

## **POLICY ISSUE INFORMATION**

April 26, 2007

SECY-07-0074

FOR: The Commissioners

FROM: Luis A. Reyes  
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SUBJECT: UPDATE ON THE IMPROVEMENTS TO THE RISK-INFORMED  
REGULATION IMPLEMENTATION PLAN

### PURPOSE:

To provide the Commission: (1) the staff's progress on improving the Risk-Informed Regulation Implementation Plan (RIRIP); (2) a summary of the significant accomplishments completed over the past six months and anticipated for the next six months; and (3) potential policy issues associated with a risk-informed and performance-based regulatory structure, that may be transmitted to the Commission in the next six months.

### BACKGROUND:

On May 3, 2006, the staff of the U.S. Nuclear Regulatory Commission (NRC) and representatives of the nuclear power industry briefed the Commission on the status of risk-informed and performance-based reactor regulation. As discussed during that meeting, the staff has made significant progress on the agency's risk-informed initiatives, but much work remains. As a result of the meeting on June 1, 2006, the Commission issued a Staff Requirements Memorandum (M060503B), which directed the staff to improve the RIRIP so that it is an integrated master plan for activities designed to help the agency achieve the Commission's goal of a holistic, risk-informed and performance-based regulatory structure. It also directed the staff to seek ways to communicate the purpose and use of probabilistic risk assessments (PRAs) in NRC's reactor regulatory program more transparently to the public and stakeholders.

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On October 25, 2006, the staff provided the Commission with its proposal to improve the RIRIP in SECY-06-0217, "Improvement to and Update of the Risk-Informed Regulation Implementation Plan" (ML062650356). In the SECY paper, the staff committed to update the Commission in the next semi-annual RIRIP update (i.e., April 2007) on progress made in implementing the RIRIP improvements which will result in an integrated master plan. The staff also committed to maintain the schedule for conducting effectiveness reviews, and to develop and implement a communications plan in conjunction with the launch of a new Web site.

#### DISCUSSION:

This paper provides the staff's progress on the commitments, as noted above, in SECY-06-0217. It also provides the significant accomplishments completed by the staff since September 2006, and those planned for the near term, and any potential policy issues associated with a risk-informed and performance-based regulatory structure.

#### RIRIP Improvements

The staff continues to make progress in developing an integrated master plan to achieve the Commission's goal of establishing a holistic, risk-informed and performance-based regulatory structure. In the past, the RIRIP focused largely on risk-informed initiatives. In this improved plan, the objectives have been expanded to more fully achieve a risk-informed and performance-based regulatory structure. This improved plan will now be referred to as the **Risk-Informed and Performance-Based Plan (RPP)**. The RPP is provided in Enclosure 1.

In addition to including the performance-based element, the RPP addresses the improvements described in SECY-06-0217 by: (1) focusing on the up-front planning process through development of objectives and goals for each arena to determine what initiatives should be continued, what initiatives should be sunset, and what new initiatives are needed; (2) focusing on the back-end following completion of the RPP initiatives by performing an effectiveness review consistent with the schedule in the RPP; and (3) restructuring the plan by the different regulatory arenas (i.e., reactor, materials, waste). The staff has developed draft objectives for each arena (Enclosure 1). The staff will provide the final objectives and their bases in the next status report.

To achieve the Commission's expectations for a risk-informed and performance-based regulatory structure, the RPP process also includes explicit criteria for the staff's review and consideration of performance-based approaches for initiatives that are to be risk-informed.

In the past, the RIRIP described the risk-informed initiatives including a detailed discussion of their purpose, milestones, and schedule. Their status was updated semi-annually in RIRIP which was included in an enclosure to the SECY paper. As noted in SECY-06-0217, a major change to the RPP is that a database, accessible on the NRC public Web site, will be developed summarizing each RPP initiative. An individual plan will be developed for each initiative (in many cases, these plans are already in place) and will be maintained by each responsible office. This database will link each initiative to its individual plan that will provide the associated activities, milestones, and schedule. The database and initiative plans will be updated semi-annually and will indicate the latest revision date. The database will present the RPP initiatives at a high level. An initial draft of this database is provided in Enclosure 1.

To support development of the RPP, the staff held a public meeting on February 23, 2007, to solicit stakeholder input. Stakeholders attending the meeting provided positive feedback and indicated that they support the efforts to clearly define the future direction of risk-informed and performance-based initiatives. Nuclear Energy Institute (NEI) representatives expressed interest in the ultimate use of the RPP. In addition, the NEI representatives did not see an immediate need to initiate any new risk-informed initiatives for operating reactors, and stated that the NRC should focus on completing and implementing current risk-informed reactor initiatives. The staff indicated that they would continue to interact in all three arenas (i.e., reactors, materials, and waste) with stakeholders and solicit their input.

In the past, a semi-annual status report on risk-informed initiatives was provided to the Commission. The update generally included two enclosures: (1) the RIRIP which provided detailed information on the risk-informed initiatives and (2) past and planned accomplishments. The staff will continue to provide the Commission with a semi-annual status report of the accomplishments as previously provided. However, with the implementation of the web-based database of the risk-informed initiatives, the need to provide the Commission with a hard copy in future updates will no longer be necessary and will not be provided to the Commission in future status reports.

#### Communication Plan and Web Site

Significant progress has been made on the risk-informed NRC public Web site. The redesign will make information on the purpose and use of PRAs and risk-informed initiatives easier to find and more understandable. This Web site has been tested, but its launch was delayed because of the overall redesign of the agency's public Web site (ML063260378). In the interim, the staff is updating the redesigned site to include performance-based elements. The completion of the Web site will be coordinated with the Office of Information Services (OIS). A communication plan for launching this Web site is being developed and will be used.

#### Significant Accomplishments

Enclosure 2 summarizes the highlights of the staff's major risk-informing initiatives completed over the past six months, as well as those planned for the next six months.

#### Policy Issues

In continuing to develop a risk-informed and performance-based regulatory structure, the staff plans to identify any policy issues for Commission consideration in each semi-annual report. No policy issues have been identified in this report.

#### COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper:

1. The staff will complete the development of the RPP database.
2. The staff will complete the Web site in coordination with OIS.

3. The staff will provide the Commission with any potential policy issues associated in achieving a holistic, risk-informed and performance-based regulatory structure in the periodic status reports.
4. The staff will finalize the objectives and supporting bases for each regulatory arena.

RESOURCES:

The staff determined priorities of risk-informed and performance-based initiatives through the agency's planning, budgeting, and performance management process, according to a common prioritization methodology developed by the program offices and used to derive a prioritized listing of planned initiatives. Resources for the RPP initiatives have been budgeted in FY 2007 and FY 2008.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the General Counsel has also reviewed this paper and has no legal objection.

***/RA Martin J. Virgilio Acting for/***

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Enclosures:

1. Risk-Informed and Performance-Based Plan
2. Significant Accomplishments

# Risk-Informed and Performance-Based Plan

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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.<sup>1</sup>

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.

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<sup>1</sup>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<sup>2</sup> has achieved the desired outcome and whether lessons should be applied to future initiatives.

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<sup>2</sup>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.

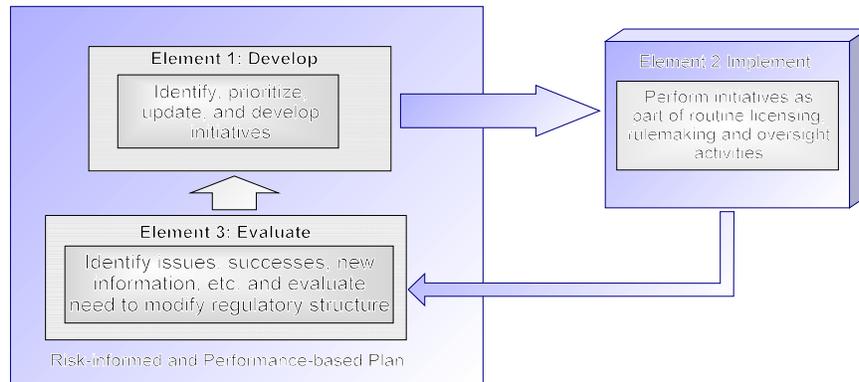


Figure 1 Process to Develop, Implement, and Evaluate Risk-Informed and Performance-Based Regulatory Structure

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.

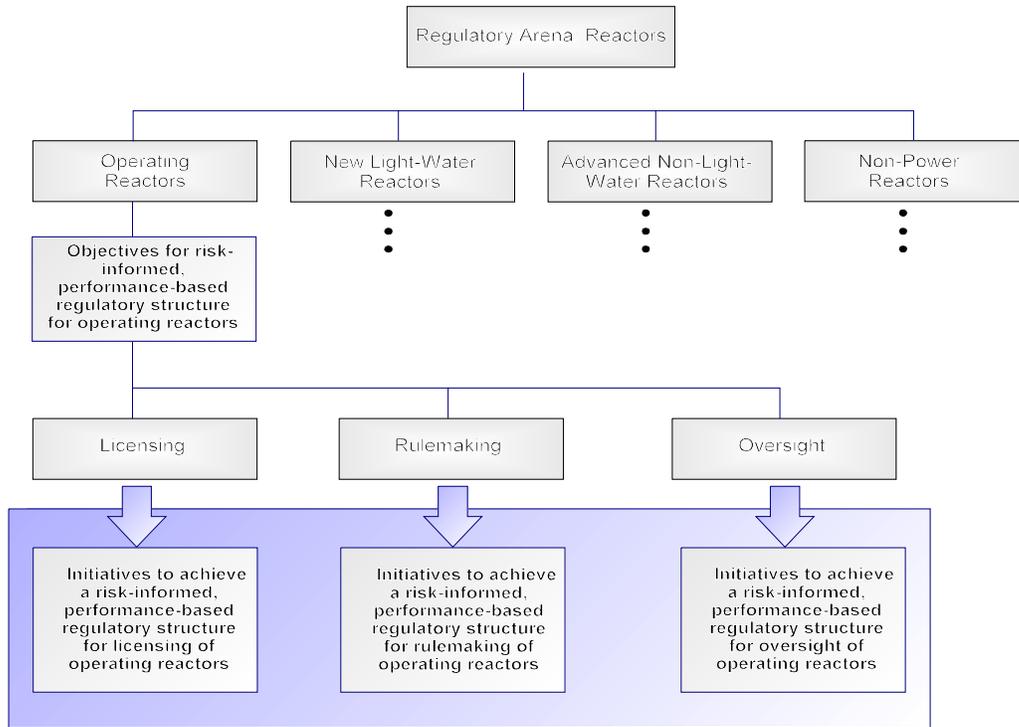


Figure 2 Illustration of the Development of Objectives for Regulatory Arenas

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.

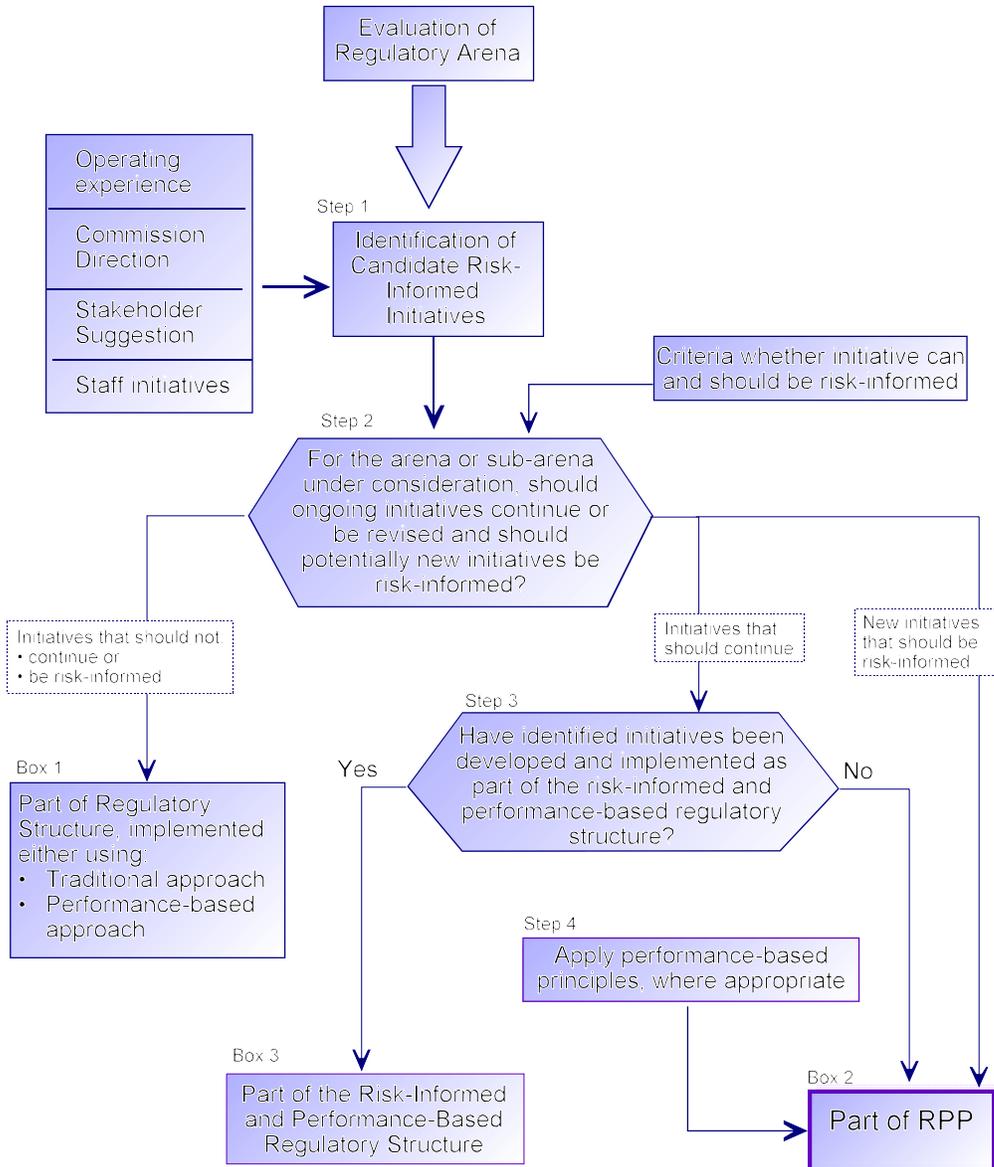


Figure 3 Process to Identify RPP Initiatives.

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:<sup>3</sup>
  - 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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<sup>3</sup>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.

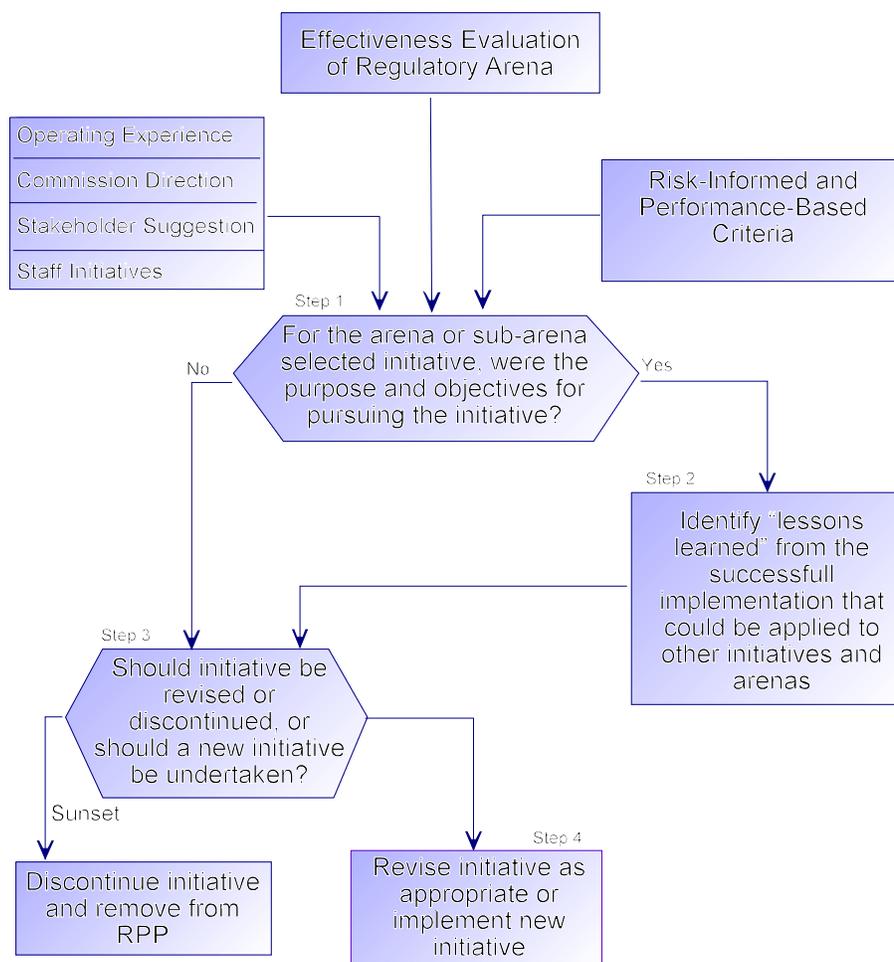


Figure 4 Effectiveness Review Process.

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

<b>REACTOR ARENA</b>
Sub-Arena – Operating Reactors
<u>Objective:</u> 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
<u>Objective:</u> 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
<u>Objective:</u> Increase the use of risk insights in the design certification, licensing, and oversight of new LWRs.
Sub-Arena – Advanced Non-LWRs
<u>Objective:</u> Develop a coherent risk-derived regulatory structure for design, licensing, and oversight of advanced non-LWRs.
<b>MATERIALS ARENA</b>
Sub-Arena – Fuel Cycle
<u>Objective:</u> 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
<u>Objective:</u> Utilize risk information on a case-by-case basis for byproduct material licensing and oversight.
<b>WASTE ARENA</b>
Sub-Arena – Spent Fuel Storage and Transportation
<u>Objective:</u> 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
<u>Objective:</u> 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
<u>Objective:</u> 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.

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Reactor (NRR)	Oversight	Reactor Oversight Process (ROP)	ROP	Develop a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information.	Implement process to monitor licensee performance with respect to reactor safety cornerstones and to monitor licensee activities using performance indicators. Depending on the assessment results, inspection resources may be expended to focus on licensees with degraded or declining performance.	Complete: The results and lessons learned from ROP implementation are documented in annual reports to the Commission.
					Implement Mitigating System Performance Index (MSPI) program. MSPI monitors risk associated with changes in performance of selected mitigating systems, accounting for plant-specific design and performance data.	Complete
Reactor (RES)	Oversight	Accident Sequence Precursor	Accident Sequence Precursor	Systematically review and evaluate operating experience to identify precursors to potential severe core damage sequences, documenting precursors, categorizing them by plant-specific and generic implications, and providing a measure of trends in nuclear plant core damage risk.	Determine the safety significance of events and their regulatory implications; provide feedback to improve probabilistic risk assessment (PRA) models; and provide NRC Strategic Plan performance measures and the ASP occurrence rate trending for the annual Performance and Accountability Report to Congress.	Complete: The results and lessons learned from Accident Sequence Precursor are documented in annual reports to the Commission and Congress.
Reactor (NRR)	Oversight	Risk-informed Decision-Making	Improve NRR risk-informed decision making	NRR Office Instruction for emergent issues	Revise LIC-504, "Integrated Risk-Informed Decision Making Process for Emergent Issues," to incorporate feedback from pilot application	Complete
				Training on use of risk in decision making	Develop course on modeling assumptions and uncertainty of risk models for technical reviewers.	In progress
					Develop course on uncertainties in risk-informed decision making for managers.	In progress
Reactor (RES)	Oversight	Maintenance of PRA Infrastructure	Logic Model Development	Develop SPAR models for each unique plant-specific design, as applicable; maintain models to support user needs	Develop Level 1 Rev. 3 SPAR Models	<a href="#">Link to plan</a>
					Develop External Event SPAR Models	<a href="#">Link to plan</a>
					Develop Low Power / Shutdown Models	<a href="#">Link to plan</a>
					Develop Level 2/LERF Models	<a href="#">Link to plan</a>
			SAPHIRE Code	Maintain SAPHIRE code and GEM interface to support user needs and new methods	Develop the SAPHIRE and GEM Interface and maintain them	<a href="#">Link to plan</a>

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Reactor (RES)	Oversight	Maintenance of PRA Infrastructure	Technical Guidance	Provide guidelines for analysis of events; maintain guidelines in support of revised methods and user needs	Provide integrated handbook for the analysis of internal, external, and low power/shutdown events, LERF, and Level 2	<a href="#">Link to plan</a>
					Provide revised methods and write tutorials for estimating CCF, equipment unavailability, independent failure probability, and initiating event frequency	<a href="#">Link to plan</a>
			Technical Support	Maintain analysis methods to support user needs; provide on-call technical assistance to senior reactor analysts and NRR	Provide event-specific methods and SPAR model modifications (MD 8.3, ROP, ASP)	<a href="#">Link to plan</a>
					Provide SDP analysis reviews, as requested	<a href="#">Link to plan</a>
					Provide support to RASP help desk (methods and models)	<a href="#">Link to plan</a>
Reactor (NRR)	Rulemaking	Special Treatment	Risk inform 10 CFR 50.69	Develop an alternative risk-informed approach to special treatment requirements in Part 50 to vary the treatment applied to structures, systems, and components (SSCs) on the basis of their safety significance, using a risk-informed categorization method. (NRR/ADRA/DRA)	Issue final rule for new § 50.69 to allow risk-informed approach to special treatment requirements.	Staff activities complete. Final rule issued. Awaiting industry implementation.
			Pilot Application	Industry proposing alternative approach to passive categorization aspects of 50.69.	Complete review of 50.69 implementation at 1 pilot plant.	Review initiated
		ECCS requirements	LOCA re-definition	Change technical requirements of 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors"	Issue final rule for revised 50.46 to redefine large LOCA	Resolving ACRS comments and soliciting Commission guidance
			LOCA/ LOOP	Remove requirement to consider LOOP in conjunction with large LOCA.	Complete safety evaluation of BWROG LOCA-LOOP topical report	Staff review continuing and on schedule
				Issue final rule to remove LOCA-LOOP requirement	Schedule may be impacted by delay in review of topical report due to re-submission by BWROG and use of alternative bases.	

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status	
Reactor (NRR)	Rulemaking	H2 gas control	10 CFR 50.44	Change the requirements for combustible gas control.		Staff activities complete. Available for industry implementation	
		PTS	10 CFR 50.61a	Voluntary risk-informed alternative pressurized thermal shock limits.	Re-define Reference Transition Temperature	Draft rule under development	
		Risk-informed Part 50	10 CFR 53	Determine need for separate rule to risk-inform Part 50 (ANPR RIN 3150-AH81)	Receive and evaluate public comments on the ANPR.	Complete	
					Provide public comment summary and recommendation to the Commission (SECY)	SECY under development.	
Reactor (NRR)	Licensing	Risk-informed ASME Code Case	N-716	Alternative risk-informed in-service inspection methodology	Support ASME review and approval.	Under review	
					Review two pilot plant applications.	Under review	
			N-752	Alternative risk-informed repair and replacement of passive components	Support ASME review and approval.	Under review	
			OMN-3	Alternative to RG 1.175 risk-informed surveillance interval for IST	Support ASME review and approval.	Completed	
		N-751, 752, 753	Alternative to RG 1.178, risk-informed in-service inspection	Support ASME review and approval.	Under review		
		Topical Reports	WCAP-16168	Risk-informed extension of reactor vessel weld inspection from ten to twenty years	Review and approve topical.	Under review	
			EPRI TR-1009325 rev. 1	Risk-informed extension – permanent 15-year ILRT extension	Review and approve topical.	Under review	
Reactor (RES/NRR)	Licensing	Risk-related Reg Guides	RG 1.200	An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities	Issue Revision 1 endorsing ASME Standard on at power, internal events, Level 1 and LERF PRA.	Complete	
					Issue draft to Revision 2 endorsing PRA standards on external events, internal fires and low power/shut down.	<a href="#">Link to plan</a>	
		Risk-related Standard Review Plan Sections	Section 19.0	Probabilistic Risk Assessment and Severe Accident Evaluation.	Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities	Guidelines for Categorizing SSCs in NPPs According to Their Safety Significance	Staff activities complete. Awaiting industry implementation
						New SRP section to address COL and Design Certification.	In final revision to address Commission direction.
						Update to incorporate Revision 1 to RG 1.200, which adopts ASME PRA Standard Addendum B.	In final revision to address Commission direction.

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Reactor (RES/NRR)	Licensing	Risk-related Standard Review Plan Sections	Section 19.2	Review of Risk-Information used to Support Permanent Plant-Specific Changes to the Licensing Basis: General Guidelines.	Revise and update. (Re-numbered from original SRP Chapter 19.)	In final revision to address Commission direction.
Reactor (NRO)	Licensing	<u>Risk-Informing the Standard Review Plan (SRP)</u>		<p>Develop a reviewer's "desk guide" for NRO technical staff to apply risk insights to the review of new reactor license applications for those areas of the SRP that are amenable to being risk-informed.</p> <p>Specific objectives include:</p> <ul style="list-style-type: none"> <li>• Ensure effective review, identifying any non-conforming aspects or other issues that would be inimical to public health and safety.</li> <li>• Facilitate efficient review using a graded approach, in which the level of resources applied to a given review area is commensurate with the importance to assuring public health and safety.</li> </ul>	Form technical team to identify possible approaches to risk-inform the SRP to enhance new reactor review efficiency; obtain management approval of selected approach	Complete
					Identify SRP sections amenable to being risk-informed and develop a template to transmit risk insights for these sections	Complete
					Develop samples based on AP1000 design and present to management	<a href="#">Link to plan</a>
					Develop guidance document for transfer of plant-specific PRA information on SRP sections.	<a href="#">Link to plan</a>
					Develop and conduct training for staff who will review new reactor PRA submittals and contribute risk information to the desk guide	<a href="#">Link to plan</a>
					Conduct training for staff who will use the risk insights in the desk guide	<a href="#">Link to plan</a>
					Provide risk insights for each reactor type as they become available	<a href="#">Link to plan</a>
Reactor (NRR)	Licensing	RI-Tech Specs	Develop risk-informed improvements to the standard technical specifications (STS).	Initiative 1	Define the preferred end state for technical specification actions (usually hot shutdown for PWRs).	CE and GE – complete. Westinghouse and B&W - in progress.
				Initiative 2	Increase the time allowed to delay entering required actions when a surveillance is missed.	Complete
				Initiative 3	Modify the existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk).	Complete
				Initiative 4b	Modify the current system of fixed completion times to allow reliance on a configuration risk management program (CRMP) to determine risk-informed completion times	Draft industry guidance and pilot plant application under review
				Initiative 5	Optimize surveillance frequencies	Pilot plant approved STS Change for all Plant types in progress.

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Reactor (NRR)	Licensing	RI-Tech Specs		Initiative 6	Modify LCO 3.0.3 actions to allow a risk-informed evaluation to extend operating time prior to shut down	STS revision for CE plants being prepared
				Initiative 7	Define actions to be taken when equipment is not operable but is still functional	Snubbers and hazard barriers – complete. Industry currently preparing additional proposals.
				Initiative 8	Risk-inform the scope of 10 CFR 50.36.	Industry working on proposals
Reactor (NRR)	Licensing	Fire Protection	NFPA 805 Support	Fire protection for operating nuclear power plants	National Fire Protection Association Standard NFPA 805 Rule and Regulatory Guide 1.205.	Complete
				Pilot Application	Review NFPA-805 implementation at 2 pilot plants.	In progress
				Circuit Analysis	Post-Fire Safe-Shutdown Circuit Analysis Resolution Program.	In progress
Reactor (RES/NRR)	Licensing, Rulemaking, Oversight	Phased approach to PRA quality	PRA Standards	Develop standards and related guidance for appropriate PRA quality and the application of risk-informed, performance-based regulation in conjunction with national standards committees and industry organizations.	Develop at power, internal events, Level 1 and LERF PRA standard (ASME).	Complete
					Develop external events PRA standard (ANS).	Complete
					Develop internal fire PRA standard (ANS).	<a href="#">Link to plan</a>
					Develop low power/shutdown PRA standard (ANS).	<a href="#">Link to plan</a>
			RG 1.200	Provide guidance in 4 areas: (1) technically acceptable PRA; (2) NRC position on consensus standards and related industry guidance; (3) demonstration that PRA used in regulatory application is of sufficient technical adequacy; and (4) documentation to support regulatory submittal	Issue Revision 1 endorsing ASME Standard on at power, internal events, Level 1 and LERF PRA.	Complete
					Issue draft to Revision 2 endorsing PRA standards on external events, internal fires and low power/shut down.	<a href="#">Link to plan</a>
			Prioritization	Encourage industry to shift towards phases 2 and 3 of the phased approach to PRA quality	Develop a prioritization system for license amendments based on the phased approach to PRA quality.	Complete
Implement prioritization system for license amendment requests.	Revision to LIC-101, "License Amendment Review Procedures," in process.					

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status		
Reactor (NRR/RES)	Licensing, Rulemaking, Oversight	Digital Systems PRA	Develop short term guidance on how to use risk-insights to assist in the resolution of key digital system issues	Develop short term guidance how to use risk-insights to assist in the resolution of key digital system issues	Issue a Regulatory Information Summary (RIS) that provides interim guidance, and acceptance criteria for licensing reviews of digital systems in operating reactors	Awaiting stakeholder input		
					Issue licensing guidance and acceptance criteria (Regulatory Guide or other appropriate guidance) and update Standard Review Plan (SRP)	In progress		
					Risk-inform digital systems reviews	Develop guidance for incorporation of risk-inform decisionmaking in licensing reviews of digital systems for current and future reactors	Complete research to identify or develop acceptable modeling methods, assess failure data, determine criteria for level of modeling detail, assess uncertainties and determine how to interface digital system models with the rest of the PRA, to support risk-informed decisionmaking for digital systems. Issue NUREG/CR's to provide needed technical bases	In progress Two NUREG/CRs on dynamic methods issued Another on quantification in development
					Issue Regulatory Guide on Risk-Informed decisionmaking review methods applicable to digital I&C systems	In development		
					Update NRC PRA data, models and tools to support NRC assessment of digital system risk and reliability	In progress		
					Update Standard Review Plan (SRP) and other NRC guidance (RG 1.200, etc.)	Awaiting completion of other tasks		
Reactor (NRR)	Licensing, Rulemaking, Oversight	Risk-Informed Environment		Broaden staff's knowledge and acceptance of risk in day-to-day activities.  Specific objectives include: • Improve individual employee priority on risk-informed regulation • Improve perception of risk-informed regulation's contribution to regulatory effectiveness • Increase management attention to processes, tools, and training that enable implementation of risk-informed regulation	Add units on risk-informed regulation to office qualification plans	complete		
					Increase risk knowledge among first-line supervisors through position criteria and training	<a href="#">Link to plan</a>		
					Provide formal training on risk-informed regulation to all NRR and NRO technical staff	<a href="#">Link to plan</a>		
					Develop informal web-based training on risk-informed regulation	<a href="#">Link to plan</a>		
					Create a web-based forum of expertise for knowledge transfer	Complete		

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Reactor (NRR)	Licensing, Rulemaking, Oversight	External Communications on PRA		Communicate the purpose and use of PRAs in NRC's reactor regulatory program more transparently to the public and stakeholders.	Update fact sheets on probabilistic risk assessment and nuclear reactor risk	Complete
					Redesign risk-related pages on the NRC public website	<a href="#">Link to plan</a>
					Develop a brochure on risk-informed regulation	<a href="#">Link to plan</a>
					Organize a broad-scope public meeting on risk-informed activities (if needed)	<a href="#">Link to plan</a>
Materials (NMSS)	Rulemaking		Part 40 Jurisdictional Working Group	Develop an approach to more clearly specify NRC's authority over source material to uranium and thorium that is extracted and/or purposely concentrated for the use of uranium and thorium.	Provide Recommendations/Legislative Package to Commission	<a href="#">Link to plan</a>
Materials (NMSS)	Rulemaking		Exemptions from licensing, general licenses, and distribution of byproduct material	Systematic re-evaluation of exemptions from licensing in 10 CFR Parts 30 and 40	Final Rule 1	<a href="#">Link to plan</a>
					Proposed Rule 2	<a href="#">Link to plan</a>
Materials and Waste (NMSS/FSME)	Licensing, Rulemaking, Oversight	Developing a framework for incorporating risk information in the NMSS regulatory process	Update Risk-Informed Decision-Making guidance document	Develop an approach to more clearly specify NRC's authority over source material to uranium and thorium that is extracted and/or purposely concentrated for the use of uranium and thorium.		Revised guidance scheduled for 9/2007
Materials (NMSS)	Licensing, Oversight	Implementation of Part 70 Revision	10CFR70 Interim Staff Guidance Development	Develop guidance to address issues encountered in implementing Subpart H (Integrated Safety Analysis).		Continuing
			Review Integrated Safety Analyses (ISA) for existing facilities	Through interaction with licensees address remaining ISA review issues.		Continuing
			Revise Inspection Procedures for Part 70	Risk-informed review procedures consistent with Subpart H		Continuing

Table B-1 Initial Draft Database of Risk-Informed and Performance-Based Initiatives

Regulatory Arena - Responsible Office	Regulatory Functional Area	Initiative	Program or Project	Project Description and Major Activities	Major Project Activities	Status
Materials (NMSS)	Licensing, Oversight	Incorporate Risk Information into the High Level Waste Regulatory Framework	Pre and Post Closure key technical issue resolution	Risk-Inform Pre and Post Closure key technical issue resolution		TBD
			Model Abstraction Review Team Strategies	Develop strategies using risk insights.		Completed 3/2007
			Total System Performance Assessment, TPA 5.1	Develop TPA code version 5.1		Scheduled 6/2007
Waste (FSME)	Licensing, Oversight	Risk-Informing Division of Spent Fuel Storage and Transportation Standard Review Plans for Storage and Incorporating Interim Staff Review Guidance-Purpose to save staff resources	Application of selected risk Methodology to revised storage SRP chapters	Proposed 3 methods, trial application on two SRP chapters, resulting in selection of methodology		Scheduled to be Completed 5/3/07
			Application of selected risk Methodology to revised storage SRP chapters	Combined efforts of NRC Staff and contractor to risk inform specific SRP chapters		Scheduled to be completed 1st quarter FY 2008. Competing priorities and resource needs may delay schedule.
Waste (FSME)	Licensing, Rulemaking	Probabilistic risk assessment of dry cask storage systems	Pilot PRA of dry cask storage facility	A pilot PRA of one specific dry cask storage facility was performed.		Completed

## Significant Accomplishments

## HIGHLIGHTS OF MAJOR RISK-INFORMING INITIATIVES

The following paragraphs highlight the major risk-informing initiatives that either the staff has completed over the past six months or are scheduled to be conducted over the next six months.

1. **Fire Protection for Nuclear Power Plants:** The staff continues its effort on fire protection. The following summarizes the past and planned accomplishments in this area:
  - The staff completed the rulemaking to endorse an alternative performance-based and risk-informed fire protection rule for operating nuclear power plants. The final rule incorporated National Fire Protection Association (NFPA) Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," into 10 CFR 50.48. Since the U.S. Nuclear Regulatory Commission (NRC) issued Regulatory Guide 1.205, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants," in May 2006, 40 operating nuclear power plants have indicated a desire to adopt this alternative rule.
  - During the past six months, as part of the NFPA 805 implementation process, the staff conducted observation visits to the pilot plants and conducted a number of public meetings. As part of this process, the staff plans to issue a Regulatory Information Summary (RIS) to communicate resolution of emerging issues identified and resolved during the NFPA 805 pilot implementation process. The staff also plans to revise the enforcement discretion policy for NFPA 805 transition plants and to conduct at least one workshop for regional inspectors.
  - In the area of fire modeling, the Advisory Committee on Reactor Safeguards (ACRS) recommended that NUREG-1824, "Verification and Validation of Selected Fire Models for Nuclear Power Plant Applications," be published. The staff plans to issue it by May 2007. The staff has initiated the next phase of the fire modeling project which will be a joint project with Electric Power Research Institute to develop a fire model user's guide for nuclear power plant applications. A fire model Phenomena Identification and Ranking Technique meeting is also planned for the Summer of 2007. The staff has completed testing and analysis for the Cable Response to Live Fire (CAROLFIRE) project which supports the resolution of technical areas identified in NRC RIS 2004-03, Revision 1, "Risk-Informed Approach for Post-Fire Safe-Shutdown Circuit Inspections." The draft NUREG/CR reports are expected to be issued in May 2007, for a 45-day public comment period.
2. **Standardized Plant Analysis Risk (SPAR) Model Development Program:** The staff is developing plant-specific probabilistic risk assessment (PRA) (known as SPAR models) that model accident sequence progression, plant systems and components, and plant operator actions. These models are easy-to-use tools that enable the NRC staff to perform risk-informed regulatory activities by independently assessing the risk of events or degraded conditions at operating nuclear power plants. The following summarizes the past and planned accomplishments in this area:

- SPAR models for internal initiating events during full-power operation are available for all 72 plant sites in the United States. The staff is currently developing models for external initiating events (fires, floods, seismic events, high winds, etc.). Two Level 2 models are being developed and evaluated as part of a proof-of-concept to support other agency initiatives.
  - The staff is currently using SPAR models to support the development of the state-of-the-art reactor consequence analysis of severe accidents at nuclear power plants.
  - The staff is developing a Browns Ferry 1 SPAR model to be completed in August 2007.
  - The staff has begun discussions with industry in an effort to resolve several generic technical issues that influence both SPAR and licensee PRA quantification results.
3. **Digital Systems PRA:** The staff is developing guidance on integrating risk insights into digital system reviews and comprehensive guidance for risk-informing digital system reviews. In March 2007, the staff published a NUREG/CR on “Dynamic Reliability Modeling of Digital Instrumentation and Control Systems for Nuclear Reactor Probabilistic Risk Assessments.” The report illustrates how the dynamic models, Markov modeling, and dynamic flowgraph modeling, can be developed and integrated into PRAs. This report is one part of the overall NRC effort to advance the state-of-the-art in digital system risk and reliability modeling to the point where it will be possible to risk-inform licensing reviews for digital systems.
4. **Risk Management of Technical Specifications (RMTS):** The staff continues to work on the RMTS initiatives to add a risk-informed component to the standard technical specifications. The following summarizes the major accomplishments in this area:
- Initiative 1, “Modified End States”: This initiative would allow (following a risk assessment) some equipment to be repaired during hot shutdown rather than cold shutdown. The topical reports supporting this initiative for both boiling water reactor and Babcock & Wilcox plants have been approved. The Westinghouse topical report, submitted September 2005, is under review.
  - Initiative 4b, “Risk-Informed Completion Times”: The overall objective of this initiative is to modify technical specifications (TS) to reflect a configuration risk management approach that is more consistent with the approach of the maintenance rule in Title 10, Section 50.65(a)(4), of the Code of Federal Regulations (10 CFR 50.65(a)(4)). Draft industry guidance and pilot plant applications are undergoing review. The South Texas Project and Fort Calhoun Station pilot plants reviews are to be completed in FY 2007.
  - Initiative 6, “Modification of Limiting Condition for Operation (LCO) 3.0.3, ‘Actions and Completion Times’”: A revised Combustion Engineering (CE) topical report will be submitted late spring 2007, for staff review. This topical report will support a future revision to the CE Standard TS to incorporate this initiative.

- Initiative 7, “Non-TS Support System Impact in TS System Operability”: This initiative would permit a risk-informed delay time before entering LCO actions for inoperability attributable to a loss of support function provided by equipment. Guidance documents have been approved for snubbers and hazard barriers and the industry is preparing additional proposals.
5. **Risk-Informed Decision-Making:** Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-504, “Integrated Risk-Informed Decision Making for Emergent Issues,” was developed to address recommendations raised by the Government Accountability Office report [GAO-04-415, “Nuclear Regulation—NRC Needs to More Aggressively and Comprehensively Resolve Issues Related to the Davis-Besse Nuclear Power Plant’s Shutdown,” issued May 2004]. A revision to LIC-504 was issued on February 12, 2007, to incorporate comments from pilot applications of revision 1. In the next six months, the staff will conduct training on LIC-504 for the NRR Executive and Leadership Teams.
  6. **Risk-Informed Environment:** In December 2006, the staff issued an action plan entitled “Fostering a Risk-Informed Environment in Nuclear Reactor Regulation.” This plan outlined five major actions designed to broaden staff knowledge and application of risk insights in its day-to-day activities. These actions relate to staff qualification plans and training, first-line supervisor risk knowledge, and knowledge management tools. Over the last six months, two actions have been completed. The staff added a unit on risk-informed regulation to office qualification plans and created a web-based forum for knowledge management on risk-informed regulation. An interoffice PRA Training Focus Group will develop an initial draft of new basic courses on risk-informed regulation for managers and non-PRA technical staff. These courses are expected to be piloted in the fourth quarter of FY 2007.
  7. **Phased Approach to PRA Quality:** A key part of implementing the phased approach is the development of PRA standards and related guidance documents. The increased use of PRAs in the NRC’s regulatory decision-making process requires consistency in the quality, scope, methodology, and data used in such analyses. To achieve this objective, professional societies, industry, and the staff have undertaken initiatives to develop national consensus standards and guidance on the use of PRA in regulatory decision-making. Based on updates to the standards and guidance documents issued by the American Society of Mechanical Engineers (ASME) and the Nuclear Energy Institute, the staff issued in January 2007 Revision 1 to Regulatory Guide 1.200, “An Approach for Determining the Technical Adequacy of PRA Results for Risk-Informed Activities.” Revision 1 to Regulatory Guide 1.200 is an important step in the phased approach to PRA quality, because it removes the designation of that Regulatory Guide as “for trial use.” The staff participated in an industry workshop (March 27-29, 2007) on Revision 1 of Regulatory Guide 1.200, which covered licensing impacts, process considerations, regulatory positions, and technical issues associated with removing the “for trial use” designation from that Regulatory Guide. Future revisions of Regulatory Guide 1.200 will address PRA quality standards for fire, external events, and low power and shutdown operations risk assessments.

Also in the last six months, the staff participated in ASME votes on risk-informed ASME code cases. In the upcoming six month period, the staff plans to issue revisions to Standard Review Plan, Chapter 19, “Probabilistic Risk Assessment and Severe Accident Evaluation,” to address new reactors, and to issue Regulatory Guide 1.206, “Combined License Application for Nuclear Power Plants (LWR edition).”

- 8. Risk-Informed Rulemaking:** Risk-informed rulemaking activities include changes to 10 CFR 50.46, changes to 10 CFR 52, and soliciting stakeholder interest in a risk-informed and performance-based Part 50, to be designated as 10 CFR 53. These are discussed below.
- Changes to Technical Requirements of 10 CFR 50.46: This rulemaking is to redefine the large break loss-of-coolant accident requirements to provide a risk-informed alternative maximum break size. The staff prepared a proposed rule containing emergency core cooling system evaluation requirements as an alternative to those specified in 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems (ECCS) for Light-Water Nuclear Power Reactors," which could be used in lieu of the current requirements in 10 CFR 50.46. Since October 2006, the staff produced a draft final rule and briefed the ACRS. The ACRS recommended that the proposed rule not be issued in the current form. The staff will provide a SECY paper to the Commission with a plan for responding to ACRS comments on the proposed change to 10 CFR 50.46, including resource and schedule estimates.
  - In 2005, the staff completed the development of the technical basis necessary to support a risk-informed rulemaking effort to modify the pressurized thermal shock screening criteria in 10 CFR 50.61. This technical basis was reviewed at various stages by NRC's external stakeholders, a select external peer review panel of technical and regulatory experts, the ACRS and NRC technical staff. In July 2006, the technical basis reports were made available to the public and the reports were published in final form in December 2006. This rulemaking concludes with provision of a revised version of 10 CFR 50.61 for Commission approval in January 2008.
  - The staff received and evaluated public comments on the Advanced Notice of Proposed Rulemaking (ANPR RIN 3150-AH81) regarding whether to make a risk-informed and performance-based revision to 10 CFR Part 50 (10 CFR 53). The staff will provide the Commission with a recommendation on whether to proceed with rulemaking in May 2007.
- 9. External Communications on PRA:** The staff is developing a range of communication approaches to reach the agency's diverse body of stakeholders. Over the last six months, three actions have been completed. The staff revised Office of Public Affairs (OPA) fact sheets on "Nuclear Reactor Risk" and "Probabilistic Risk Assessment." Such fact sheets are publicly available and OPA commonly uses them as reference material to respond to questions from the media and other stakeholders. Additionally, the staff developed a public-outreach brochure on risk-informed regulation and transmitted it to OPA for review and further development.

Over the next six months, the staff expects to implement a revision to the NRC public Web site to make information on the purpose and use of PRAs and risk-informed activities easier to find and more understandable to stakeholders. The staff is updating the redesign to include performance-based elements.

- 10. Develop Improved Human Reliability Analysis (HRA) Methods for Calculating Risk in Support of Risk-Informed Regulatory Decision-Making:** Currently, there are many HRA methods available for use in risk-informed regulatory applications. The ACRS has made specific recommendations on the need to compare the fundamental assumptions behind NRC models as well as the NRC and industry HRA models. Furthermore, the Commission directed the ACRS to “work with staff and external stakeholders to evaluate the different Human Reliability models in an effort to propose either a single model for the agency or guidance on which models should be used in specific circumstances.”

As a result of these interactions, the staff initiated work for testing HRA methods using empirical data. The results of this study will be used to better assess the accuracy, strengths, and weaknesses of the various HRA methods in order to create a tool box of HRA methods.

This study will be conducted with the collaboration of the Halden Reactor Project and its signatory organizations. Halden is offering its simulator facilities to perform the simulator runs and collect the data. About a dozen domestic and international organizations will participate in the study. Currently, a “Pilot” of the study is being conducted with the objective of testing the experimental methodology, which expected to be completed by September 2007.

- 11. Incorporating Risk Information into the High Level Waste Regulatory Framework:** The Yucca Mountain Review Plan (NUREG-1804, Rev 2, 2003) provides guidance to the staff on implementing the risk-informed, performance-based regulations of 10 CFR Part 63. The staff will use the Yucca Mountain Review Plan to ensure that licensing reviews are risk-informed and the proper level of effort is focused on areas important to the safety of the potential geologic repository at Yucca Mountain, Nevada.

Using risk insights, Model Abstraction Review Team strategies were developed and completed in March 2007. Total System Performance code, version 5.1 is scheduled to be developed for June 2007.

- 12. PRA of Dry Cask Storage Systems:** In support of the Commission’s policies on risk-informing the regulatory process and performance goals, the staff developed PRA methods and quantified the risk associated with dry cask storage of spent nuclear fuel. This study provided (a) methods to quantify the risk of dry cask storage of spent nuclear fuel, (b) insights into decision-making on how to improve regulatory activities associated with 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste,” and (c) analytical tools that can be used to implement future waste safety goals and risk-informed regulatory activities. The study has been completed and documented in NUREG-1864, “A Pilot Probabilistic Risk Assessment of a Dry Cask Storage System at a Nuclear Power Plant.” Insights gained from the report are being applied to the review and revision of the dry cask storage SRP and to the dry cask storage inspection program in the near future.

- 13. RAMQC Inspections:** On July 19, 2005, NRC issued Orders to NRC and Agreement State licensees imposing additional security measures (ASMs) with respect to the transportation of radioactive material quantities of concern (RAMQC). A risk-based approach was used in developing the RAMQC ASMs. The Orders apply to shipments of

radioactive materials in quantities greater than or equal to the Category 1 values in the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources (Code). Category 1 is the most risk significant category in the Code. The Orders also apply to spent nuclear fuel shipments greater than 27,000 curies but less than 100 grams of material. The RAMQC requirements are more stringent than the transportation security requirements for smaller quantities of radioactive material. The RAMQC Temporary Instruction was issued on September 18, 2006. One hundred forty nine licensees have implemented the RAMQC Orders. Inspections of these licensees have begun and are expected to be completed in the latter part of 2007.

14. **Design Basis Threat:** On March 19, 2007, the NRC published the final rule for the design basis threat in 10 CFR 73.1. This rule requires licensees to establish and maintain a physical protection capability that provides high assurance that public health and safety will be protected should the facility be threatened by an adversary. The physical protection regulatory regimen allows licensees flexibility to develop risk informed defensive strategies to protect the most risk significant nuclear equipment from the design basis threat.

The inspection of the licensee defensive strategies is risk-informed and performance-based. Force-on-force exercises are conducted wherein the licensee defends against a simulated threat to demonstrate the ability to protect risk significant nuclear safety equipment. The significance determination process for inspection findings is risk-informed in that the significance of any physical protection failure is stratified by the effect the failure would have had on public health and safety had the exercise been actual. The overall regulatory regimen focuses on protection of risk significant equipment and verification through performance based inspection.

15. **Emergency Action Levels for Advanced Passive Light Water Reactors:** The NRC staff is performing a review of the industry developed draft emergency action levels (EALs) for advanced reactors. The staff is working with industry to ensure the EALs address potential advanced reactor accidents in a risk informed manner. EALs are used to declare one of four classes of emergency in response to events at nuclear power plants. The EALs and the resulting emergency response are stratified according to the risk significance of the event. The staff has previously endorsed risk informed EAL schemes for the current fleet of operating reactors and the intention is to endorse the advanced reactor EALs for use in emergency plans when staff concerns are fully addressed in the next six months.