated with Issue *Note: address the specific issue first; then assess impacts on other risk contributors potentially impacted*	Potential Impact of Action					
	None	Very Small	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome and Delta Risk (Uses upper bound of current risk and potential impact; should account for uncertainty; can always refine; Mid- and lower bound also provided for illustration)					
Green (VL) CDF <1E-6 LERF <1E-7	VL/Green (0.0)	VL/Green (.25E-6 /.25E-7)	VL/Green (.5E-6 /.5E-7)	VL/Green (.9E-6 /.9E-7)	VL/Green (1E-6 /1E-7)	Maximum reduction is 1E-6/1E-7
Mid (assume Green above are upper bound; mid is factor of 3.33 lower)	VL/Green (0.0)	VL/Green (.75E-7 /.75E-8)	VL/Green (1.5E-7 /1.5E-8)	VL/Green (2.7E-7 /2.7E-8)	VL/Green (3E-7 3E-8)	No change from upper bound
Lower Bound	< VL/Green	< VL/Green	< VL/Green	< VL/Green	< VL/Green	No change from upper bound
White (L) CDF 1E-6 to 1E-5 LERF 1E-7 to 1E-6	VL/Green (0.0)	L/White (.25E-5 /.25E-6)	L/White (.5E-5 /.5E-6)	L/White (.9E-5 /.9E-6)	L/White (1E-5/1E-6)	Maximum reduction is 1E-5/1E-6
Mid	VL/Green (0.0)	*VL/Green (.75E-6 /.75E-7)*	L/White (1.5E-6 /1.5E-7)	L/White (2.7E-6 /2.7E-7)	L/White (3E-6 3E-7)	Only change is 25% Category
Lower Bound	VL/Green (0.0)	VL/Green (.25E-6 /.25E-7)	VL/Green (.5E-6 /.5E-7)	VL/Green (.9E-6 /.9E-7)	VL/Green (1E-6/1E-7)	All Green versus White above 25% category
Yellow (M) CDF 1E-5 to 1E-4 LERF 1E-6 to 1E-5	VL/Green (0.0)	M/Yellow (.25E-4 /.25E-5)	M/Yellow (.5E-4 /.5E-5)	M/Yellow (.9E-4 /.9E-5)	M/Yellow (1E-4/1E-5)	Maximum reduction is 1E-4/1E-5
Mid	VL/Green (0.0)	*L/White (.75E-5 /.75E-6)*	M/Yellow (1.5E-5 /1.5E-6)	M/Yellow (2.7E-5 /2.7E-6)	M/Yellow (3E-5 3E-6)	Only change is 25% Category
Lower Bound	VL/Green (0.0)	L/White (.25E-5 /.25E-6)	M/White (.5E-5 /.5E-6)	L/White (.9E-5 /.9E-6)	L/White (1E-5/1E-6)	All but 0% and 25% are near breakpoint of L (White) and M (Yellow)

Table 4: Simple Matrix by Current Risk and Potential Impact

Current Risk associated with Issue *Note: address the specific issue first; then assess impacts on other risk contributors potentially impacted*	Potential Impact of Action					
	None	Very Small	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome and Delta Risk (Uses upper bound of current risk and potential impact; should account for uncertainty; can always refine; Mid- and lower bound also provided for illustration)					
Red (H) CDF > 1E-4 LERF > 1E-5	?	H/Red	H/Red	H/Red	H/Red	
Mid	?	H/Red	H/Red	H/Red	H/Red	No change
Lower Bound	?	M/Yellow (.25E-4 /.25E-5)	M/Yellow (.5E-4 /.5E-5)	M/Yellow (.9E-4 /.9E-5)	M/Yellow (1E-4/1E-5)	Addressed by upper bound Yellow

Table 5: Simple Matrix by Current Risk and Potential Impact						
Current Risk associated with Issue *Note: address the specific issue first; then assess impacts on other risk contributors potentially impacted*	**Potential Impact of Action**					
	None	Very Small	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome					
Green (VL) UB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	Maximum reduction is 1E-6/1E-7
Green (VL) Mid	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	No change from upper bound
Green (VL) LB	< VL/Green	< VL/Green	< VL/Green	< VL/Green	< VL/Green	No change from upper bound
White (L) UB	VL/Green	L/White	L/White	L/White	L/White	Maximum reduction is 1E-5/1E-6
White (L) Mid	VL/Green	VL/Green	L/White	L/White	L/White	Only change is 25% Category
White (L) LB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	All Green versus White above 25% category
Yellow (M) UB	VL/Green	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Maximum reduction is 1E-4/1E-5
Yellow (M) Mid	VL/Green	L/White	M/Yellow	M/Yellow	M/Yellow	Only change is 25% Category
Yellow (M) LB	VL/Green	L/White	M/White	L/White	L/White	All but 0% and 25% are near breakpoint of L (White) and M (Yellow)
Red (H) UB	?	H/Red	H/Red	H/Red	H/Red	

Table 5: Simple Matrix by Current Risk and Potential Impact						
Current Risk associated with Issue *Note: address the specific issue first; then assess impacts on other risk contributors potentially impacted*	**Potential Impact of Action**					
	None	Very Small	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome					
Red (H) Mid	?	H/Red	H/Red	H/Red	H/Red	No change
Red (H) LB	?	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Addressed by upper bound Yellow

APPENDIX E   APPENDIX E: GUIDANCE FOR STEP 3A

[To be completed following pilot]

Step 3A uses Table 4-1, copied below, combined with the guidance for Step 2, to place a potential action into a safety significance category as follows.

First, establish the relative risk significance of the issue so as to establish the appropriate row in Table 4-1.

Second, using below guidance and Table 4-1 establish significance for each of the following **(Note: The potential for multiple impacts will be addressed later.)**

1. ☐ YES ☐ NO The relative decrease in frequency of occurrence of a risk significant accident initiator

Justification:

2. ☐ YES ☐ NO The relative improvement in the availability, reliability, or capability of SSCs and personnel relied upon to mitigate a risk significant transient, accident, or natural hazard

Justification:

3. ☐ YES ☐ NO The relative decrease in the consequences of a risk significant accident sequence?

Justification:

4. ☐ YES ☐ NO The relative improvement in the capability of a fission product barrier?

Justification:

5. ☐ YES ☐ NO The relative improvement in defense-in-depth capability? Examples include:

   j. Strengthen balance of accident prevention and mitigation
   k. Reduce reliance on programmatic activities
   l. Reduce probability of common-cause failures

Justification:

Note: The vision for the implementation guidance document is the following: A process flow diagram illustrating the approach; then for each block or question, guidance similar to this draft guidance; then the actual checklist template; addresses each step; so as to be contained in one attachment.

Risk Significant Accident Initiator Frequency

The first step is to identify the risk significant accident initiators that have been evaluated that could be affected by the proposed activity.

- For regulatory initiated actions, this may have been determined on a generic basis by NRC
- Then a determination should be made as to whether the frequency of these accident initiators occurring would be more than minimally decreased.

Accidents initiators can be divided into categories, for example:

Accident Initiator Categories (Representative)	Risk Significance (VL, L, M, H)?	Potential Improvement (VL, L, M, H) or Adverse?
Transients initiated by frontline systems		
Transients initiated by support systems		
Primary system integrity loss		
Secondary system integrity loss		
Internal flooding		
Internal fires		
Earthquakes		
External flooding		
Tornados and High Winds		
Other External Hazards		

Risk Significance: Risk Significance should be based on:

- The definition used in the PRA Standard OR
- Matrix benchmarks, which is based on SDP risk significance, THUS
    - Accident initiators that are not risk significant, i.e. minimal or less than minimal, are those contributing less than 1E-6/year and 1E-7/year for CDF and LERF, respectively OR
    - Less than 1% of total CDF/LERF (consistent with RG 1.174) OR
    - Less than 10% change in frequency

External Hazards: Practically, external hazard frequencies cannot be reduced or increased by a plant initiated or NRC initiated change. However, the frequency and/or severity might be changed for certain external hazards (such as external flooding) with changes beyond the nuclear power plant site. For example strengthening a dam could reduce the frequency/severity of an external flood which could affect the nuclear power plant site. Such changes can be considered in this process if owned by the licensee. Otherwise changes related to external hazards will be considered in the second question.

Considerations for changes to accident initiator frequencies: The frequency of accident initiators can be changed in several ways, such as:

Considerations	**Potential Action Effect?**	**Potential Improvement (VL, L, M, H) or Adverse?**
Changes in maintenance		
Changes in specific SSCs (e.g., installing a more reliable component)		
Changes in materials		
Equipment replacements to address age related degradation		
Changes in redundancy and diversity		
Additional of equipment		
Changes in operating practices		

Industry, NRC and each plant have programs and practices for managing accident initiator frequency. Existing programs and practices will support determination of changes in frequency (10 CFR 50.59, NFPA-805, age management programs, piping integrity programs, etc.).

Reasonable engineering practices, engineering judgment and PRA techniques, as appropriate, should be used in determining whether the frequency of occurrence of a risk significant accident initiator would decrease, and by how much, as a result of implementing a proposed activity. A large body of knowledge has been developed in the area of accident frequency and risk significant sequences through plant-specific and generic studies. This knowledge, where applicable, should be used in determining any decrease in the frequency of occurrence. The effect of a proposed activity on the frequency of a risk significant accident initiator must be discernible and attributable to the proposed activity in order to exceed the more than minimal decrease standard.

SSCs and Personnel [To be developed following pilot]

Similar to accident initiators the availability, reliability, or capability of SSCs and personnel can be changed in several ways, such as:

Considerations	Potential Action Effect?	Potential Improvement (VL, L, M, H) or Adverse?
Changes in maintenance		
Changes in specific SSCs (e.g., installing a more reliable component)		
Changes in materials		
Equipment replacements to address age related degradation		
Changes in redundancy and diversity		
Additional of equipment		
Strengthening of equipment		
Moving equipment (to reduce the impacts of spatial events)		

Considerations	Potential Action Effect?	Potential Improvement (VL, L, M, H) or Adverse?
Eliminating the need for recovery action (RA)		
Improving performance shaping factor related to human performance		
Changes in operating practices		

Consequences [To be developed following pilot]

Containment Bypass

- How much impact would the proposed action result in the frequency of an ISLOCA event?
- How much would the proposed action provide improvement in the level of mitigation of an ISLOCA event?
- How much would the proposed action result in improvement in the ability isolate a faulted steam generator following a steam generator tube rupture event?

Containment Isolation

- How much would the proposed action result in improvement in containment isolation for containment penetrations that are:
  - Directly connected to containment atmosphere, and
  - > 2” in diameter, and
  - Not locked closed or only locally operated?
- How much would the proposed action result is improvement in containment isolation for containment penetrations that are:
  - Part of the reactor coolant system pressure boundary, and
  - > 3/8” in diameter, and
  - Not locked closed or only locally operated?

Early Hydrogen Burns

- How much would the proposed action result in improvement in operation of hydrogen igniters in ice condenser and Mark III containments?

Long-Term Containment Integrity

- How much would the proposed action result in improvement in a system function that is not considered in CDF and LERF, but would be the only means for preserving long-term containment integrity post-core damage (e.g., containment heat removal)?

Emergency Planning

Fission Product Barriers (Later)

Defense in Depth (Later)

Copy of Table 4-1: Simple Matrix by Current Risk and Potential Impact						
UB is upper bound of the risk range; Mid is "mid-range" (0.3 times UB); LB is factor of 10 lower than UB						
Current Risk associated with Issue *Note: Address the specific issue first; then assess impacts on other risk contributors potentially impacted*	**Potential Impact of Action (Reduction in Risk)**					
	None	Very Small/Minimal	Small	Medium	High	Comments
	0%	0-25%	25-50%	50% to 90%	>90%	Can adjust these initial ranges as appropriate
	Outcome Note: Quantitative values are delta CDF/LERF					
Green (VL) UB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	Maximum reduction is 1E-6/1E-7
Green (VL) Mid	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	No change from upper bound
Green (VL) LB	< VL/Green	< VL/Green	< VL/Green	< VL/Green	< VL/Green	No change from upper bound
White (L) UB	VL/Green	L/White	L/White	L/White	L/White	Maximum reduction is 1E-5/1E-6
White (L) Mid	VL/Green	*VL/Green*	L/White	L/White	L/White	Only change is 25% Category
White (L) LB	VL/Green	VL/Green	VL/Green	VL/Green	VL/Green	All Green versus White above 25% category
Yellow (M) UB	VL/Green	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Maximum reduction is 1E-4/1E-5
Yellow (M) Mid	VL/Green	*L/White*	M/Yellow	M/Yellow	M/Yellow	Only change is 25% Category
Yellow (M) LB	VL/Green	L/White	M/White	L/White	L/White	All but 0% and 25% are near breakpoint of L (White) and M (Yellow)
Red (H) UB	?	H/Red	H/Red	H/Red	H/Red	
Red (H) Mid	?	H/Red	H/Red	H/Red	H/Red	No change
Red (H) LB	?	M/Yellow	M/Yellow	M/Yellow	M/Yellow	Addressed by upper bound Yellow