Risk-Informed and Performance-Based Plan

Enclosure 1

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RISK-INFORMED AND PERFORMANCE-BASED PLAN

1. BACKGROUND

In 1995, the Commission issued a policy statement regarding the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities. It was published in the *Federal Register* on August 16, 1995 (60 FR 42622). One purpose of the policy statement was to ensure that the many potential applications of PRA were implemented in a consistent and predictable manner that would promote regulatory stability and efficiency. The policy statement directed that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data, and in a manner that complements the U.S. Nuclear Regulatory Commission's (NRC's) deterministic approach and supports the NRC's traditional defense-in-depth philosophy. In addition, the policy statement directed that the agency should use PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices.

The staff first proposed a PRA implementation plan in 1994 (SECY-94-219, "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)"). The staff developed the plan concurrent with the PRA policy statement to ensure that PRA would be implemented in a consistent and predictable manner. The PRA implementation plan was considered to be a "living" document that was used as a management tool to help ensure the timely and integrated agency-wide use of PRA methods and technology.

In March 1999, the General Accounting Office (GAO, now the Government Accountability Office) made the following recommendation in GAO/RCED-99-95, "Nuclear Regulation - Strategy Needed to Regulate Safety Using Information on Risk":

> To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the staff to develop a comprehensive strategy that includes but is not limited to objectives, goals, activities, and time frames for the transition to risk-informed regulation; specifies how the Commission expects to define the scope and implementation of risk-informed regulation; and identifies the manner in which it expects to continue the free exchange of operational information necessary to improve the quality and reliability of risk assessments.

In response to the GAO report, in a January 13, 2000, memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. That strategy evolved into the first complete version of the Risk-Informed Regulation Implementation Plan (RIRIP), which the staff provided to the Commission in SECY-00-0213, "Risk-Informed Regulation Implementation Plan," dated October 26, 2000. Since then, the staff has updated the RIRIP twice a year as a status report on risk-informed initiatives. In addition, because of other interactions between the Commission, staff, and stakeholders, various modifications and enhancements to the RIRIP have occurred. For example, the plan was restructured in SECY-05-0068, "Update of the Risk-Informed Regulation Implementation Plan," dated April 22, 2005, to align with the goals outlined in the Fiscal Year 2004-2009 Strategic Plan.

On May 3, 2006, the NRC staff and representatives of the nuclear power industry briefed the Commission on the status of risk-informed and performance-based reactor regulation. Although meeting participants recognized that the staff has made significant progress on the agency's risk-informed initiatives, work remains. In response to the May meeting, the Commission issued a Staff Requirements Memorandum (SRM), M060503B - Briefing on Status of Risk-informed and Performance-based Reactor Regulation dated June 1, 2006. The SRM directed the staff to improve the RIRIP so that it is an integrated master plan for initiatives designed to help the agency achieve the Commission's goal of a holistic, risk-informed and performance-based regulatory structure.

In response to the Commission's direction, on October 25, 2006, the staff issued SECY-06-0217, "Improvement to and Update of the Risk-Informed Regulation Implementation Plan." In this paper, the staff proposed the following improvements:

- Focus on the up-front planning process and on the back-end following completion of initiatives through the addition of an effectiveness review process.

- Focus on the NRC's three arenas (i.e., reactors, materials, and waste) and sub-arenas (e.g., operating reactors, new reactors, advanced reactors, and non-power reactors), and the three functional regulatory areas (i.e., licensing, rulemaking, and oversight).

- Define objectives for each arena (or subarena), as appropriate.

- Maintain a separate plan for each individual identified initiative.

- Perform an effectiveness review of selected initiatives.

In its response, the staff expanded and revised the structure of the plan to assist in achieving a risk-informed and performance-based regulatory structure. As such, the plan provides for a more consistent overview and treatment of the reactor, materials, and waste arenas; focuses upon those initiatives that are significant in a risk-informed regulatory structure; and provides the explicit criteria for the staff's review and consideration of performance-based approaches.[1]

The improved plan, now referred to as the Risk-Informed and Performance-Based Plan (RPP), documents the staff's plans to achieve the Commission's risk-informed and performance-based regulatory structure. The NRC has already completed many significant and far-reaching accomplishments in this area, and many risk-informed and performance-based initiatives are already an inherent part of the NRC's regulatory structure and are used on a daily basis. Likewise, there are, and will remain, areas where a risk-informed and performance-based approach is not the most appropriate, efficient, or effective mechanism for the NRC's regulatory structure. Consequently, the RPP focuses on forward-looking improvements to NRC's regulatory structure, and is not a compendium of the numerous risk-informed and performance-based initiatives that have already been implemented and are carried out as part of the NRC's normal course of business.

[1]Note that not every risk-informed initiative can or should be performance-based. In this plan, the focus remains on initiatives that are to be risk-informed and that a separate assessment is made to determine if a performance-based approach is appropriate.

2. OBJECTIVES

2.1 Risk-Informed and Performance-Based Regulation Objectives

The Commission's goal is to achieve a holistic, risk-informed and performance-based regulatory structure. On March 11, 1999, it was stated in Yellow Announcement #019 that "The Commission has issued a white paper that defines the terms and Commission expectations regarding risk-informed and performance-based regulation."

The Commission in the white paper stated that:

> "The Commission is advocating certain changes to the development and implementation of its regulations through the use of risk-informed, and ultimately performance-based, approaches. The Probabilistic Risk Assessment (PRA) Policy Statement (60 FR 42622, August 16, 1995) formalized the Commission's commitment to risk-informed regulation through the expanded use of PRA."

Explicitly, the Commission's PRA policy statement states that:

(1) The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and support the NRC's traditional defense-in-depth philosophy.

(2) PRA and associated analyses should be used in regulatory matters, where practical within the bounds of the state-of-the art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109. Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed.

(3) PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

(4) The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licenses.

The Commission, in the white paper, noted that "to understand and apply the commitment expressed in the PRA Policy Statement, it is important that the NRC, the regulated community, and the public at large have a common understanding of the terms and concepts involved." The following provides the Commission's definitions of the terms and the Commission expectations regarding risk-informed and performance-based regulation.

- **Risk-informed regulation** – "A risk-informed approach to regulatory decision-making represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory attention on design and operational issues commensurate with their importance to public health and safety."

- **Performance-based regulation** – "A performance-based regulatory approach is one that establishes performance and results as the primary bases for regulatory decisionmaking, and incorporates the following attributes: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee, performance, (2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history, (3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes, and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern."

- **Risk-informed and performance-based regulation** – "A risk-informed and performance-based approach to regulatory decision-making combines the risk-informed and performance-based elements discussed . . . above, and applies these concepts to NRC rulemaking, licensing, inspection, assessment, enforcement, and other decision-making."

It is expected that meeting the above objectives will achieve the Commission's goal, as expressed in the PRA policy statement, "to improve the regulatory process in three areas:

- foremost, through safety decision making enhanced by the use of PRA insights
- through more efficient use of agency resources
- through a reduction in unnecessary burdens on licensees."

2.2 Risk-Informed and Performance-Based Plan Objectives

The purpose of the RPP is to describe the staff's initiative to achieve a holistic, risk-informed and performance-based regulatory structure. As such, this plan will explain the agency's approach to risk-informed and performance-based regulatory policy to internal and external stakeholders.

3. OVERALL APPROACH

The staff will implement a holistic, risk-informed and performance-based approach through (1) ensuring that all NRC regulatory arenas are included in the RPP, (2) defining overall risk-informed and performance-based objectives, and (3) developing a common approach to determine whether specific initiatives can, and should be, risk-informed and performance-based.

Ideally, implementation of a holistic, risk-informed and performance-based regulatory structure at the NRC would be an iterative process, beginning with a high-level view of the degree to which a regulatory arena may be amenable to a risk-informed and performance-based approach, either in total or in part. Decisions would then focus on determining whether a particular risk-informed and performance-based initiative[2] has achieved the desired outcome and whether lessons should be applied to future initiatives.

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[2]In focusing on agency efforts that should be risk-informed, an initiative could be a process (e.g., Reactor Oversight Process), a program (e.g., Phased Approach to PRA Quality), a project (e.g., developing improved human reliability analysis methods), or an activity within an overall program (e.g., changes to 10 CFR 50 as part of risk-informed rulemaking). For the purpose of explaining the process, these are referred to as "initiatives."

Given this basic framework and the presence of constraints (e.g., voluntary adoption of risk-informed alternatives), the RPP focuses on identifying initiatives that should be improved through a risk-informed and performance-based approach. Once the initiatives have been fully adopted into the NRC's normal business process, they are no longer part of the RPP. Therefore, it focuses on the initiatives needed to achieve the objective of a risk-informed and performance-based regulatory structure and not on initiatives that are part of routine agency activities. This overall approach is shown in Figure 1.

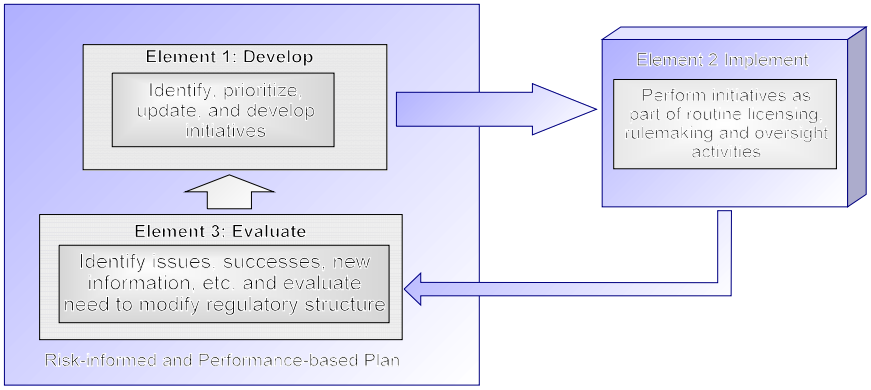

Figure 1 Process to Develop, Implement, and Evaluate Risk-Informed and Performance-Based Regulatory Structure

As shown in Figure 1, the process has three elements. The first element is to identify, prioritize and develop the initiatives to be risk-informed and performance-based. The staff has already accomplished much of this work, but ongoing review may be appropriate based on new information, trends, or industry requests. Once the initiative has been developed and implemented (Element 2), it becomes part of routine licensing, rulemaking, and oversight activities. These routine activities are no longer in the scope of the RPP (right side of figure). In Element 3, the staff evaluates the implemented initiatives, as appropriate, to determine if the initiative was effective, identify lessons that may be applied elsewhere, and determine if the initiative needs to be modified (bottom left of figure). This generic process can be applied to each regulatory arena (i.e., reactors, materials, waste). This evaluation also ensures the integration of these different arenas throughout the ongoing process of developing a risk-informed and performance-based regulatory structure.

4. TASKS

This section identifies the staff activities to implement the approach described above, which involves two major tasks:

(1) activities to develop the regulatory structure
(2) activities to evaluate and update the regulatory structure

4.1 Develop the Regulatory Structure

Purpose –

The purpose of this task is to develop, revise, or modify, as appropriate, the regulatory structure to be risk-informed and performance-based. To accomplish this objective, the necessary initiatives need to be identified and implemented for each regulatory arena.

Workscope –

The staff has accomplished a great deal in establishing a risk-informed and performance-based regulatory structure since the initiation of the original PRA implementation plan. To structure future work, objectives are defined for each arena and used to assess current risk-informed initiatives to determine which initiatives should continue, and whether any new ones are needed. The objectives established for the various arenas will differ because of such factors as:

- The inherent major differences in the complexities and risk associated with NRC-regulated licensed activities (e.g., a nuclear power plant versus a sealed radioactive source).
- The state-of-the-art with regard to PRA (and other risk) technologies and methods (i.e., PRA methods are relatively well developed for the reactor arena versus the materials and waste arenas).
- The identification of measurable (or calculable) outcomes (i.e., performance results) that can be met.
- The level of commitment of stakeholders in the various arenas interested in pursuing risk-informed initiatives.
- The potential cost and benefits associated with the adoption of risk-informed and performance-based initiatives.

In addition, depending on these factors, the objectives also may need to be defined at different levels (i.e., sub-arena level). For example, for the reactor arena, a common set of objectives may not be practical when considering operating reactors, new light-water reactors (LWRs), advanced non-LWRs, and non-power reactors. Figure 2 shows an example of the reactor arena.

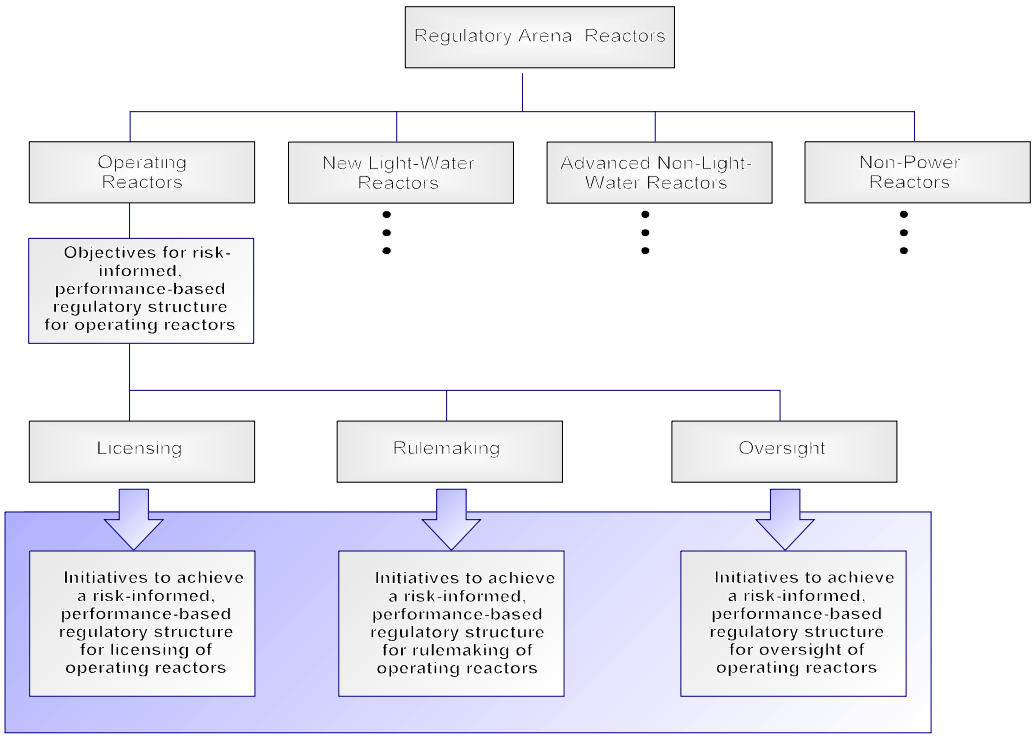

Figure 2 Illustration of the Development of Objectives for Regulatory Arenas

Once the objectives are defined, the necessary initiatives are identified. This process involves first determining what initiatives should continue and what new initiatives are needed, and then second, within that set, where they can be performance-based. Figure 3 depicts this overall process.

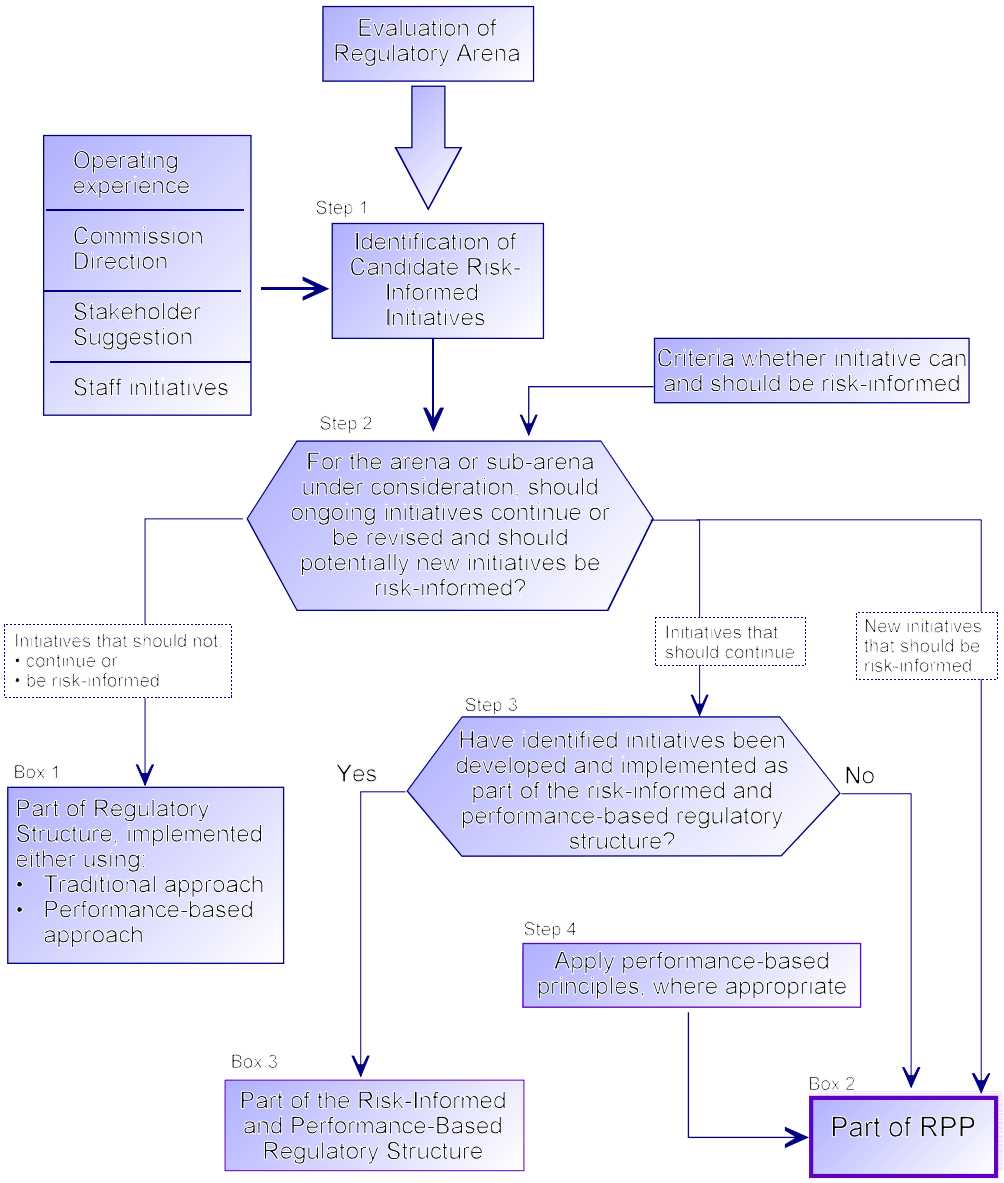

Figure 3 Process to Identify RPP Initiatives.

In Step 1, the staff identifies initiatives for each arena (or sub-arena) which include ongoing efforts and potential new initiatives. The new initiatives are based on input from operating experience, Commission direction, stakeholder suggestions, and ongoing staff initiatives.

In Step 2, the staff evaluates the identified initiatives. First, the staff evaluates the ongoing initiatives to determine whether they should continue or should be revised in some manner. To not continue or to revise is determined because the initiative is not fulfilling its original intent, or is no longer meeting the criteria used for deciding the initiative should be risk-informed. Second, for potentially new initiatives, the staff determines if they warrant being risk-informed based on the set of criteria for risk-informed. In each decision, input from operating experience, Commission directions, stakeholders, staff, or some combination will also be used.

For both ongoing and potentially new initiatives, the criteria include the following:

- Would a risk-informed regulatory approach achieve the following:[3]
  - — Help to resolve a question with respect to maintaining or improving safety?
  - — Improve the efficiency or the effectiveness of the NRC regulatory process?
  - — Reduce unnecessary regulatory burden for the applicant or licensee?
  - — Help to effectively communicate a regulatory decision or situation?

- Does information (data) and analytical models exist that are of sufficient quality or could the information and models be reasonably developed to support risk-informing?

- Has or can the startup and implementation of a risk-informed initiative be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit? The net benefit will be considered to apply to the public, the applicant or licensee, and the NRC.

- Do other factors exist (e.g., legislative, judicial, adverse stakeholder reaction) which would preclude changing the regulatory approach in an arena, and therefore, limit the utility of implementing a risk-informed approach?

The output from Step 2 results in the following:
- Ongoing initiatives that should not continue
- New initiatives that should not be risk-informed
- Ongoing initiatives that should continue and/or be revised
- New initiatives that warrant being risk-informed

In Box 1, these are initiatives that have not met the criteria to be risk-informed, and therefore, they are not in the scope of the RPP. However, these initiatives can be performed and implemented in the traditional deterministic manner, or in a performance-based manner. The same criteria for performance-based would be used to determine whether a non-risk-informed initiative should be performance-based as described below in Step 4.

In Step 3, the staff determines, for ongoing risk-informed initiatives, if they are complete and have become part of the risk-informed regulatory structure. The output from Step 3 results in either of the following:
- Initiatives that have been completed
- Initiatives that have not been completed

In Box 3, these are risk-informed initiatives that have been completed and implemented. For example, once a risk-informed rulemaking has been completed and the first couple pilot applications approved, it is no longer part of the RPP. Future application of the rule is an inherent part of the risk-informed regulatory structure, as such, it is no longer in the scope of the RPP.

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[3]These criteria are derived from the Commission's expectations, as stated in the PRA policy statement, that "implementation of the policy statement will improve the regulatory process in three areas: (1) foremost, through safety decision making enhanced by the use of PRA insights, (2) through more efficient use of agency resources, and (3) through a reduction in unnecessary burdens on licensees."

In Box 2, these are ongoing risk-informed initiatives that are not complete and new initiatives that warrant being risk-informed. These initiatives are in the scope of RPP. For these initiatives, the staff will develop a separate plan specific to that initiative. The responsible office will maintain and update these individual plans which will identify the activities, milestones, schedule, and other details related to that initiative. Note that although the RPP contains the process to identify which initiatives should be risk-informed, the staff will use the agency's existing Planning, Budgeting, and Performance Management process to request resources for these initiatives and prioritize them consistent with all other agency activities. In a similar vein, the staff will use existing practices to manage progress and completion of the RPP initiative. As such, decision to accelerate, delay, or cancel any RPP initiatives will be subjected to the same management practices as all other NRC activities.

In Step 4, the staff evaluates the new initiatives to determine whether they can and should be performance-based using the following criteria:

(1) Measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist, or can be developed, to monitor system, including facility and licensee, performance.

(2) Objective criteria to assess performance exist, or can be established, based on risk insights, deterministic analyses and/or performance history.

(3) Licensees flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes exists or can be developed.

(4) A framework exists, or can be developed, in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern

Products –

Appendix A to this plan summarizes the draft objectives for each arena (or sub-arena). The objectives and their supporting bases will be finalized with the next status report. The staff will also document them in an RPP database maintained on the NRC public Web site. This database will also provide a high-level summary of the associated initiatives and their status. For each initiative, the database will contain a link to the relevant initiative plan. The staff will update the database and initiative plans semi-annually which will indicate the latest revision date. These individual plans will be maintained by the responsible office. As indicated in SECY-06-0217, the staff will complete the RPP database in October 2007. A draft of the initial database is shown in Appendix B.

4.2 Evaluate the Regulatory Structure

Purpose –

The purpose of this task is to evaluate the risk-informed and performance-based regulatory structure.

Workscope –

This task will focus on determining whether selected, completed RPP initiatives have achieved their desired outcomes. In addition, this evaluation (or effectiveness review process) will identify lessons to be applied to future initiatives.

The effectiveness review process is shown below in Figure 4.

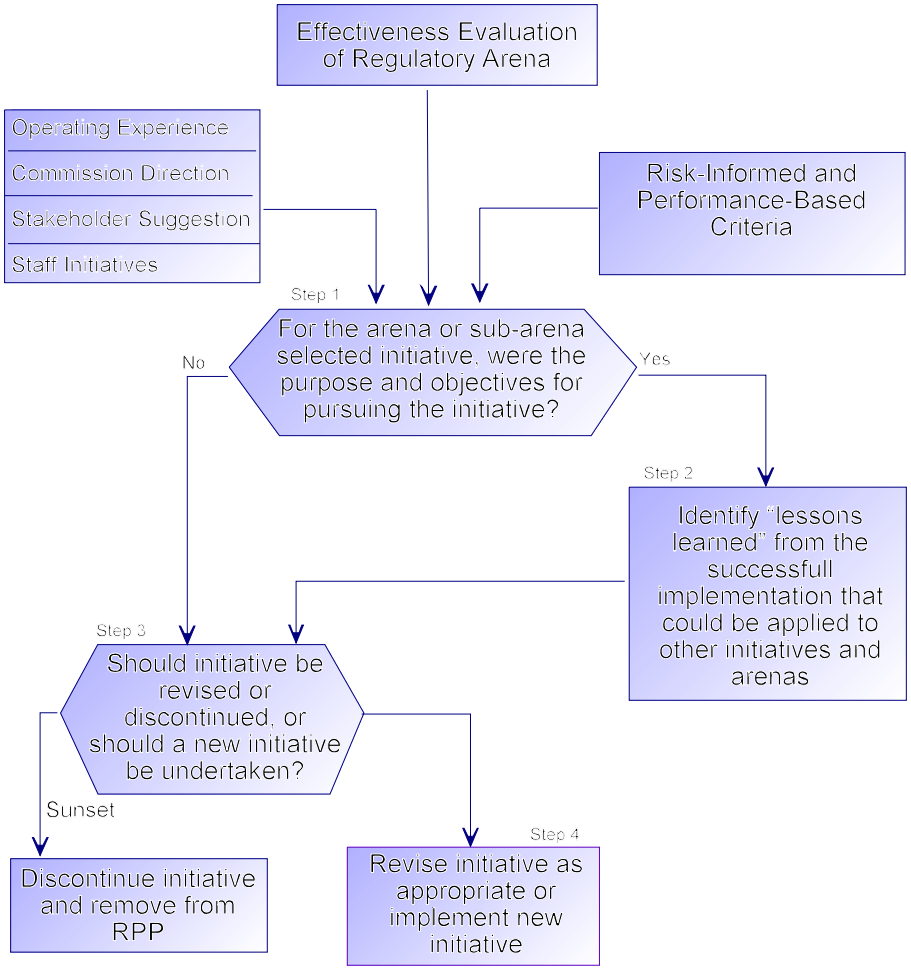

Figure 4 Effectiveness Review Process.

In Step 1, the staff selects specific initiatives from an arena or sub-arena to review to determine their effectiveness. This selection is based on information (e.g., trends) or input from, for example, stakeholders (e.g., industry requests), the Commission, operating experience, and/or staff initiatives.

This effectiveness review, performed by the responsible office, is an integral part of each initiative plan. The staff considers the following to determine effectiveness:

(1) Has the initiative been consistent with the established objectives for the arena or sub-arena? The basis for any discrepancies will be noted.

(2) Have the criteria for making an initiative risk-informed been met? If not, the basis will be noted.

(3) Have the criteria for making an initiative performance-based been met? If not, the basis will be noted.

In Step 2, as part of the review, the staff will identify lessons learned from the successful implementation. In some situations, case studies are useful to identify attributes that may be applied in other situations. These lessons will be incorporated into other initiatives, within and across arenas, as appropriate.

In Step 3, the staff will evaluate the initiatives that have been identified as not being effective to determine whether the initiative should be revised, a new initiative undertaken, or the initiative discontinued. The staff will make the determination by examining the basis for the negative effectiveness. Further, lessons learned from successful implementation will be incorporated, as appropriate. For example, the initiative was determined not effective because there was inadequate training on the part of the recipient staff. In this example, the initiative does not necessarily need to be revised, but a new initiative, training, needs to be undertaken.

Products –

The RPP database will document the results of an effectiveness review only if the review has resulted in a revision to the initiative or if a new initiative has been undertaken. That is, if the initiative needs to be revised and updated or a new initiative undertaken based on the effectiveness review, the staff will enter the information into the RPP database with a link to the relevant initiative plan.

APPENDIX A DRAFT OBJECTIVES AND GOALS FOR REGULATORY ARENAS

The draft objectives developed for the three arenas (i.e., reactor, materials, and waste) are listed in Table A-1. It is anticipated that there will be differences in the objectives established for the various arenas because of the inherent major differences in the complexities and risk associated with NRC-regulated licensed activities. (e.g., nuclear power plant versus a sealed radioactive source).

In addition, the objectives may need to be defined at the sub-arena level. For example, for the reactor arena, a common set of objectives may not be practical when considering operating reactors, new light-water reactors (LWRs), advanced non-LWRs, and non-power reactors.

Table A-1 Draft Objectives for Regulatory Arenas

REACTOR ARENA
Sub-Arena – Operating Reactors
Objective: Make incremental/continuous improvements in licensing, rulemaking, and oversight of operating reactors while focusing on implementation of existing risk-informed initiatives.
Sub-Arena – Non-Power/Test Reactors
Objective: Utilize risk information on a case-by-case basis. Note: Licensees include universities and government agencies. In general, PRA studies have not been done for these reactors and there has been no interest in risk-informed license amendment requests or other submittals.
Sub-Arena – New LWRs
Objective: Increase the use of risk insights in the design certification, licensing, and oversight of new LWRs.
Sub-Arena – Advanced Non-LWRs
Objective: Develop a coherent risk-derived regulatory structure for design, licensing, and oversight of advanced non-LWRs.
MATERIALS ARENA
Sub-Arena – Fuel Cycle
Objective: For fuel cycle facilities, make continuous improvement in licensing and oversight, and risk-inform new regulations as needed, while focusing on executing existing risk-informed functions.

Table A-1 Draft Objectives for Regulatory Arenas

Sub-Arena – Byproduct materials
Objective: Utilize risk information on a case-by-case basis for byproduct material licensing and oversight.
WASTE ARENA
Sub-Arena – Spent Fuel Storage and Transportation
Objective: Utilize risk information on a case-by-case basis to prioritize and address regulatory initiatives in Spent Fuel Storage and Transportation.
Sub-Arena – High Level Waste Repository Safety
Objective: Utilize risk information to prioritize and assess licensing information to implement existing risk-informed framework for Repository Safety.
Sub-Arena – Low Level Waste and Decommissioning
Objective: Utilize risk information on a case-by-case basis for low-level waste disposal and decommissioning initiatives.

APPENDIX B INITIAL DRAFT RISK-INFORMED AND PERFORMANCE-BASED PLAN DATABASE

Table B-1 provides the initial draft Risk-Informed and Performance-Based Plan (RPP) database. The RPP database provides a high-level summary of the RPP initiatives and their status. This database will be maintained on the NRC public Web site and, for each initiative, the database will contain a link to the relevant initiative plan. The staff will update the database and initiative plans semi-annually in conjunction with the SECY status paper. The database and individual plans will indicate the latest revision date. The initiative plans will be maintained by the responsible office outside the structure of the RPP.