

Phase II: Creating a Risk-Informed Environment Initiative in the NRC Reactor Program

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Executive Summary

Background

For the reactor program, the Office of Nuclear Reactor Regulation (NRR) began the risk-informed environment (RIE) initiative in 2001. The project's objective was to: create an environment in which risk-informed methods are integrated into staff activities, and staff plans and actions are naturally based on the principles of risk-informed regulation. The RIE initiative addressed one of NRR's Operating Plan goals and was conceived by the NRR Leadership Team.

The staff's plan for this program included four phases: (1) evaluate the current environment; (2) design an improved risk-informed environment; (3) implement changes to achieve the target environment; and (4) assess effectiveness of environmental changes.

For the purposes of the RIE initiative, the term 'environment' is used to reflect a collection of entities important to the functioning of the reactor program, including the following:

- policy direction set by the Commission and senior agency management,
- the work processes and procedures used to achieve the goals of the reactor program,
- the attitudes and perceptions of staff members regarding the use of risk-information in the regulatory process, and
- the means for communicating and learning about new regulatory approaches and the tools and other resources needed to implement a regulatory approach.

To respond to barriers and challenges identified in the evaluation and to accelerate progress by addressing the design and implementation phases concurrently, the RIE team offered assistance to several ongoing NRR projects that were in the process of incorporating risk-informed concepts. This report summarizes lessons learned from these activities and suggests next steps for continuing to implement risk-informed regulatory processes in the reactor program.

RIE Pilot Projects

In particular, the RIE team worked with staff to address the key areas of Communication and Information, Training, and Process Improvement. The RIE team set up pilot projects that involved staff currently working on specific risk-informed activities and focused on helping to move the projects forward. This hands-on approach allowed the RIE team to function within current NRR staff activities without interrupting ongoing work, and to capture information that can be used to help further develop a RIE within the reactor program. Because solutions were developed by NRC staff both impacted by and working toward the change to a risk-informed environment, the suggestions can be considered proven and therefore, can be implemented across NRR.

The formal objectives for the pilot projects were to (1) define the components of a risk-informed environment by accumulating lessons learned from addressing the environmental needs of several current specific technical activities being risk-informed within NRR and (2) provide concrete assistance in one or more areas of communications, training or organization to the

participating technical activities to support broad implementation of the activities throughout the reactor program. The following pilots were initiated:

- Supporting Risk-Informing Technical Specifications Initiative 4B (TS4B)
- Research paper: Concepts Useful in Promoting a Risk-Informed Environment.
- Communication
 - o Newsletter
 - o Brown Bag Seminars
 - o Supporting the Operability Workshop

In addition to the pilot projects, the RIE team sought out experiences from both within the NRC and from the nuclear industry on what worked or didn't work for risk-informing organizations or programs. NRC can build on what it has learned by learning from other organizations that have implemented similar changes. Several organizations in the nuclear industry have successfully transitioned to risk-informed plant management by implementing extensive organizational and cultural changes that helped their staff understand and begin to use risk-informed approaches. Within NRR, the Balance of Plant Systems (BOP) Section was successful in beginning to transition its staff to using risk-informed practices. The RIE team interviewed and researched both these areas and documented lessons learned and best practices from the following:

- Case Study: Defining risk-informed and integrating risk concepts into staff roles and responsibilities at the section level (Balance of Plant Systems Section)
- Case Study: Nuclear industry practices
- Risk Communication Guidance & Training (Office of Research)

Next steps for continuing to implement risk-informed regulatory processes in the reactor program

NRR is in the midst of a multi-year culture change impacting many aspects of its traditional approaches to regulation and oversight. Research shows that a culture change of this magnitude can take up to 10-15 years in an organization the size and complexity of NRC. Using that timeline, one could conclude that NRC is on track with risk-informing its regulatory approaches. While some staff acknowledge they have always used PRA or risk-information on some level, the formal direction to integrate PRA more thoroughly into NRC's business structure came from the Commission in 1996. In 2003, NRC is perhaps half way to its goal. While ongoing improvement is needed, and frustration is still high in some areas, progress is being and will continue to be made. Based on the outcomes of this project, the following specific next steps should be considered to further improve the use of risk-informed activities within the reactor program.

Organizational Structure & Process Improvement

- Devote significant financial and personnel resources to risk-informing NRC.
- Demonstrate management support verbally and with consistent actions. Work to ensure the most senior managers are communicating the same message.
- Change job descriptions/responsibilities; include PRA measures in performance criteria and evaluations.
- Provide additional expertise where needed and integrate that expertise into existing organization groups.
- Enable ongoing education and debate among staff as they learn these new approaches.
- Provide specific guidance, standards, and definitions of risk-informed topics.
- Minimize movement of key knowledgeable staff and management who can make a significant impact on staff understanding of PRA and risk-informed approaches. In general,

NRC's predilection for advancement through transfer and promotion slows down progress and change because staff and management are continually adapting to new circumstances, projects and bosses.

- Provide the staff information about and definitions of risk-informing
- Share information about other risk-informed initiatives within the agency
- Raise and answer questions about risk-informing
- Encourage extensive dialogue and debate
- Develop individualized goals for each staff member related to taking proactive steps to be more risk-informed.
- Involve senior staff in risk-informed projects.
- Demonstrate top management support, buy in, and dedication of resources.
- Tie performance and forecasting plans to risk-informed approaches. Restructure and realign responsibilities as needed.
- Publicize and discuss benefits of PRA and emphasize that the new approach is using a mix of risk insights and traditional decision making applications.
- Participation in risk-informed processes is enforced through management policy and organizational change.
- Infuse the organization with PRA expertise B decentralize it.
- Work with staff on a case-by-case basis to raise and answer risk-related questions and to help resolve technical challenges.

Communication

- Provide tools and forums for improving two-way communication about risk-informed topics such as
 - o Informal knowledge sharing seminars such as brown bag presentations
 - o Easy to read newsletters such as Risk-e Business
 - o Publicizing progress and events related to risk-informed topics in other internal NRC publications
- Publish Guidance on internal and external communication about risk topics
- Encourage staff to develop communication plans that identifies the internal stakeholders, , the objectives of the internal communication, and the meetings and other mechanisms that will be used.

Training

- Create new formal training opportunities that address not only the technical aspects of PRA technology, but the ways it can be applied effectively such as:
 - o how risk assessment and its results should be applied in regulatory matters
 - o the bases for such application
 - o review of the key developments that lead to the Commission's policy statement on the use of PRA in regulatory activities
 - o an overview of current established risk-informed processes and the available guidance for implementing them.
- Create and foster ongoing informal training activities such as:
 - o technical seminars on specific subjects
 - o mentoring through on-the-job projects performed under the supervision of more experienced peers
 - o self-paced learning via intranet-based tutorials or other media

Project support

- Encourage planning for risk-informed initiatives to stimulate needed changes to processes and involvement.
- Invest in the staff who are involved through training and practical guidance.
- Increase proactive management involvement and support.

Monitoring effectiveness of initiatives

- Develop metrics to evaluate progress using both process and outcome indicators
- Monitor and measure progress using:
 - o Focus groups
 - o Individual interview
 - o Feedback forms and surveys

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1 Introduction and Background

1.1 Background

The Commission has provided high-level guidance in its Probabilistic Risk Assessment (PRA) Policy Statement to increase the use of PRA technology while complementing traditional regulatory decision making methods. The staff was directed to implement a risk-informed regulatory framework that allows the areas of highest risk to receive the greatest focus while conserving resources, reducing regulatory burden, and incorporating PRA insights into regulatory decisions. Using the PRA Policy Statement and the NRC's Strategic Plan as a foundation, the Risk-Informed Regulation Implementation Plan (RIRIP) describes staff activities to implement that policy. The goal of implementing risk-informed regulatory processes is to increase focus on safety, conserve resources, reduce regulatory burden, and incorporate probabilistic risk assessment (PRA) insights into regulatory decisions.

For the reactor program, the Office of Nuclear Reactor Regulation (NRR) began the risk-informed environment (RIE) initiative in 2001. The project's objective was to: create an environment in which risk-informed methods are integrated into staff activities, and staff plans and actions are naturally based on the principles of risk-informed regulation. The RIE initiative addressed one of NRR's Operating Plan goals and was conceived by the NRR Leadership Team.

The staff's plan for this program included four phases: (1) evaluate the current environment; (2) design an improved risk-informed environment; (3) implement changes to achieve the target environment; and (4) assess effectiveness of environmental changes. As this plan suggests, the basic strategy for the program was to first understand the current environment, and then, address weaknesses and build on strengths to facilitate increased understanding and application of risk-informed approaches.

For the purposes of the RIE initiative, the term 'environment' is used to reflect a collection of entities important to the functioning of the reactor program, including the following:

- policy direction set by the Commission and senior agency management,
- the work processes and procedures used to achieve the goals of the reactor program,
- the attitudes and perceptions of staff members regarding the use of risk-information in the regulatory process, and
- the means for communicating and learning about new regulatory approaches and the tools and other resources needed to implement a regulatory approach.

1.2 Phase I RIE Evaluation Report

Phase One was designed to gather insight into staff perceptions of risk-informed regulatory practices, identify barriers to implementing risk-informed approaches, and target ideas that facilitate successful risk-informed processes. An evaluation report (ADAMS # ML022460161), completed in August 2002 characterized common themes agreed upon by NRR staff and management and outlined systemic challenges related to risk-informed work activities and processes. The report was widely distributed in hard copy within NRR and the regions, and the RIE team conducted presentations to the LT/ET, to divisions across the reactor program, to the Risk Management Team, and to several NRC professional conferences during the summer and fall of 2002.

The evaluation report identified barriers to implementing risk-informed approaches as well as catalysts for achieving successful risk-informed processes. This was done by exploring the views and perceptions of staff members regarding their past experiences using PRA techniques in regulatory matters. The evaluation also examined staff experiences in developing and implementing risk-informed regulatory processes, including the reactor oversight process, risk-informed technical specifications, maintenance rule implementation, and the South Texas exemptions for special treatment of systems, structures, and components. The evaluation was conducted through extensive interviews and focus groups with NRR headquarters and regional staff and management.

The evaluation found that the current environment within the reactor program is represented by the following key issues.

- Overall, respondents, particularly those in the regions, indicated there is general acceptance that PRA and risk insights have a significant and potentially positive role to play in the reactor program. However, in general, NRR staff believe that burden reduction is the driving force behind the use of PRA.
- While respondents believed that increasing the use of PRA within NRR is a priority, they complained that there is not always a match of resources and incentives to help make a risk-informed environment a reality.
- Respondents felt that a clear, consistently agreed-upon definition of what is meant by 'risk-informed' either doesn't yet exist or has not been adequately communicated across NRR. Concern about lack of standards for PRA applications was also frequently mentioned.
- Non-PRA staff have limited knowledge of existing guidance.
- A significant proportion of respondents from Headquarters noted that they don't see how risk directly relates to their job.
- There is general agreement among all the respondents that current PRA training classes are good for a basic explanation of risk analysis. However, they do not address the rationale for PRA, but instead focus on PRA processes (e.g., fault trees). This is seen as problematic in part because it does not help non-PRA experts understand the value of a risk-informed approach.
- An overriding issue that emerged during the focus groups and interviews relates to trust in the PRA technology itself. Respondents indicated that many NRR staff and managers outside the PRA branch are not well-versed in the calculations, data or assumptions that feed PRA results. One barrier to acceptance of risk-informed approaches, therefore, is the lack of knowledge and experience with the technology.
- Staff across NRR asked repeatedly for standards and for the opportunity to review industry created PRAs.
- The results of the focus groups and interviews reveal that an information vacuum has created uncertainty in the minds of staff and management about each other's motivations in regards to implementing risk-informed approaches and using PRA in regulatory matters.
- Staff range from being experts at conducting PRAs to self-describing a lack of familiarity with risk technology and applications. In itself, that large experience gap is one cause of the communication and integration challenges discussed in this report.

Based on these findings the evaluation report identified the following potential improvements to more fully implement a risk-informed environment.

1. Provide clear, detailed direction for the creation of a risk-informed environment.
Respondents reported they heard mixed messages and saw inconsistencies in risk

policies and practices. There is not a uniform, detailed vision from all levels of management on what it means to be risk-informed, and there is not a consistent method or standard.

2. Address the lack of trust in PRA technology.
Staff who have limited experience with risk have misgivings about the PRA data, analysis process, assumptions, development and use of the final numbers. While standards are part of this concern, understanding PRA analysis and application is central to the issue of trust, as is clear, respectful communication from senior management. Non-risk analysis staff need opportunities to address their lack of familiarity with the technology.
3. Improve training and experience.
The consistent and responsible use of risk requires an understanding of probabilistic risk assessment analysis, and equally importantly, its applications and implications. Respondents observed that while existing PRA training classes are adequate to teach technique, they do nothing to help an employee make the transition to applying that new concept to ongoing daily responsibilities.
4. Provide models for risk-informed approaches.
Staff and management do not have a clear understanding of what is meant by risk-informed and integrated decision making. This creates a somewhat reactive climate of low trust and high concern.
5. Improve communication.
Improve internal communications to address concerns and misconceptions about PRA technology and its place in regulatory activities, and to build consensus regarding the creation of a risk-informed environment. An effective communication initiative can allay concerns, promote consensus about risk-informing activities in the reactor program, and facilitate ongoing change management.
6. Focus on safety.
Most groups have questions about the extent to which current implementation of risk-informed activities has achieved the desired results. Common questions include: Is the current use of risk analysis and insights improving safety or hurting it? Is there more or less regulatory uncertainty? Is there more or less regulatory burden?
7. Provide for feedback and evaluation.
By nature, the process of creating a risk-informed environment is iterative, requiring evaluation and feedback to facilitate positive progress. As additional technical review areas, work planning activities and decision making processes are risk-informed, unanticipated concerns and consequences will surface. Evaluation methods are needed to enable these issues to be identified and addressed during implementation and to capture and share lessons learned.

The evaluation report summarized the issues and improvement areas and provided a matrix of solution and problem areas to use for future planning in RIE activities. This is shown in Figure 1 below. The RIE team used Figure 1 to summarize evaluation findings and to provide a structure for discussing next steps. The three primary solution areas needing attention were summarized

as: Communication and Information, Training, and Process Improvement. Each of these areas need attention to improve the application of risk-informed principles to regulatory processes.

Figure 1

Challenges	Solutions		
	Communication and Information	Training	Process Improvement
Create shared vision of ‘risk-informed’ and ‘integrated decision making’			
Integrate PRA into roles and responsibilities			
Improve knowledge and experience levels			
Open communication channels			
Correct misconceptions about PRA technology			
Generate buy-in to risk technology			

1.3 Phase II Report Overview

The RIE team offered assistance to several ongoing NRR projects that were in the process of incorporating risk-informed concepts. This report summarizes lessons learned from these activities and suggests next steps for continuing to implement risk-informed regulatory processes in the reactor program.

- Supporting Risk-Informing Technical Specifications Initiative 4B (TS4B)
- Research paper: Concepts Useful in Promoting a Risk-Informed Environment.
- Communication

- o Newsletter
- o Brown Bag Seminars
- o Supporting the Operability Workshop

In addition to the pilot projects, the RIE team sought out experiences from both within the NRC and from the nuclear industry on what worked or didn't work for risk-informing organizations or programs. NRC can build on what it has learned by learning from other organizations that have implemented similar changes. Several organizations in the nuclear industry have successfully transitioned to risk-informed plant management by implementing extensive organizational and cultural changes that helped their staff understand and begin to use risk-informed approaches. Within NRR, the Balance of Plant Systems (BOP) Section was successful in beginning to transition its staff to using risk-informed practices. The RIE team interviewed and researched both these areas and documented lessons learned and best practices from the following:

- Case Study: Defining risk-informed and integrating risk concepts into staff roles and responsibilities at the section level (Balance of Plant Systems Section)
- Case Study: Nuclear industry practices
- Risk Communication Guidance & Training (Office of Research)

2 Designing a Risk-Informed Environment

2.1 Methodology

The Phase One evaluation results demonstrated that staff, even those who are supportive of risk-informed regulation, have experienced difficulties with implementing risk-informed regulatory approaches at the working level. The detailed results of the evaluation were shared with staff, management and stakeholders. The RIE team presented its findings to the LT/ET, and the LT/ET determined a vision was needed for the RIE. Several initiatives were begun to address this need, and risk-informed projects continued within NRR. Within this framework of multiple groups working to improve risk-informed initiatives, the RIE team determined the RIE initiative would be served best by working with ongoing projects needing assistance to identify and potentially implement solutions for specific problem areas, using the knowledge gained from the evaluation process. The RIE team offered assistance to several ongoing NRR projects that were in the process of incorporating risk-informed concepts and helped the projects respond to the barriers and challenges identified in the evaluation report.

Conceptually, this meant Phases Two and Three of the RIE initiative would overlap, as shown below in Figure 2. The RIE team felt this would facilitate more rapid progress and identify the positive characteristics that improve risk-informed approaches by addressing the design and implementation phases concurrently. Designing and implementing a RIE would initially consist of assisting staff who were already attempting to risk-inform specific projects in the following ways:

- identifying what kinds of support are most helpful,
- developing solutions to risk-informed challenges,
- identifying specific infrastructure needs in applying PRA technology and risk insights,
- capturing and documenting lessons learned from implementing risk-informed methods and processes, and
- sharing the results across NRR.

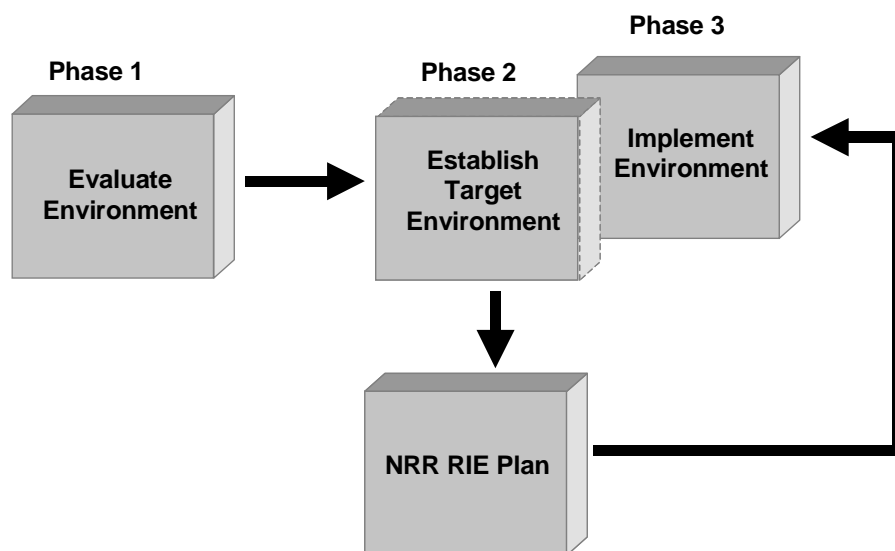


Figure 2 Risk-Informed Environment Project Model

Figure 2 also shows the next step. While progress has been made, and continues to be made

in risk-informing NRR, an office-wide strategy should be developed in order to increase the rate of change and provide for a consistent approach.

The RIE team planned to work with staff to address the solution areas summarized in the evaluation report matrix in Figure 1: Communication and Information, Training, and Process Improvement. Pilot projects were set up that involved staff currently working on specific risk-informed activities and focused on helping to move the projects forward. This hands-on approach allowed the RIE team to function within current NRR staff activities without interrupting ongoing work, and to capture information that can be used to help further develop a RIE within the reactor program. Because solutions were developed by NRC staff both impacted by and working toward the change to a risk-informed environment, the suggestions can be considered proven and therefore, can be implemented across NRR.

The formal objectives for the pilot projects were to (1) define the components of a risk-informed environment by accumulating lessons learned from addressing the environmental needs of several current specific technical activities being risk-informed within NRR and (2) provide concrete assistance in one or more areas of communications, training or organization to the participating technical activities to support broad implementation of the activities throughout the reactor program. The RIE team's goal was to provide tangible risk-informed solutions that contribute to developing a NRR-wide plan that outlines an infrastructure that supports risk-informed activities. The following pilots were initiated:

- Supporting Risk-Informing Technical Specifications Initiative 4B (TS4B)
- Research paper: Concepts Useful in Promoting a Risk-Informed Environment.
- Communication
 - o Newsletter,
 - o Brown Bag Seminars,
 - o Facilitation for Workshop on GL 91-18: guidance for operability, degraded, and nonconformance areas.

In addition to the pilot projects, the RIE team sought out experiences from both within the NRC and from the nuclear industry on what worked or didn't work for risk-informing organizations or programs. NRC can build on what it has learned by learning from other organizations that have implemented similar changes. Several organizations in the nuclear industry have successfully transitioned to risk-informed plant management by implementing extensive organizational and cultural changes that helped their staff understand and begin to use risk-informed approaches. Within NRR, the Balance of Plant Systems (BOP) Section was successful in beginning to transition its staff to using risk-informed practices. The RIE team interviewed and researched both these areas and documented lessons learned and best practices from the following:

- Case Study: Defining risk-informed and integrating risk concepts into staff roles and responsibilities at the section level (Balance of Plant Systems Section)
- Case Study: Nuclear industry practices
- Risk Communication Guidance & Training (Office of Research)

Building a risk-informed environment within NRR is incremental and iterative. But can NRR improve a risk-informed environment without a clearer definition of what that means? Staff and management alike have asked this question repeatedly and the evaluation results from Phase One noted the importance of more clarification of expectations, and a vision for a RIE. By working with staff in the throes of trying to answer these questions, the RIE team determined another solution area should be added to the matrix in Figure 1 from the evaluation report:

Project Support. This new area captures the need for and benefits of working directly with staff who are struggling with and resolving the questions and challenges inherent in integrating risk-informed perspectives to traditional regulatory approaches within a current project.

Figure 3 below summarizes the actions taken during this part of the RIE initiative and shows where they fit. In each section that follows, a summary list of RIE Pilot Project Target Areas is provided at the beginning of the discussion showing what areas were addressed from this matrix.

Figure 3

Challenges	Solution Ideas			
	Communication and Information	Training	Project Support	Process Improvement
Create shared vision of 'risk-informed' and 'integrated decision making'			Research paper	- Coherence Program - RMT
Integrate PRA into roles and responsibilities			TS4B support	
Improve knowledge and experience levels	- Newsletter - Brown Bag Seminars - Risk Communication Guidance (RES)	- Brown Bag Seminars - Research paper	TS4B support	- Case study: BOP section - Case study: nuclear industry practices
Open communication channels	- Newsletter - Brown Bag Seminars	- Risk Communication Guidance & Training (RES)	TS4B support	- Coherence Program - RMT
Correct misconceptions about PRA technology	- Newsletter - Brown Bag Seminars		TS4B support	- Coherence Program - RMT
Generate buy-in to risk technology	- Newsletter - Brown Bag Seminars		TS4B support	- Coherence Program - RMT

2.2 Pilot Projects

2.2.1 Supporting Risk-Informing Technical Specifications 4B (TS4B)

RIE Pilot Project Target Areas

Application Support

- Create shared vision of ‘risk-informed’ and ‘integrated decision making’
- Integrate PRA into roles and responsibilities
- Improve knowledge and experience levels
- Open communication channels
- Correct misconceptions about PRA technology
- Generate buy-in to risk technology

The RIE team identified ongoing risk-informed initiatives, such as fire protection, 10CFR 50.69 rulemaking, heavy loads, significance determination process (SDP), and risk-informed technical specification initiatives, and worked with management to identify which ones were appropriate within the time frame of this project. After reviewing these options, the RIE team began by working with Technical Specifications Initiative 4B (TS4B) on risk-informing flexible completion times¹. TS4B was chosen based on the following criteria:

- Modifications to technical specifications to allow for flexible completion times would impact staff activities in many branches across NRR (e.g. SPSB, IIPB, IEHB, SPLB, SRXB, EEIB, DLPM);
- Based on reactions to other risk-informed initiatives within the agency, TS4B has the potential to be controversial both within NRC and with external stakeholders; and
- TS staff and managers were interested in working with the RIE team.

The RIE team initially met with staff from Division of System Safety Assessment’s (DSSA) Probabilistic Safety Assessment Branch (SPSB) and the Division of Reactor Improvement Programs (DRIP) technical specifications (TS) section in January 2003 and provided assistance to the TS staff in two areas: project planning and review team formation.² The RIE team met approximately monthly with the TS4B team from DRIP to discuss the project needs

¹ **Initiative 4b, Flexible Completion Times:**

Current technical specifications contain equipment-specific outage times, limiting conditions for operation, and action statements (e.g., if the diesel generator is inoperable, restore within 7 days. If not restored, take actions to proceed to plant shutdown within 24 hours.) Current technical specifications address systems that directly support other systems, but otherwise do not generally account for the combined risk impact of multiple concurrent out of service conditions. The maintenance rule configuration risk assessment requirement was added to address this consideration, but does not obviate compliance with current technical specifications requirements. These current requirements may present inconsistencies with the maintenance rule requirements, and may require plant shutdown, or other actions, that are not the most risk-effective actions given the specific plant configuration. The overall objective of this initiative is to modify the technical specifications to reflect a configuration risk management approach that is more consistent with the maintenance rule (a)(4) approach. The proposal involves a combination of the current TS AOTs, an (a)(4) risk assessment to determine AOT extension feasibility, and AOT backstop limits. The AOT backstop limits ensure that low risk safety functions are not permitted to be inoperable for an indefinite period of time.

Status: The NEI RITSTF is coordinating multiple pilot programs, including CEOG and STP pilots, to ensure a single integrated methodology for Initiative 4b. A pilot plant that has converted to the STS is being sought by the RITSTF. While each pilot may not address the proposed methodology completely, the RITSTF will ensure the various approaches will prove the entire proposed methodology. The RITSTF will ensure a single coordinated methodology will emerge from and be supported by the individual pilots. The RITSTF will provide a draft management guidance document, an STP pilot application, a CEOG single system TSTF, and an integrated TSTF-424 early in CY 2003.

² The Risk Management Team (RMT) was an initiative within the reactor program to provide a structured opportunity for dialogue among managers working on reactor safety issues. The RMT was made up of staff from across the agency who met periodically to address specific issues related to risk-informed approaches. The meetings increased interaction among staff with traditional engineering approaches and staff with PRA expertise. The RIE team participated with the RMT by attending meetings, presenting status reports on its activities, and asking for approval and feedback on next steps. The RMT lost momentum when its chairperson was promoted to a new position within the agency.

and discuss possible approaches for providing communication, training, or process support for the technical review of the industry submittals. The RIE team and the DRIP team worked together to address initial planning and communication needs, and to create a definition of stakeholders and a list of potential RIE activities related to TS4B that could be done in the future (this list is included in Appendix A).

One outcome of the planning meetings was the change in overall approach that the TS staff applied to TS4B. Staff had originally planned to have a technical review team that was limited to TS and SPSB. Other areas of the reactor program would have been briefed once the majority of the technical review was completed. Internal stakeholders would have had the opportunity to provide input as part of the comment period. In other words, the tech spec staff planned to use the traditional NRR approach for TS4B. Due in part to the involvement of the RIE team and discussion held about the potential impacts of this approach, as well as lessons learned from past projects (such as the South Texas request for exemptions), the review team was expanded to include representatives from other branches that would be impacted by the implementation of flexible allowed outage times (AOTs). Thus, staff from DRIP, DIPM, DSSA, DLPM, and DE were included in the review team to provide their expertise and the perspective of the potentially impacted areas from the beginning of the TS4B process. This early involvement is more likely to allow for substantive contributions from branches outside of TSS and SPSB and the achievement of an end product that has greater internal support and addresses the needs of different sections and branches. It is too soon to determine the extent to which this will be true; however, staff involved in this effort believe this approach is more likely to be successful than the traditional one.

Other outcomes of the involvement of the RIE team included the development of a presentation on the background, objectives, and implications of TS4B, and the identification of training and other background resources that might be useful for the review team. While TS sent some of its staff to training, they discovered that the training available in PRA and risk insights is not adequate to meet the needs of the staff involved in TS4B.

In addition to participating in the monthly planning meetings, WPI facilitated the first TS4B review team meeting and Bob Youngblood of ISL provided a presentation on 'Concepts Useful in Promoting a Risk-Informed Environment' to the RIE team and the lead TS staff.

Interviews were conducted with the TS section chief and lead staff member to gather feedback on the involvement of the RIE team in TS4B. Interview questions included: What impact did the RIE team's involvement have on the TS4B initiative? How useful was the input of the RIE team? What are you doing differently as a result? What kinds of things have you learned that you didn't know before?

According to feedback received from the interviews, the RIE had a positive impact on the TS4B process.

- "Our meetings have forced me and the tech specs section to come up with briefings, put pencil to paper, synthesize the method we're going to see for achieving acceptability of risk-informed tech specs. They [the RIE team] were a catalyst to the thought process we're using now."
- "Very useful and constructive. The group has been a useful sounding board. Generated new ideas about how to do things and concrete ways to move forward. Changed our approach to the review."

- “The group been a useful sounding board. It generated new ideas about how to do things and concrete things to pursue now. It changed our approach to the review. We now have more time to think about it - it makes more sense to view things in a different relationship between RIE and tech specs... Now we’re communicating more with regional folks. This will serve as the demonstration RIE project due to its scope and where we are in the NRC culture. It’s not just helping hands. This is a good project for RIE.”
- “We expanded the internal community reviewing the initiative to avoid a ground swell of rejection from within the agency and end up with a criticism and reject mode. WPI (RIE team) involvement crystallized our realization of just how much we had to involve others and that we better go ahead and do it.”
- “From our meetings with you (the RIE team) I learned about my own organization things I hadn’t heard anywhere else!”

In particular, the staff members involved said the RIE Team provided:

- better understanding of the challenges faced by risk-informed initiatives and their acceptance within NRC;
- better understanding of the need for involving internal stakeholders in this change process;
- structure for identifying which branches within NRR to involve in the technical review based on areas that would be impacted by potential changes;
- assistance in the development of a presentation for reviewers and their managers;
- information about other risk-informed related initiatives throughout NRR (i.e., current status of the PRA quality guidance.)
- support from management in engaging additional reviewers from other branches;
- identification that training was needed and assistance in determining training needs; and
- facilitation of initial team meeting to lead off with a team approach and identify perspectives and background materials needs of the different branches involved.

There were several issues identified during the involvement of the RIE team with the TS4B initiative. First, although the tech spec staff were aware of the broad impacts of TS4B prior to the involvement of the RIE team, the RIE team provided the stimulation to change from the traditional model of reviewing industry submittals. With the assistance of the RIE team, the TS4B team expanded its review to include additional internal stakeholders and paid special attention to the training and background information needs of the reviewers.

Second, the actual implementation of an expanded review team required the TS staff to go through various levels of management to recruit members from other branches. This took time, preparation of background materials explaining the project and its potential impacts, and intervention from management to allocate staff resources from other branches that had not budgeted for involvement in TS4B. A common complaint heard during the Phase one evaluation project was that NRR tends to operate in silos and staff input from other areas is not sought until near the end of a project. The experience with TS4B illustrates the challenges that are faced when early involvement is attempted and what needs to be done to overcome them.

Third, the training in PRA and risk insights that is available through the NRC was not adequate to meet the needs of the staff involved in TS4B. The only course that is available is the one designed for the inspectors. Several of the TS staff attended it and found parts of it beneficial, but reported that a large part of the course was not relevant to their needs. In addition to formal training, the TS4B reviewers identified several areas where more shorter, more informal briefings would be beneficial to provide background needed for the technical review (e.g. the

Maintenance Rule and PRA Quality). Finally, the timeline for TS4B process has been adjusted to allow for more upfront planning, training, and involvement.³ This experience highlights the need to devote more time and resources to planning when applying risk-informed approaches.

2.2.2 Research paper: Concepts Useful in Promoting a Risk-Informed Environment

RIE Pilot Project Target Areas

Application Support

- Create shared vision of ‘risk-informed’ and ‘integrated decision making’
- Correct misconceptions about PRA technology

Most of the RIE activities within the reactor program are aimed at promoting broader staff acceptance of a risk-informed paradigm by making it easier for staff to understand and apply risk analysis. However, it has been suggested that staff acceptance and implementation of risk-informed approaches would improve if the paradigm itself were improved, because some of the current difficulties relate to shortcomings of the current paradigm. This topic was explored in a paper developed as part of this project (“Concepts Useful in Promoting a Risk-Informed Environment,” R. Youngblood, August 2003). The general themes of the paper are that certain issues would be focused more clearly if decision-analysis terminology were used more widely across NRC, and that progress would be easier if the current risk-informed paradigm were adjusted to align better with standard decision-analytic approaches.

In the Phase One evaluation report (ADAMS # ML022460161), WPI summarized issues and challenges relating to the difficulties of improving the risk-informed environment within NRR. The Youngblood paper addresses several of the issues identified in that report. The paper’s main points are summarized below.

- According to the evaluation report, many of the staff expressed a need for better definitions and a better concept of where risk-informed regulation (RIR) is supposed to be going. The paper argues that decision analysis provides the right vocabulary and conceptual tools to address this staff need.⁴ Adopting decision analysis tools would also help to focus RIR itself. In recent years, the agency has made increasing use of some of the machinery of decision analysis (e.g., objectives hierarchies), but it is desirable to go farther.
- The evaluation report reflects a widespread perception that risk-informed or risk-based reasoning is wholly different from what is called “deterministic” reasoning (here called “classical” practice). The paper discusses important ingredients that the two cultures have *in common*. This is intended to promote a better understanding of the relative strengths of RIR and certain of its needs, and to suggest how to improve the formulation of RIR by retaining the best parts of “classical” practice.
- The evaluation report documents a perception on the part of some staff that RIR is more about reduction of regulatory burden than safety improvement. This relates to the

³ It must be noted that the lengthened timeline was also a result of delay in receiving the submittals from industry.

⁴ Although decision-making is a major staff activity, and much discussed in regulatory guidance, formal decision methods do not seem to play a major role for many of the staff.

implementation measures⁵ adopted in many recent regulatory alternatives. In many discussions of RIR, implementation receives much less discussion than so-called “importance.” The paper presents a framework within which implementation receives significant attention; working within this framework, a better (more defensible) determination could be made of the regulatory burden appropriate to a given situation.

At the time of this report writing, the research paper is being presented and discussed within NRR. It is recommended that the concepts be further explored.

2.2.3 Communication

The evaluation found that communication about risk issues was a critical problem area for both staff and management. The RIE team developed several communication tools to address this need: the brown bag seminar series and an electronic newsletter delivered via email. The RIE team also supported the Workshop on GL91-18 on operability issues.

Brown Bag Seminars

RIE Pilot Project Target Areas

Communication

- Create shared vision of ‘risk-informed’ and ‘integrated decision making’
- Improve knowledge and experience levels
- Open communication channels
- Correct misconceptions about PRA technology
- Generate buy-in to risk technology

The brown bag seminar series was designed to provide open forums for staff to learn about risk-informed activities and topics in a casual setting that encouraged discussions, questions and answers, relationship building, and debate. By widely advertising the seminars NRC-wide, the brown bags provided employees throughout the agency an opportunity to learn more about risk topics, meet one another in some cases for the first time, and exchange ideas, language, and procedures associated with risk. During the brown bags, attendees learned how PRA was being applied or evaluated and how they could address it in their area. The underlying concept of the brown bags addressed the need to improve knowledge and experience levels by providing an informal information exchange and training experience.

The session format emphasizes interaction and dialogue rather than lecture, and topics presented reflect recommendations from staff and managers. The brown bags last 1.5 hours and consist of a 20-minute presentation followed by open discussion. A facilitator is present to help generate questions and manage conversation if needed. An evaluation form is distributed to gather feedback that will allow the seminars to remain flexible and responsive to the audience’s level of interest and needs. The seminars are held during the mid-morning time frame to encourage attendance, and a TAC charge number is provided so staff don’t need to justify their time spent at a brown bag seminar to their management. One purpose of the informal format is to provide an opportunity for employees from different areas to express

⁵ Defined in the main body of the paper.

concerns and questions about risk issues in an environment where questions are expected and welcomed.

At the writing of this report, three brown bags had been held; attendance and topics are shown below in Figure 3. Program topics were selected from suggestions and by volunteer speaker availability.

Evaluation responses have been positive. Participants said they attended the brown bags because the topics affected their job or they had a professional interest or curiosity in what was being discussed. Participants said they liked the format and found the shorter presentations educational and informative. All presenters were praised for being knowledgeable and sharing their expertise in an effective way. Participants liked the format and that it included an opportunity for interesting and engaging discussion.

Figure 3 - Tentative Schedule for Brown Bag Seminars

Topic	Presenter	Date	Location	Status
Use of Risk-Assessment in Event Evaluation	Ian Jung	7/21/03	O14B6	C
Status of PRA Quality Initiatives	Gareth Parry	9/10/03	O14B6	C
Recent Shutdown Risk Activities	Marie Pohida	10/09/03	O14B6	C
Concepts Useful in Creating a Risk-Informed Environment	Bob Youngblood	12/10/03	O14B6	C
Seminar on Operational Decisionmaking Using Risk	Mark Reinhart	Jan 04	O14B6	T
Seminar on Industry Methods for Configuration Risk-Management	TBD	Feb 04	O14B6	T
Seminar on Risk-Informing 10 CFR 50.46	E. McKenna	Mar 04	O14B6	T
Seminar on Risk Associated with Sabatoge and Terrorist Attacks	G. Kelly	April 04	O14B6	T
Seminar on Risk Management TS Initiatives	B. Tjader	May 04	O14B6	T
Seminar on Strong and Weak areas of PRA technology	G. Parry	June 04	O14B6	T
Seminar on Internal Risk Communications	TBD	July 04	O14B6	T

C - Complete

T - Tentative

Brown bags have been advertised through emails, newsletters, and the banner announcements that run on boards outside elevators throughout the NRC buildings. In the evaluations, most of the attendees said they heard about the brown bag through some form of email communication or from Risk-e Business, the electronic newsletter that discusses risk-informed activities in the reactor arena (see below for more information). Others heard about it through communications within their department or word of mouth. Email appears to be the easiest and most effective way to promote the brown bags, however support from management would help encourage even more employees to attend them.

Participants indicated they would like the brown bags to continue indefinitely. The amount of time needed to organize them is minimal, and the benefits are high, providing a low cost, low-pressure way to share risk information widely.

Future brown bag topics should be based on the availability of a competent speaker as well as suggestions from past participants. Brown bags should continue until (or if) attendance drops off precipitously. Detailed evaluation responses from the brown bags are included in Appendix B.

Potential topics for future brown bags suggested by participants include the following:

- PRA quality/use
- External Events Risk (may need RES person)
- Uncertainty and decision making
- Transition risk B how to decide if a shutdown is less risky than staying at power.
- Treatment of common cause interactions in PRAs
- Basis for component reliabilities in PRAs
- Sensitivity studies and their acceptability
- Security issues (the extent to which it can be presented)
- Thermal-hydraulics code
- Severe accident phenomena
- RIS-ISI -- What is it? What are the issues?
- RI TS initiatives -- What is it? What are the issues?
- Maintenance Rule implementation -- What is it? What are the issues?
- SDP -- What is it? What are the issues?
- How is risk information used in NOED decisions?
- Add performance-based PRA -- how to use performance-based criteria in relief requests
- 50.69
- RMTS
- 50.46
- Discussing strengths/weaknesses in any process (at a high level) would help identify future areas for assistance.
- Treatment of Aging in PRA-- focus on a long-lived passive components and structures.
- SPAR models subtleties
- PRA Modeling Techniques B limitations and how that affect regulatory decision making
- Limitations in PRA database
- Lessons learned from Davis-Besse
- Evaluation of Human Performance, impact of reduced regional inspection resources on event evaluation process, etc.

Newsletter: Risk-E Business

RIE Pilot Project Target Areas

Application Support

- Create shared vision of 'risk-informed' and 'integrated decision making'
- Improve knowledge and experience levels
- Open communication channels
- Correct misconceptions about PRA technology
- Generate buy-in to risk technology

The RIE team decided to begin an electronic newsletter to present news and information regarding risk-informed regulatory activities in NRC headquarters and Regional offices, and risk management and risk assessment activities in industry to the Commission and staff. The newsletter is published monthly and contains short news articles on risk-informed activities within NRR, Research, Regions, ACRS, and industry, a calendar of events and references to newly published documents related to risk issues, and links or sources for more information.

News items mentioned in the newsletter have included completion of key milestones in risk-informed programs or activities, arrival of major industry submittals of a risk-informed nature, results of public meetings and workshops, risk-significant inspection findings, operating experience that highlights risk insights (including risk assessments of operating events), and news items from utilities or owners groups that enhance the NRC's understanding of the industry's use of risk information in plant operation or plant modification.

To distinguish the newsletter from other emails it is formatted as an html/web based email note so it stands out from other emails in staff mailboxes. The newsletter has a color masthead, a catchy title - Risk-e Business - and embedded color graphics and photos, when they are readily available. It was developed with minimal investment in house and requires just 0.1-0.2 FTE over the course of a year to publish. Each issue is reviewed and approved by management.

The newsletter has been well received. To date it has been distributed in May, June, July, September, and October. Usage statistics are available only on whether the email has been opened in GroupWise. Data from the May distribution is not available, however the email statistics show that Risk e-Business was opened by 1,729 recipients in June, 1,664 recipients in July, and 1,586 recipients in September.

Unsolicited staff comments on the newsletter have included the following:

- Excellent, informative publication. I hope it gets the green light to continue.
- Fantastic newsletter! Great initiative! Keep it up!
- I like this - it will be helpful to me in my job. Thanks for your support of this effort; this kind of thing takes a lot of personal time and commitment.
- nice summary of the big picture...please keep me on distribution for this newsletter.
- This is great! Besides giving a quick update (in one place) of all the RIE activities going on, it should be a big help when we get routinely hit up by management to provide synopses of these activities for Commissioner periodic briefings, reports to Congress, RIRIP updates, etc. Format looks good, and level of detail seems about right.
- Great job on the presentation of the information. I would like to receive newsletters like this more often.

Aside from some technical issues about receiving the email that were easily resolved, some recipients have had concerns about the title and how it might be perceived negatively by the public.

Overall, the Risk-e Business email newsletter has been a successful activity and should be continued. It easily supports several of the communication needs identified in the FY02 evaluation report without being labor intensive or intrusive to NRC staff. Future issues should follow the established format and be distributed at regular intervals.

Supporting the Operability Workshop

RIE Pilot Project Targeted Solution Areas

Communication

- Create shared vision of 'risk-informed' and 'integrated decision making'
- Open communication channels

As a result of questions from both staff and industry related to NRC's guidance for operability, degraded, and nonconformance areas (GL 91-18), NRC staff and management determined the generic letter needed revision. NRC's typical approach to a revision is for staff to develop a draft revised guidance and then submit it for review and comment with both internal and external stakeholders. The staff responsible for addressing these issues requested support from the RIE team to implement a different approach. The staff wanted to host a workshop to identify areas of the current guidance that were confusing or inconsistent. Staff were also interested in collecting examples of operating experience that illustrate areas that the revised guidance would need to address. Staff believed that gathering this input in a preliminary workshop would strengthen the draft that was released for comment.

The RIE team was brought in to help plan and implement the workshop. While not directly related to the other risk-informed environment pilots, this activity was representative of the kind of culture change and the type of increased communication that can improve and implement risk-informed approaches. The RIE team determined that supporting this activity fit within the project's framework and objectives. As one staff member put it:

One of the reasons why things don't change is you don't have time to rethink and redo your infrastructure and align it with a risk-informed approach. Having a RIE project will help us bring our infrastructure along, that's what the operability meeting is about in August. We are rewriting the original guides, not just overlaying a risk idea over the existing stuff. We're correctly characterizing the evolution of how we've managed and kept safety margins. It's not the faster 'tastes great less filling' approach we have around here.

The RIE team helped NRC staff with the following activities:

- Participated in planning meetings to:
 - o develop a workshop plan, an agenda and meeting process, including plans for facilitation, attendee participation, and recording
 - o identify participants and determine how to invite them
 - o select topics and presenters for opening the workshop
 - o support logistics planning
- Developed workshop description and topic questions issued before the workshop in the Federal Register

- Facilitated the workshop, including developing discussion questions for use during specific sessions
- Recorded workshop notes for use in developing a workshop summary

The workshop was announced in the Federal Register along with specific questions staff wanted feedback on. Publishing these questions along with the workshop announcement helped to set the tone for and frame the intended discussion and workshop purpose. The questions included the following: Can a degraded SSC ever be determined operable? If so, what are the requirements for an operable but degraded determination? What is the distinction between operable but degraded and inoperable? If you remove a hazard barrier that is considered a support system but is not in TS, what analysis is needed to maintain the support system operable?

Comments and responses to these questions were received before the workshop, and a compilation of these responses was provided to workshop participants. The workshop was divided into 4 topic areas based on experience with issues raised previously, NRC staff needs, and the feedback from the questions published in the Federal Register before the workshop: 1) Definition of operable but degraded, 2) Support system operability (TS and non-TS equipment), 3) Operational Leakage, and 4) Component reliability and its relationship to operability.

Workshop participants included regional staff, licensees, and other interested or affected stakeholders. The workshop began with a plenary question and answer session with an expert panel from within NRC and was followed by breakout sessions on the topic areas. The workshop design provided lots of opportunity for participants to provide input on issues they felt needed to be addressed. A summary of each breakout was presented at the end of the workshop, followed by closing remarks.

Participant feedback -- The majority of the responses to the workshop were positive and demonstrated an appreciation for the new approach NRC was using. Participant comments included the following:

- Excellent coordination with meeting and breakouts. Excellent NRC participation and dialogue.
- Great NRC preparation for [communication with] industry with long standing 91-18 issues.
- It is very good to have a meeting of this type before issuing the draft for comment.
- Excellent activity that greatly enhanced my understanding of the issues.

The participants were pleased with the workshop because they were given the opportunity to provide their input for revising the guidance. Positive feedback was also received on the interactive format and the small group discussions. However, there were some comments indicating that participants had misunderstood the purpose of the workshop prior to attending. They believed they would be receiving information on the topics or hearing the staff proposal about the new draft guidance, rather than providing input for its development. For more details on participant feedback, see Appendix C.

NRC feedback -- The workshop resulted in benefits for NRC staff responsible for revising GL 91-18. The information gathered will enable staff to preemptively address issues and questions that would typically come up after a draft revised letter was issued. Staff indicated that they were pleased with the amount and quality of the feedback that was captured during the

workshop. In addition, the workshop supported early involvement of regional staff both during the actual workshop and in a preliminary meeting held the day before the event among NRC regional and headquarters participants.

Operability workshop lessons learned include the following:

- Gathering industry and regional input to guidance that is being revised provides information to NRC staff that enables the new draft guidance to address more areas needed for clarification and improvement
- NRC headquarters and regional staff benefitted from the early involvement of the regions in the revision of GL 91-18.
- Changing processes internally can engender some confusion in stakeholders who are accustomed to a specific way NRC conducts business.
- NRC has a need for facilitation that is not met by internal resources.

2.2.4 Case Study: Defining risk-informed and integrating risk concepts into staff roles and responsibilities at the section level.

RIE Pilot Project Target Areas

Process Improvement

- Create shared vision of 'risk-informed' and 'integrated decision making'
- Integrate PRA into roles and responsibilities
- Improve knowledge and experience levels
- Open communication channels
- Correct misconceptions about PRA technology
- Generate buy-in to risk technology

Throughout the reactor program there are examples of risk-informed approaches being implemented; however, the Balance of Plant Systems (BOP) Section in the Plant Systems Branch of NRR was selected as a case study for the RIE initiative because 1) the staff had not previously had much contact with risk information and applications; 2) a section chief was appointed who had a risk background; and 3) the section chief was given a mandate by his management to risk-inform his staff. Interviews were conducted with several managers, the section chief, and several staff members. In addition, a focus group was held with some of the staff from the section.

The BOP section chief took the following steps when he began working with the section. One of his first actions was to give a presentation to staff about his view of what 'risk-informed' means and use it to open discussion with his staff about risk information and its applications. The presentation included the following definition of risk-informing: 'Risk-informing is using results of risk analysis in a manner that complements traditional engineering approaches, supports the defense-in-depth, and preserves safety margins.' The presentation also provided a brief overview of risk-informed initiatives within the agency (i.e., Regulatory Guides 1.174 and 1.177 and Rule changes 50.44). Questions that staff had about risk-informed regulation were explicitly raised for discussion including: Do we have adequate PRA methods? Do we have adequate data? Do we have a common understanding of defense-in-depth? Do we have a common understanding of safety margins? The final section identified possible candidates for risk-informing and listed do's and don'ts for using risk information (such as probabilities and frequencies). The presentation was brief and allowed plenty of time for questions and

discussion.

The section chief also developed individualized goals for each staff member related to taking proactive steps to be more risk-informed. These goals were tailored for each person's areas of expertise, responsibilities, and familiarity with risk. Each staff member was asked to review his/her goals to ensure that they were appropriate and acceptable.

A third action taken in the BOP section was to involve senior staff in risk-informed projects that involve them with risk analysis and insights in an area that is directly applicable to their own work.. Two examples of such projects are the development of a joint seminar with RES on initiating event studies, system reliability studies, and reactor performance data sources that was held on May 28, 2003; and the application of commission policies on defense in depth to issues in the BOP section.

Finally, the section chief worked with staff on a case-by-case basis to raise and answer risk-related questions and to help resolve technical challenges the staff faced. He was able to reach staff when they had a need and demonstrate how to apply risk insights and perspectives to the problems/issues they were facing in their work. In the case of heavy loads, for example, probabilities were used to resolve a licensee amendment request. This assistance requires that the section chief have the risk expertise to raise and answer questions and to provide risk tools that could potentially address staff problems.

Both staff and managers reported that these efforts had a positive impact in creating understanding and acceptance of risk information and applications within the section. Staff were given the knowledge, tools, and opportunities to apply risk information in their own job areas and management expectations were clear and supportive.

- "We have better guidance to ask the right questions to get the answers we need. We have more confidence in ourselves and our projects. He knows the range of things that PRA can and cannot do for us."
- "Risk-informed is really a tool. I have more knowledge about where the strengths and weaknesses lie. When I'm standing up in front, I feel more comfortable speaking the language because I understand the uncertainties."

Staff within the BOP section still had concerns about risk-informed regulation but they also felt that having a section chief who understood risk information and applications was important and rare. He was not only able to provide them with insights into how risk tools could be applied in their job areas, but he also made the effort to inform them about what risk-informed initiatives were occurring across the agency. In addition, he was able to support his staff's technical expertise in interactions with risk analysts. It is also necessary to note that the personal approach that he used required management and people skills as well as risk knowledge and expertise.

The section chief was effective in impacting his staff, however, he was moved to another position within the agency within six months, as a result, it is not clear what the long term impacts of his leadership in the BOP section will be.

2.2.5 Case Study: Nuclear industry practices

RIE Pilot Project Target Areas

Application Support & Process Improvement

- Create shared vision of 'risk-informed' and 'integrated decision making'
- Integrate PRA into roles and responsibilities
- Improve knowledge and experience levels
- Open communication channels
- Correct misconceptions about PRA technology
- Generate buy-in to risk technology

Industry in general is beginning to recognize the economic and safety advantages of using risk-informed approaches. Some industry organizations have had greater success than NRC in implementing a new culture related to risk-informed approaches. NRC can learn from their experiences. To gather input from industry, the RIE team conducted focus groups at owner's group meetings and individual interviews with specific industry leaders from Exelon who had presented their organization's experiences with PRA technology at conferences. The focus groups and interviews demonstrated that industry groups and NRC face similar implementation issues but are responding to potential changes brought about PRA technology somewhat differently than NRC. One industry representative explained the differences around adoption of PRA technology this way:

“When [industry] people see the real tangible financial gains they become strong supporters [of PRA/risk-informed approaches]. That's not NRC's concern, they are completely focused on safety. If you appear to have reduced safety in any way (lower standards, fewer inspections) the doubting Thomas will say you've reduced safety. Industry would say we are maintaining a reasonable amount of safety and reducing cost in a measurable way. NRC is more likely to say I don't feel confident that we've demonstrated that we've really kept the same level of safety even if you say you know or understand it better with the PRA data.”

While industry has motivating factors related to implementing risk-informed approaches - there is potential cost savings associated with appropriate risk-informed approaches - they also face some of the same challenges as NRC: use of PRA technology remains unproven in some applications, doing PRAs is very expensive, some NRC directives and requirements don't incorporate risk-informed approaches, people are accustomed to the current approach to doing business, there is a wide range among management and staff of understanding of PRA technology, and as a result, sometimes PRA technology is misused or misunderstood.

However, despite these uncertainties, some licensees see a benefit to proactively implementing PRA and risk-informed approaches by demonstrating through PRA analyses that regulatory requirements can be changed to impact areas of less or greater safety significance. Interviewees pointed out that that increased use of PRA technologies and approaches actually increases responsibility on the plant side to focus on safety. While industry can't change it's approaches without approval from NRC, in anticipation of the move to risk-informed approaches directed by the Commission, some plants have completely restructured their management teams and retrained staff. Others are waiting, for example: “They've [my management] stayed status quo for 10 years because they want to stay focused on what needs to be done for compliance. There are lots of risk-based initiatives in industry, but none that is cost effective. They are waiting and watching and reading success stories from the industry before they make a change.”

While the RIE team didn't interview every licensee, the interviews and focus groups conducted yielded some helpful feedback. In addition, Excelon's experience yields specific ideas NRC could potentially consider.

General licensee experiences implementing PRA

While some plants have instituted organizational and management changes to implement risk-informed approaches, others have focused more on improving knowledge about PRA technology. This has been in the form of hands-on training, changes to existing training classes to include more information on risk assessment and PRA technology, and hiring outside experts to work with staff on the job and help guide them through the process of risk-informing traditional approaches.

Some plants changed their standard training classes to include more information on PRA applications or added PRA-specific classes. Others added more informal training seminars with self-testing exams available on-site to enable their staff to take classes on an as needed basis without the need for travel or extensive time off work.

For example, at one plant, PRA experts were hired as consultants and tasked with training staff in the appropriate application of PRA technology through on the job training. The consultants job was considered completed when the staff could apply their own understanding of PRA technology to a license amendment or other safety related issue without outside help. At another plant, employees with PRA expertise were relocated within the organization with the direction to share knowledge on a daily basis and conduct on the job training as needed. Another suggestion was to rotate staff, particularly new employees, through a PRA and risk assessment position, no matter what the final job was. Over time PRA expertise became integrated into the existing organizational structure, with every part of the organization having risk insight and understanding.

Plants that implemented a change in the use of risk were characterized by strong management support. Management communicated a commitment to incorporate risk insights and issued some basic ground rules on how to proceed. In at least one case, management mandated the use of risk. In at least one case, the organization changed the name of the group using PRA tools in an effort to improve the reputation and perception of PRA concepts and their application.

Interviewees noted several common reasons for implementing PRA at plants, including the use of the maintenance rule, paragraph A-4, and ability to make risk-informed license amendments, and a general safety culture/ability to improve plant safety brought about through the application of risk-informed approaches, as well as the anticipated cost savings, despite initially high investments required to implement PRA technology. The plants with success in changing their culture invested time and resources in communicating this rationale to the change to staff, and included in their communication that the change was not away from the deterministic approach but in a direction that adds risk insights to decision making and safety assessments. As a result, the plants reported increased communication among plant workers and risk analysts and management about risk issues, in some cases driven by need and in some cases driven by management directive, as well as increased communication with stakeholders as they struggled to understand risk insights. There is also recognition that how risk information is communicated has an impact on understanding PRA and risk-informed approaches.

At one plant, a key to success was a published schedule for making a change that defined specific activities for risk-informing.

Focus on Excelon experiences implementing PRA

Industry leaders from Excelon had presented their organization's experiences with PRA technology at several conferences in the last several years. The RIE team reviewed these papers and interviewed Excelon executives to gather additional data about how the organization has implemented risk-informed approaches.

Excelon demonstrated many of the same ideas used by other licensees. Strong management support was demonstrated by endorsement from senior management that were vocal and present at every plant.

“Without senior management endorsement and money, we couldn't have succeeded as well. I watched other utilities in that exact same time period be very frustrated because they couldn't get senior management buy in because their senior management didn't see the return on the investment, they didn't understand PRA and they didn't see it as a legitimate tool. Having a well educated and supportive senior management is the highest priority.”

The initial focus was entirely on education and training, and shifted later to the development of tools. PRA expertise was added and spread throughout the organization through the following actions:

- placed a resident PRA expert at each of its 10 plants,
- changed the name of the PRA group to Risk Management to shift the perception of PRA to the functional and beneficial application of a technique,
- shifted the role of the Risk Management Engineer at every plant to become an internal consultant on PRA.

In the midst of implementing these changes, Excelon and its predecessor businesses went through some merger activity. The Excelon managers interviewed believed this served to advance the cause of risk-informed approaches because there was less resistance to the PRA standardization that was being integrated and built in to the new overall business. Actions the merged company, Excelon, took included the following:

- standardized its PRA activities at all its sites by selecting the best practice from among the companies that were merging together,
- aligned responsibilities to be consistent at every plant,
- standardized approaches and realigned job responsibilities (without job loss),
- held regular team meetings to work through PRA issues and questions,
- developed arguments that explained why traditional applications changes could be justified with PRA without negatively impacting safety.

Another focus was keeping up with developments in PRA technologies. At Excelon, management hired a contractor with extensive experience to cross-check PRAs at different plants. The contractors doubled the full time staff so there were 4 people with PRA expertise per plant. Excelon also used proactive compensatory measures to help justify a change without expending significant resources to gather or measure data. For example, visual inspections for fire issues were proposed to ensure there were no leaks or potentially combustible issues. As

one person explained, “I don’t need to do a PRA calculation to provide how much less the risk of a fire is if I do a visual inspection.” These kinds of approaches were favorably received by NRC as well.

To demonstrate the results of using PRA, Excelon identified savings and improvements. For example, A-4 enabled Excelon to have cost avoidance, though that is hard to measure. In-service inspections decreased time and exposure by 30-40%. Other benefits to Excelon included life extensions and power renewals. As a result of applying risk-informed approaches (specifically, installing new turbines), Excelon was able to add the equivalent of a 100-megawatt reactor to their system through power upgrades without the expense and risk of building a new plant. Publicizing these kinds of results internally among the plants generated additional support. The combination of all these changes enabled the culture to shift and encouraged people to either accept the new change or leave, with no punitive affects.

Lessons learned from nuclear industry practices

Industry representatives specified what kinds of things are required to implement effective risk-informed processes and effectively change a culture from purely deterministic to risk-informed decision making. They include the following:

- Provide more management oversight and a changed management environment with a focus on risk and a budget for bringing in risk experts as needed.
- Recognize it’s a culture change as well as a new approach.
- Provide performance indicators, definitions and standards of measurement for quality and decisionmaking.
- Increased communication internally and with stakeholders.
- Provide on the job training and exposure to experts in PRA either through rotating through risk analysis positions or temporarily assigning PRA experts to groups and/or individuals. The organizational infrastructure must support the analysis and data needed for developing quality PRAs.
- Document lessons learned and implement them in other places.
- Ensure managers as well as staff have knowledge in risk-informed approaches
- Decentralize and integrate PRA expertise into all plant activities.

2.2.6 Risk Communication Guidance & Training

The Office of Nuclear Regulatory Research (RES) is spearheading an agency-wide effort to improve the ability of the staff to communicate about risk-information with internal and external stakeholders. The two outputs of this project are practical guidelines for effective risk communication and risk communication training. The guidelines are brief and contain practical guidance and tips for communicating risk information. The current plan calls for separate volumes for external and internal communication. The topics to be covered in the internal guidelines volume include communicating risk information with decision makers and communicating risk across technical disciplines. In conjunction with the guidelines, risk communication training is being developed. NRR is represented on the Risk Communication Steering Committee that is providing oversight of the project.

As part of developing the guidelines, the RES team conducted dozens of interviews across the NRC at headquarters and in the regions. These interviews were conducted in 2003. Although the focus was not PRA, the subject of risk-informed approaches came up frequently. Based on

the comments gathered in these interviews, it appears there is still a high degree of frustration throughout NRC about risk-informed approaches. One source remains the uncertainty. Another is the difficulties experience in risk-informed projects that leave a residual sense of frustration. A compilation or quotes is included in Appendix D. A few are excerpted below.

“Internal -- we have too many organizational conflicts/silos. Silos cause poor communication. NRR risk vs. RES risk vs. NMSS risk -- all are different perceptions and definitions. Too many terms: risk-informed, risk based, design based, deterministic etc. None of this is English. It’s either risky or not, period.”

“If we don’t have good communication internally how can we have it externally? Levels of understanding are inconsistent. Not improving much in this area. I have not had training in this area. I was given a book about understanding risk...that was supposed to explain it all to me, but I found it impenetrable.”

“In the Different Professional View process, there are problems with internal risk communication. Inspectors don’t feel like they are heard. The systems in plants are so redundant, that if an engineer finds a problem, the risk value may still come back green (no risk) due to the redundancies. Before, everything was deterministic vs. probabilistic risk assessment, so the person who pounded his fist loudest on the table got attention. Now, the engineers’ concerns seldom come up as important. They are told that their findings are not key things. I try to convey to them that their value is in preparing for an inspection and asking risk-informed questions in an inspection, not getting risk values changed to red or white. The inspections staff is now bigger than the operations staff, so you have a large portion of the staff frustrated because they feel like they are finding things that they are told don’t matter.”

“I don’t know if we can get there. We need to deal on a fundamental level with these issues, for example, what do you mean when you say ‘risk’-- a fatality? property damage? core damage frequency? system failure? What’s the relationship among these? Which is most risky?”

“The staff is frustrated because they feel they have done a good job technically and then are frustrated that communication doesn’t get through. They are obligated to follow regulations. If they have done this, then feel they are doing their job. Frustrated that message is not getting out. There is often a risk communication issue when we grant exemptions. Hard for public to grasp why we would grant an exemption. Throws in engineering judgment. Doesn’t satisfy external stakeholders. Most staff does not communicate with public personally. Just through documents. “

3 Creating a Risk-Informed Environment

This report summarizes the results of an effort to capture lessons learned from ongoing reactor program risk-informed activities and suggests next steps for continuing to implement risk-informed regulatory processes in the reactor program.

The RIE team implemented Phases Two and Three of NRR's RIE initiative concurrently. The RIE team focused on working with current reactor program projects to identify and potentially implement solutions for specific problem areas and to identify characteristics that advance effective risk-informed approaches. Lessons learned from activities to date can be used to further improve the RIE for NRR and to develop a NRR-wide plan for risk-informing the organization.

3.1 Organizational Structure & Process Improvement

Incorporating risk-informed approaches into design basis regulatory practices is neither linear nor discrete. In other words, designing or defining the end point is, in this case, a Fuzzy problem without a well-defined end point because it involves a culture change. A culture change can be defined as a shift in the fundamental assumptions people bring to an organization about how and why they do their jobs. The shift can be prompted through leadership direction or outside influences. In NRR's case, both apply: the Commission has provided some direction on risk-informing regulatory practices, and industry is applying PRA to exemption requests and relicensing.

3.1.1 Leadership

Within industry and with the ROP, a strong measure of success was not only powerful management support and investment of resources, but also specific guidance and changes provided by management, including changes in job responsibilities, addition of expertise where needed, and standardization. Within NRR, in the BOP section, change was facilitated through strong, knowledgeable leadership that was able to engage in debate, educate staff, and justify changes.

NRC would benefit from applying some of these ideas more widely in part because its current culture enables the opposite. Perhaps one reason for NRC's regulatory effectiveness is the intellectual independence of its staff. The potential downside is entrenchment and the ability for staff to simply wait out a change or bury a change in bureaucratic reports and analysis. In the case of risk-informing, management may need to provide more specific guidance and consequences to enable some staff to change. For example, PRA measures may need to be included in performance evaluations. Specific guidance, standards, and definitions may need to be generated and published. Job descriptions and functions may need to be changed. Additional opportunities for informal training -- and as importantly, the debating and exchange of ideas that engenders -- are also needed.

The LT/ET acknowledged the need to focus on a RIE vision by attempting to address risk-

informed needs through the Risk Management Team (RMT) and Coherence Group⁶. However, whether or not a definition exists, the agency is implementing risk-informed practices, reacting to PRA analyses done by industry, and reviewing exemption requests. Staff and management are working to develop solutions right now, without a target definition. To make progress in creating a risk-informed environment in the reactor program, NRR needs management direction and additional resources. The RMT will be re-energized in the fall of 2003 with a new leader in place from NRR's SPSB branch. If that manager is able to stay in his position long enough to implement changes, the RMT may be able to tackle some of the tough PRA questions that inhibit further progress. While its unclear where the Coherence Group stands, consistent leadership (that is, a leader that stays in place for some time without being promoted or transferred) could enliven that activity as well. Both activities also need to coordinate with the PRA Steering Committee's activities.

3.1.2 Resources

Office-wide review of the resources needed to support current and future risk-informed policies should be considered. Does the agency have the depth and breadth of risk expertise to regulate an industry that is becoming more risk savvy? There needs to be a systematic review of the regulatory expertise needed to support the new risk-informed regulatory policies. This should include projections on the increase in licensee amendments and other actions that require risk analysis in the review. Both SPSB and other parts of NRR should be considered in terms of staffing and the need for experience and training in risk applications. This needs assessment should include both long term staffing needs, as well as the training, project assistance, and consulting resources that are needed to support the staff during the transition to more risk-informed regulatory approach.

3.1.3 Defining risk-informed and integrating risk concepts into staff roles and responsibilities at the section level

The Balance of Plant Systems (BOP) Section provided a model that should be considered for replication in other areas of NRR. When there are section chief position openings, management should consider the level of experience of candidates with risk applications. A section chief with a risk background can both share that expertise with the staff and also support the integration of traditional and risk-informed approaches across the organization. This is needed to support the correct application of defense in depth and the right balance of engineering judgment and risk analysis. Incumbent section chiefs, with or without a

⁶ The Coherence Group was developed in response to a February 2002 Commission SRM directing staff to address regulatory structure convergence with our risk-informed processes. The Commission mentioned specific examples, such as the risk-informed significance determination process findings that some non-compliance situations identified through the reactor oversight program (ROP) were not risk-significant. Another example the Commission noted was that since risk was not assessed when most reactor design basis regulations were promulgated, use of the risk-informed ROP emphasizes safety issues not directly addressed in licensee Final Safety Analysis Reports or other docketed material. The Coherence Group was intended to address inconsistencies between the approaches and the objectives that the staff used to risk-inform different activities. An inter-office working group was formed and the group developed a detailed draft action plan for improving coherence among risk-informed activities. The plan was designed to provide an approach in which risk-informed reactor regulations, staff programs, and processes could be properly integrated so they complement one another. *A Plan for Achieving Coherence* (draft) was issued in Fall 2002, with the intention to hold ongoing public meetings and workshops, including briefing the Advisory Committee on Reactor Safeguards and the Commission. The RIE team worked in parallel with the Coherence Group, participating in meetings and providing input from the evaluation report. However, personnel transfers and promotions of staff among divisions and offices resulted in the Coherence Group losing momentum, as the RMT did.

background in risk, can also take proactive steps to encourage the integration of risk information. The following table includes a summary of steps that can be used to increase the ability of the staff to understand and apply risk concepts at the working level, as well as an alternative approach if the risk expertise needs to come from outside of the section.

Implemented by Section Chief	Alternative Approach
Give a presentation to staff providing a working definition of risk-informed and including risk applications relevant for the responsibilities of the section. Allow plenty of time for discussion and questions.	Have another manager or senior staff member with risk expertise and good communication skills give the presentation to the staff. A member of the section's staff can work with this individual to identify technical areas that might benefit from the application of risk insights.
Share information about other risk-informed initiatives within the agency	Encourage staff to attend training, seminars, or brown bags about risk-informed topics.
Develop individualized goals for each staff member related to taking proactive steps to be more risk-informed.	Guidance can be provided to section chiefs on the development of risk-informed goals, including examples from other sections.
Involve senior staff in risk-informed projects, such as defining defense in depth for specific applications.	
Work with staff on a case-by-case basis to raise and answer risk-related questions and to help resolve technical challenges using risk applications.	Build relationship with NRR risk practitioner to consult on issues that arise to see if there are risk insights that might be useful. This would require coordination with SPSB or RES and the encouragement of management.

3.1.4 Risk-informing roles and responsibilities

Activities to risk-inform NRR have focused almost exclusively on formal policy without a corresponding attention to the roles and responsibilities of staff.⁷ This is in contrast with the Reactor Oversight Program and with the more risk-informed of NRC licensees.

Based on the focus groups and interviews conducted with a variety of industry representatives these are the elements of a successful transition in industry success to using risk-informed approaches that NRC could consider adopting.

- First and foremost, top management support, buy in, and dedication of resources. Management, performance and forecasting plans modified to be tied to risk-informed approaches. If decision makers are satisfied and engineers aren't, senior management support is exercised to move the process forward.
- Benefits of PRA are demonstrated. In industry, management portrayed a new image of PRA/risk-informing that emphasized safety, problem solving and economic benefits. They changed the name from PRA to risk insights/risk management. Most importantly,

⁷ The exemption to this is the rotation of managers, however, this appears to be somewhat ad hoc and the purposes have not been communicated well.

management demonstrated that being risk-informed means using a mix of risk insights and traditional decision making applications. NRC management needs to provide similar messages, where applicable, to staff about risk-informed processes.

- Participation in risk-informed processes is enforced through management policy and organizational change. This includes restructuring and realignment of responsibilities (without affecting rank or salary).
- PRA expertise is both decentralized throughout the organization and supported by a central group. A dedicated project manager level person is assigned at every geographic location. NRR needs to avoid stove piping risk expertise, while at the same time ensuring a consistent approach that is based on rigorous, state-of-the-art risk analysis.
- Extensive formal and informal (peer, on the job) training opportunities are provided.

Once risk expertise needs are identified the appropriate approach to meeting these needs can be identified. Where is risk expertise needed and at what level? Different models for increasing the overall staff expertise with risk include training certain staff in risk analysis (similar to approach of the position of senior reactor analyst), recruit staff with risk analysis background for positions outside of SPSB; and using consultants as mentors.

3.2 Communication

Developing tools and forums for improving communication about risk-informed topics was an important goal of this project. Both the email newsletter and the brown bag lecture series were well received and consideration should be given to continuing these efforts as part of the Phase 3 plan for creating a risk-informed environment. In addition to these two communication vehicles, we believe that there are several other communication efforts that can help support a RIE.

3.2.1 Communication Planning

Communication planning leads to more effective communication and better use of resources. Especially in cases requiring communication across different areas of the NRC, including both intra- and inter-office interaction, staff should be encouraged to develop a communication plan that identifies the internal stakeholders, the objectives of the internal communication, and the meetings and other mechanisms that will be used. The increased integration of risk information is a significant change for the reactor program and as new processes, procedures, and policies are developed and implemented, it should not be assumed that the standard operating communication procedures, whether formal or informal, are adequate. Planning up front for the communication around new and potentially challenging issues is necessary for effective communication. It can also move the organization toward a new way of functioning. The NRC already has a protocol for the development of communication plans for external and internal stakeholders and staff have developed communication plans for several risk-informed tasks.

3.2.2 Risk Communication Guidance & Training

Another strategy for improving communication is to strengthen the skills of the staff at the individual level. The Office of Nuclear Regulatory Research (RES) is spearheading an agency-wide effort improving the ability of the staff to communicate about risk information with internal and external stakeholders. The two outputs of this project are practical guidelines for effective risk communication and risk communication training. The guidelines are brief and contain practical guidance and tips for communicating risk information. The current plan calls for separate volumes for external and internal communication. The topics to be covered in the

internal guidelines volume include communicating risk information with decision makers and communicating risk across technical disciplines. In conjunction with the guidelines, risk communication training is being developed. NRR is represented on the Risk Communication Steering Committee that is providing oversight of the project.

3.2.3 General Information Sharing

The newsletter is a general information-sharing tool that can be used to reach a wide range of interested parties. A NRC staff member designed the newsletter and built it in HTML. He also interfaced with NRC's information technology staff to ensure it worked in various Groupwise applications and to gather data on readership. The level of effort to maintain the newsletter is approximately 0.1 - 0.2 FTE over the course of a year. One way to manage the newsletter is to continue with this staff member gathering information and graphics, preparing articles, and publishing it. Another way would be to have each Office assign an individual as an office reporter to gather raw information for the newsletter, and feed it to the NRR newsletter coordinator for preparation and publication. An ideal candidate would be a bright, capable, outgoing junior level person, who desires interaction with higher level staff and managers and has good interviewing and writing skills. The newsletter coordinator would be responsible for gathering information from industry sources. The RMT could serve as an editorial board, if needed.

As was mentioned in the evaluation report, another way to improve general information sharing is to feed updates on risk informed activities into other existing email newsletters, such as 'Have I Got News for You' and NR&C.

3.2.4 Two-way Communication

Brown bags and other informal seminars like the ones held in the BOP section are easy to implement and promote informal information sharing, on the job learning, and relationship building.

Seminars are usually designed to enhance the audience's knowledge of a particular subject as opposed to training people on how to do something. They enable staff from different divisions to get to know one another, enhance connectivity between difference divisions, and provide those with PRA and risk-informed knowledge an opportunity to share B and in some cases, debate B that knowledge with their peers. Seminars are an attractive tool because 1) they can be highly focused to a particular issue or activity, 2) they are relatively easy to organize and 3) they are relatively inexpensive to implement. They are an especially attractive mechanism for supporting risk-informed activities because they can be directly focused on any of the many different and complex risk-informed applications and issues. In addition, they provide a forum for discussion by individuals with diverse technical and experiential backgrounds, which can help bind them together if they need to function as a team.

Experience from industry and the BOP section, as well as NRR's own successes with its Brown Bag seminars, demonstrate these successes. Again, a champion is needed to continue momentum, and the level of effort to continue the NRR Brown Bags is minimal. Tasks include identifying topics and presenters, scheduling dates and rooms, and publicizing the events. If desired, evaluations can continue to be distributed during each event.

3.3 Training

Based on the evaluation report and experiences in this phase of the RIE initiative, it's clear there is a need for additional staff training on the practice of risk-informed regulation. In addition to formal training, there are several complementary approaches for satisfying training needs informally. Opportunities for informal training and as importantly, the debating and exchange of ideas that engenders it are needed, as well as potential additions or revisions to existing training programs.

3.3.1 Formal Training

While the NRC currently sponsors a large number of formal training courses on PRA technology, it sponsors little training on how risk assessment and its results should be applied in regulatory matters, and the bases for such application. Consequently, practices in this area have been application dependent and staff have learned to implement them primarily on their own within their organizational unit. The lack of application-oriented training was exemplified this past year when management in the former reactor operations branch determined that the best training available for their staff to prepare for review of new risk-informed technical specification initiatives was a course developed for inspection staff. This course included a number of topics related to configuration risk-management, which made it attractive. However, it was clearly a compromise with respect to the learning task at hand.

A formal training course on applying PRA in regulation can improve the efficiency with which staff and management carry out their responsibilities and help ensure consistency in the way in which a given risk-informed process is carried out. Several findings from the staff's evaluation report suggest some type of formal training could be beneficial. These findings include:

- Respondents felt that a clear, consistently agreed-upon definition of what is meant by 'risk-informed' either doesn't yet exist or has not been adequately communicated across NRR.
- Non-PRA staff have limited knowledge of existing guidance.
- A significant proportion of respondents from Headquarters noted that they don't see how risk directly relates to their job.
- There is general agreement among all the respondents that current PRA training classes are good for a basic explanation of risk analysis. However, they do not address the rationale for PRA, but instead focus on PRA processes (e.g., fault trees). This is seen as problematic in part because it does not help non-PRA experts understand the value of a risk-informed approach.
- An overriding issue that emerged during the focus groups and interviews relates to trust in the PRA technology itself. Respondents indicated that many NRR staff and managers outside the PRA branch are not well-versed in the calculations, data or assumptions that feed PRA results. One barrier to acceptance of risk-informed approaches, therefore, is the lack of knowledge and experience with the technology.

Direct quotes from interviews with staff and industry also indicate there is an educational need around risk-informed topics.

"Train people in what works. Like case studies from management science and engineering, which are problem solving oriented, you have to solve problems at end of chapter -- present case studies like that, understand theories behind that." Deputy Executive Director

"Talking to NRR was like talking through a fog...NRR needs more people who can become more knowledgeable so they can evaluate PRAs. The knowledge level at the agency about

not just PRA techniques but the tools, the utility's PRA analyses, is far too low." Industry plant manager

A formal training course on applying PRA in regulation would prepare staff in NRR for assignments involving:

- review of risk-informed changes to the current licensing basis;
- review of proposed risk-informed, performance-based changes to standard technical specifications;
- review of license amendments associated with new risk-informed, performance-based rules, for example, proposed 10CFR 50.69 on special treatment requirements for systems, structures and components;
- the development of additional risk-informed changes to 10 CFR Part 50;
- evaluation of the significance of inspection findings;
- evaluating the safety significance of operating experience reported to the NRC.

In order for staff to participate in these activities in an efficient and productive way, it is necessary that they understand:

- the fundamental elements involved in making decisions under uncertainty;
- the fundamentals of risk assessment, with emphasis on the key engineering analyses; and assumptions that support risk assessments;
- the strengths and weaknesses of probabilistic risk assessment technology and traditional engineering analysis as tools for safety assessment;
- how to apply the criteria and methods employed in risk-informed decision-making;
- how to apply engineering insights that have been derived from risk-assessments;
- how to distinguish between the risk-informed and performance-based elements of new initiatives;
- how to communicate about risk and risk assessment with peers or with the public.

Other topics that may be especially helpful to new employees and foster a continuing strong safety culture include: 1) a review of the lessons learned from actual severe reactor accidents such as TMI-2 and Chernobyl, and significant precursors events; 2) a review of the key developments that lead to the Commission's policy statement on the use of PRA in regulatory activities; and 3) an overview of current established risk-informed processes and the available guidance for implementing them.

In order to make a formal training course most effective and spread the resource impact of implementing such a course out over time, participation in the course should be a requirement only for those employees assigned to risk-informed regulatory projects, line managers whose organizational units lead or support risk-informed activities, and project managers that have overall responsibility for an individual plant or group of plants. This approach is based on the idea that the training be relevant to current or near-term job responsibilities. However, individuals that want to take the training to improve their opportunities for career growth should be permitted to do so as well.

3.3.2 Informal Training

Informal training activities include technical seminars on specific subjects, on-the-job projects performed under the supervision of more experienced peers, and self-paced learning via intranet-based tutorials or other media. These training techniques are an important ingredient in an overall training strategy in that they allow staff to stay abreast of new developments in an environment of rapid change and to refresh their knowledge on topics at the time they become relevant to work activities.

Seminars

Seminars are discussed above and are a valuable tool that require a minimum expenditure of resources. The Research paper discussed earlier is a potential topic that could expand beyond a seminar. The general themes of the paper are that certain issues would be focused more clearly if decision-analysis terminology were used more widely, and that progress would be easier if the current RI paradigm were adjusted to align better with standard decision-analytic approaches. Therefore, while a seminar on this topic will be useful, a training course on decision analysis may also be needed.

Mentors

On-the-job training for risk-informed regulatory activities is currently used throughout NRC; however, as in many organizations, it is done on an ad hoc basis. One approach for making this type of training more effective is to establish experienced individuals within appropriate organizational units as mentors or lead engineers in the area of risk-informed regulation. In the Regional Offices, this function is a formal one that is delegated to the Senior Reactor Analyst positions. This may or may not be an appropriate approach for NRR. Additional study of the Senior Reactor Analyst model should be performed prior to embarking on a program at that level. It may suffice to simply write this responsibility into the job descriptions of senior staff in the organizational unit and identify appropriate levels of training for those individuals. If resources are available, consultant model of mentoring that the nuclear industry implemented could also be useful within NRR.

Intranet Based Training

Self-paced tutorials are a convenient means of getting an overview of a new topic or reviewing the key points of a topic learned previously. Intranet based tutorials are currently in use at the NRC. Two topics that the NRC has treated with intranet based tutorials include handling of potential allegations and changes to 10CFR 50.59. There are many topics related to risk-informed regulation that could be treated with intranet based tutorials. Some examples of technical topics include:

- basic terms and concepts of PRA and risk-informed regulation;
- generic insights drawn from risk assessments;
- risk categorization techniques;
- a general review of the PRA process itself (Level 1, Level 2, Level 3 etc.)

Intranet based tutorials may also be used to refresh knowledge on established review procedures or other risk-informed processes. This could help ensure consistency in reviews, reduce confusion about roles and responsibilities and make previous review experience and other more detailed guidance available in a convenient way.

3.4 Project Support

One of the focuses of the pilot projects was consideration of what assistance is helpful for staff

involved in current risk-informed initiatives such as TS4B. Providing specific assistance to ongoing projects helps staff identify areas where additional planning is needed, where significant change is being encountered which may create conflict or confusion, and what questions need to be addressed to integrate risk-informed perspectives into traditional regulatory approaches.

3.4.1 Project planning

In the cases of the TS4B and the Operability Workshop on GL91-18, NRR staff benefitted from planning assistance. The RIE team worked with technical staff to define objectives and then plan an approach to meet these objectives. The involvement of the RIE team stimulated change. The RIE team asked questions and offered facilitation services that helped break the staff out of the current operating procedure to see their project in a new light. When this assistance is not available, planning tools, such as writing a communication plan, can be used. Planning tools would help staff consider the potential impacts of a change, identify who should be involved, and what training or other guidance would be useful to support the activity. The matrix that was developed as part of Phase One was useful for the TS4B initiative and might serve as a basis for this. In any case, management will need to provide time and direction for the planning tool to be used and to consider new approaches to technical activities that are better suited to a risk-informed environment.

Management need to stay involved and be proactive in support. This support might include consideration of the timeline with the project requiring more time upfront and throughout the effort in order to allow for broader involvement. Managers are usually in the best position to facilitate communication and interaction across the organization, because staff might not have the access needed.

3.4.2 Supporting technical staff in risk-informed initiatives

Staff, especially those involved in a risk-informed initiative for the first time, would benefit from background information, training, and guidance. Background information might be in configuration risk management, the Maintenance Rule, or other risk-informed regulatory actions. During the Phase One evaluation, many staff noted that although the basic PRA class was good the concepts that were covered were difficult to retain when there was no opportunity to apply them in day-to-day work. When staff receive formal and informal training as preparation for involvement in a specific risk-informed initiative, it is more likely that the information will be retained and utilized.

In addition, guidance from contractors or senior staff/managers who have a solid background in risk could be useful in raising questions, introducing concepts and techniques.

3.5 Monitoring effectiveness of initiatives

Effectively implementing a risk-informed environment requires ongoing measurement to assess needs and progress. The evaluation component should monitor the effectiveness of training, communication, and process tools, as well as other changes that are implemented. This needs to be done in a timely manner to make sure that the tools and training are having the desired outcome and can be adjusted as 'real life' asserts itself.

The first step is the development of metrics. These should include both process and outcome

indicators. Process indicators focus on the procedures and tasks involved in implementing a risk-informed environment. Outcome indicators are used to evaluate the immediate effects of the initiative on the target audience, including changes in knowledge, attitudes, and behavior. Outcome evaluation is most suitable when the program has clear measurable goals. Here are some examples of process and outcome indicators for each of the overall challenge areas identified in the RIE evaluation report from Phase One.

	Process Indicators	Outcome Indicators
Create shared vision	<ol style="list-style-type: none"> 1. RIE efforts are coordinated with RMT and Coherence Project. 2. Staff are aware of shared vision 	<ol style="list-style-type: none"> 1. Risk-informed activities are consistent with shared vision. 2. Staff is familiar with and understands implications of shared vision.
Integrate PRA into roles and responsibilities	<ol style="list-style-type: none"> 1. Guidance is provided on management expectations for being risk-informed. 2. Guidance is provided on how to risk-inform specific job categories. 	<ol style="list-style-type: none"> 1. Staff understands management expectations. 2. More technical areas are risk-informed. 3. Engineering expertise is integrated into PRA and risk analyses.
Improve knowledge & experience levels	<ol style="list-style-type: none"> 1. Provide opportunities for staff to participate in a RI initiative. 2. Provide job-specific training on applications of risk technology. 	<ol style="list-style-type: none"> 1. Staff can apply risk technology to range of issues and problems. 2. Staff is more comfortable working with uncertainties and variability.
Open communication channels	<ol style="list-style-type: none"> 1. Increased opportunities for interaction between technical areas and PRA branch. 2. Increased communication channels between management and staff on risk-informed issues. 	<ol style="list-style-type: none"> 1. Perception of open communication 2. More integration between PRA analysts and other technical areas.

Correct misconceptions & address concerns	<ol style="list-style-type: none"> 1. Opportunities are available for staff to ask questions and raise concerns. 2. RI success stories are communicated to staff. 3. NRR or industry efforts to address risk-informed problem areas are communicated. 	<ol style="list-style-type: none"> 1. Staff has greater understanding of strengths and weaknesses of risk technology. 2. Increase in staff perception that risk-informed policies do not undermine safety. 3. Staff believes that defense-in-depth is maintained.
Generate buy-in		<ol style="list-style-type: none"> 1. Staff suggests areas to be risk-informed.

Once these metrics have been developed the appropriate techniques can be selected to gather information to evaluate the success of the risk-informed environment initiatives and to identify ways to improve them. These include:

- **Focus groups** are a qualitative research methodology especially useful in exploring attitudes, providing insights into multifaceted behavior or motivation, and when there is a desire for ideas to emerge. These results are solicited through the use of open-ended questions, followed by discussion and clarification. A strength of this forum is that focus groups take place in a more natural environment than individual interviews because participants are being influenced by the suggestions and opinions of each other, just as in real life.
- **Interviews** are another method for capturing qualitative information. Interviews are most effective when focus groups with a target audience are difficult to schedule or when the topic is sensitive or controversial and ensuring anonymity is a priority.
- **Feedback forms** can be useful in collecting both quantitative and qualitative data. Standardized forms can be developed to accompany RIE communication and training products to both evaluate effectiveness and gather feedback about product improvements.
- **Quantitative metrics**, as mentioned above, should be identified up front so that the right data can be tracked. In the case of RIE, these metrics might include the level of participation in seminars and training about risk-informed topics, number of managers who have specified levels of expertise with using risk information, or the amount of resources provided for staff training, mentoring, and communication products that are necessary for the creation of a RIE.

4 Summary and Conclusions

Edgar Schein, an organizational culture theorist, provides the following general definition of culture:

The culture of a group can be defined as: a pattern of shared basic assumptions that the group learned as it solved its problems of external adaptation and internal integration, that has worked well enough to be considered valid and therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems.

Culture change is difficult and time consuming because culture is rooted in the collective history of an organization, and because so much of it is below the surface of awareness. When changing a culture, it's often the case that people don't know what they don't know, which makes it difficult to change even when willingness is present. As one interviewee put it:

"Before I didn't know there would be this effort to help us get agreement. I didn't appreciate (perhaps) the facilitation approach in getting people's ideas out and resolving issues as much as I do now. I didn't know about the study/eval report you did -- it brought out details I wasn't aware of, crystallized a gut sense we all had about resistance to PRA, that it's based on ignorance, not sound technical principles for rejecting it. That report also brought to light the underlying acceptance of purpose B that is that we have a common basis we can all accept and use to proceed in implementing a RIE."

Culture change literature states that several critical areas must be addressed to successfully change a culture. These include the areas noted in the evaluation report: communication, training, process. Culture change is energized and guided by effective leadership that communicates elements of the change. Training helps an organization's members to model new behaviors more consistently and more effectively.

Culture change happens more quickly when infrastructure changes. When support systems like compensation, policies, and performance reviews are changed to be consistent with a new culture or approach, new behaviors follow more naturally as people adapt to the new order. Processes have to change if culture is to change, and when processes change there is less resistance because staff quickly see commitment to the new way is real and won't disappear tomorrow morning. If people are able to do their jobs the way they always did, the culture will not change.

The RIE initiative is bringing risk-informed issues to light to be addressed, and helping NRR establish some shared assumptions that will enable a broader and more consistent use of risk-informed practices. However, organizational issues must be addressed in order for this process to continue effectively. Through the process of working with the pilot projects, the RIE team has concluded that despite some progress being made, the same issues remain today as were present in FY 02. Many of the key challenges to risk informing remain the same as they were in 02. They include:

- No overall ownership/leadership of building knowledge and skills of use of risk insights in staff throughout NRR. High management turnover within SPSB, NRR, across NRC (one staff member estimated 60% of management had changed in 12 year tenure in SPSB)

alone). Rapid changes (promotions/special assignments/moves) for managers assigned to RIE projects

- Lack of attention and resources to implementation/transition to new policies, tools and process related to risk. Resolving differences between HQ and Region knowledge/use of PRA tools.
- Lots of misperceptions within staff and management about the use of PRAs. Lack of clear guidance/understanding at various levels within NRC of what an RIE is, should be, what best serves NRC and the public's needs.
- Does NRC have the expertise (in management and at staff levels) to support increased use by industry of risk arguments, policies, tools? Lack of NRC certainty about implementing RIE correlated with industry certainty about implementing RI tools. Not enough staff and/or not enough of the right knowledgeable staff in the right places. [Recommendation: an evaluation should be done of the risk expertise needs of new regulatory policies and this should be included in long-term planning.]

Within NRC, change is usually driven in two directions. The Commission provides general direction or guidance, as it did related to risk-informed regulatory approaches, and then staff works through the specifics of implementing a new approach, and responds back to the Commission through the management chain. To implement a more thorough culture change that addresses this project's objective B to create an environment in which risk-informed methods are integrated into staff activities, and staff plans and actions are naturally based on the principles of risk-informed regulation - the following specific areas should be addressed in a comprehensive risk-informed plan for the reactor program. Addressing these challenges will require dedication of resources beyond attention to policy. A plan for risk-informing the reactor program needs to demonstrate an understanding of what is needed to support NRR's risk-informed approaches on the staffing side and allocate the resources that correspond to these needs.

4.1 Next steps for continuing to implement risk-informed regulatory processes in the reactor program

NRR is in the midst of a multi-year culture change impacting many aspects of its traditional approaches to regulation and oversight. Research shows that a culture change of this magnitude can take up to 10-15 years in an organization the size and complexity of NRC. Using that timeline, one could conclude that NRC is on track with risk-informing its regulatory approaches. While some staff acknowledge they have always used PRA or risk information on some level, the formal direction to integrate PRA more thoroughly into NRC's business structure came from the Commission in 1996. In 2003, NRC is perhaps half way to its goal. While ongoing improvement is needed, and frustration is still high in some areas, progress is being and will continue to be made. Based on the outcomes of this project, the following specific next steps should be considered to further improve the use of risk-informed activities within the reactor program.

Organizational Structure & Process Improvement

- Devote significant financial and personnel resources to risk-informing NRC.
- Demonstrate management support verbally and with consistent actions. Work to ensure the most senior managers are communicating the same message.
- Change job descriptions/responsibilities; include PRA measures in performance criteria and evaluations.

- Provide additional expertise where needed and integrate that expertise into existing organization groups.
- Enable ongoing education and debate among staff as they learn these new approaches.
- Provide specific guidance, standards, and definitions of risk-informed topics.
- Minimize movement of key knowledgeable staff and management who can make a significant impact on staff understanding of PRA and risk-informed approaches. In general, NRC's predilection for advancement through transfer and promotion slows down progress and change because staff and management are continually adapting to new circumstances, projects and bosses.
- Provide the staff information about and definitions of risk-informing
- Share information about other risk-informed initiatives within the agency
- Raise and answer questions about risk-informing
- Encourage extensive dialogue and debate
- Develop individualized goals for each staff member related to taking proactive steps to be more risk-informed.
- Involve senior staff in risk-informed projects.
- Demonstrate top management support, buy in, and dedication of resources.
- Tie performance and forecasting plans to risk-informed approaches. Restructure and realign responsibilities as needed.
- Publicize and discuss benefits of PRA and emphasize that the new approach is using a mix of risk insights and traditional decision making applications.
- Participation in risk-informed processes is enforced through management policy and organizational change.
- Infuse the organization with PRA expertise B decentralize it.
- Work with staff on a case-by-case basis to raise and answer risk-related questions and to help resolve technical challenges.

Communication

- Provide tools and forums for improving two-way communication about risk-informed topics such as
 - o Informal knowledge sharing seminars such as brown bag presentations
 - o Easy to read newsletters such as Risk-e Business
 - o Publicizing progress and events related to risk-informed topics in other internal NRC publications
- Publish Guidance on internal and external communication about risk topics
- Encourage staff to develop communication plans that identifies the internal stakeholders, , the objectives of the internal communication, and the meetings and other mechanisms that will be used.

Training

- Create new formal training opportunities that address not only the technical aspects of PRA technology, but the ways it can be applied effectively such as:
 - o how risk assessment and its results should be applied in regulatory matters
 - o the bases for such application
 - o review of the key developments that lead to the Commission's policy statement on the use of PRA in regulatory activities
 - o an overview of current established risk-informed processes and the available guidance for implementing them.
- Create and foster ongoing informal training activities such as:
 - o technical seminars on specific subjects
 - o mentoring through on-the-job projects performed under the supervision of more experienced peers
 - o self-paced learning via intranet-based tutorials or other media

Project support

- Encourage planning for risk-informed initiatives to stimulate needed changes to processes and involvement.
- Invest in the staff who are involved through training and practical guidance.
- Increase proactive management involvement and support.

Monitoring effectiveness of initiatives

- Develop metrics to evaluate progress using both process and outcome indicators
- Monitor and measure progress using:
 - o Focus groups
 - o Individual interview
 - o Feedback forms and surveys

Appendices

Appendix A

Suggested Future activities related to risk-informing TS4B

Suggested Activities			
	Pre-acceptance (pre-submittal and during initial review)	Review & SER development	Post-SER
Inform	Develop communication plan. <i>(all Tiers)</i>	Develop briefing and handouts to introduce TS 4B to staff. What are the goals of the initiative? What are the known technical issues based on review of industry submission? What is known about the potential impact on staff processes if agency goes to flexible AOT? How will staff input be included? <i>(Tier Two & Three)</i>	
		Maintain schedule of initiative and opportunities for staff input. <i>(Tier One, Two, & Three)</i>	
		Provide briefings on project status with plenty of time for Q&A. <i>(Tier Two & Three)</i>	
Educate	Use half-day seminars to lay the groundwork for involvement of internal stakeholders. Suggested topics include licensee use of PRA and Configuration Risk Management. Increased exposure to these topics will support all risk-informed TS projects. <i>(Tier One & Two)</i>		Share lessons learned. <i>(Tier Two & Three)</i>
	Provide training seminars for section chief, project manager and task leader types on how to organize and facilitate group discussions involving internal stakeholders with diverse views and perspectives. Teach how to deal with issues in risk-informed activities (i.e., problem/concern identification and solution development in a controlled setting). <i>(Tier One)</i>		Train relevant staff on SER and impact on regulatory activities. <i>(Tier Two)</i>

Involve	Identify ongoing staff concerns about risk-informed regulatory initiatives.	Provide 2-3 opportunities for staff input during review. Suggested mechanisms include workshops, meetings, internal comment periods.	Identify lessons learned. <i>(Tier One & Two)</i>
		Maintain website with information, status, and mechanisms for questions and comments.	
Integrate (Develop Ownership)		Keep management involved through champion from each relevant branch. <i>(Tier Two)</i>	
	Develop TS 4B impact assessment.	Update TS 4B impact assessment and communicate. <i>(Tier Two)</i>	
		Address ongoing staff concerns about risk-informed regulatory initiatives as they apply to TS 4B.	Address ongoing staff concerns about risk-informed regulatory initiatives as they apply to TS 4B.
Evaluate	Provide Tech Spec staff with RIE review criteria. <i>(Tier One)</i>		Report to Leadership team on RIE support.

Stakeholder Tiers:
Tier One: Primary working group with responsibility for developing SER. Tech Spec staff and other staff as determined by review of industry submittals.
Tier Two: Staff and managers from branches who will be targeted for involvement and outreach activities. Include representatives from DRIP, DIPM, DLPM, DSSA, and DE.
Tier Three: NRR staff and other interested parties.

Appendix B

Brown Bag Seminar Evaluation Results

Brown Bag Topics and attendance

Date	Topic	Presenter	Attendance
July 21	Applying Risk Assessment in NRC Decision Making Processes	Ian Jung - Operating Experience Section	17
Sept 10	PRA Quality for Regulatory Decision-Making	Gareth Parry - Senior Level Advisor for PRA in NRR	46
Sept 25	Shutdown Operations from a Risk Perspective	Marie Pohida B NRR/DSSA/ SPSB	25
Oct 30	Research paper: Concepts Useful in Promoting a Risk-Informed Environment	Bob Youngblood B ISL, Inc.	TBD

Note: questions marks in responses refer to handwriting we were unable to decipher.

Responses to Brown Bag #1

1. How did you hear about this brown bag?
 - Risk e-business (5)
 - From the presenter
 - Close contact with Mark Caruso
 - From the chairman of the OE task force
 - Email (non-specific) (3)
 - Helped plan
 - Word of mouth
 - From a coworker who read about it in Risk e-business
 - A colleague sent an email

2. What motivated you to attend this event?
 - To hear more about the OE section in this process
 - Past involvement and current interest in subject
 - To learn, hear various perspectives, and understand risk communication internally
 - Operating experience, lecturer, aging/risk assessment
 - Interest
 - Curiosity, desire to learn
 - Improving PRA knowledge
 - Need to learn more about risk assessment
 - Interest in topic (use of PRA in event evaluation process)
 - Directly related to job activities
 - The description of the seminar seemed interesting and I'm currently in SPSB
 - New to NRC, responsible for aging management, wanting to learn all I can
 - Basic interest in the subject, especially from the standpoint of pursuing a potential generic (---?---

3. What did you like about the presentation?
 - Good overview of risk used in business process at NRC
 - Way it integrated diverse NRC processes
 - Colorful slides, excellent system overview of processes

- Outstanding presentation of Ian Jung, handout, Q&A
 - Very good overview
 - Good discussion
 - Open discussion
 - Knowledgeable presenter, courage to prepare first one
 - It is a beginning that is/was long overdue
 - Good presentation, helpful to hear what other departments are doing
 - The presentation was brief and to the point and the discussion was very interesting and engaging
 - Both the presentation and the discussion afterward, good format
 - Presented a good overview of various aspects, also helpful were open discussions
4. What did you dislike?
- No management participation.
 - Increase size of slides, allow room for notes
 - Room was too warm
 - Presentation was a little long
 - Lengthy monologue
 - Connection with PRA quality
 - Not nearly enough time to scratch the surface of a very complex topic
 - Some of the slides were hard to read and the colors didn't show up
 - My inability to follow discussion due to lack of knowledge, a lot to cover in a short time
 - Not sufficient time
5. Do you have any suggestions for future brown bags?
- More of the same, part 2.
 - Discussing strengths/weaknesses in any process (at a high level) would help identify future areas for assistance.
 - Treatment of Aging in PRA -- focus on a long-lived passive components and structures.
 - SPAR models
 - PRA Modeling Techniques B limitations and how that affect regulatory decision making
 - Limitations in PRA database
 - More on risk
 - Lessons learned from Davis-Besse
 - SPAR model subtleties
 - More on the same, other aspects: Evaluation of Human Performance, Impact of reduced regional inspection resources on event evaluation process, etc.
 - Evaluation of external initiations
 - Discussion on individual components e.g. actual development of logic to conduct regulatory analysis, another will be safety goals.

Attendees from Brown Bag #1

Title	Branch	Division	Office
Materials Engineer	EMCB	DE	NRR
Sr. Research Engineer			RES
Sr. Rx. Engineer	SPLB	DSSA	NRR
Team Leader	MEB	DET	RES
Chief IOHS	IROB	DIPM	NRR
HF Analyst	REAHFB	DSARE	RES
Reactor Systems Engineer	REAHFB	DSARE	RES
SRA	SPSB	DSSA	NRR

Em. Prep Specialist	EPHP	DIPM	NRR
Gen Eng.	SPLB	DSSA	NRR
Physical Scientist	SPSB	DSSA	NRR
Technical Assistant			OCM
Risk & Reliability Analyst			
Sr. Rx. Sys. Eng.	REAHFB	DSARE	RES
Economist	REAHFB	DSARE	RES
Steam Generator Lead	PM	DLPPM	NRR
Acting Chief TSS	IROB	DIPM	NRR

Responses to Brown Bag #2

1. How did you hear about this brown bag?
 - Email (15)
 - Risk e-Business (3)
 - Through staff meeting (2)

2. What motivated you to attend this event?
 - Work in regulatory applications of PRA B chiefly TS changes
 - Implementation of risk-informed regulatory decisions
 - My job
 - Topic and speaker
 - Subject matter
 - I am participating in the effort to risk-inform 10 CFR 50.46. One of the key issues impacting the extent of change which can be made as a result of the rule making depend on the PRA quality.
 - Highly recommended by supervisor
 - Interest in use of PRA in ROP
 - Active work involved with PRA quality
 - Familiarize with the problem
 - Better understanding of Pros and Cons of PRAs for decision making
 - EMEB is receiving a number of relief requests from licensees containing PRA
 - I need a better understanding of how to challenge/defend PRA quality in litigation
 - General interest and impact on future work activities
 - Desire to keep current on issues B potentially applicable to current and future jobs.
 - Professional development
 - Applicability to RITS
 - To learn what is going on in the areas of risk-informed decision making
 - Figure out how all the pieces fit together.

3. What did you like about the presentation?
 - Everything
 - Informal presentation with Q&As
 - ___?___, answered questions directly, and said if didn't know
 - Very insightful overview of the issues with lots of give and take with the audience
 - Well prepared and interesting speaker
 - Seminar covered the current states of PRA quality initiatives in the industry.
 - Most of the seminar could be followed by technically-based non-practitioner.
 - Very knowledgeable and informative
 - Open format, interactive
 - Q&A
 - Good pace, accurate info, open environment, good discussion

- Performance-based PRA
 - Presenter stayed on topic, provided a good general overview of salient issues, well organized and conversational tone.
 - Broad, coherent discussion of major issues and status.
 - Presenter was clear, handled questions well
 - Very well structured, excellent response to questions, presenter was extremely knowledgeable
 - Excellent overview of RG/ASME S&D/and process for achieving quality PRA
 - Great presentation from the presenter
 - Attempt to qualify relationships between 1122/ASME standard/NEI ___? ___
4. What did you dislike?
- Nothing -- great job!
 - Not enough handouts for all participants
 - Need more handouts
 - Projected slides were too small for the size of the room
 - Allow too much questions from the audience which leads the presentation to off-track. Many questions are not relevant to the subject.
5. Do you have any suggestions for future brown bags?
- Mode transition risk discussion B including HER estimates for manual valve settings.
 - Treatment of common cause interactions in PRAs
 - Basis for component reliabilities in PRAs
 - Sensitivity studies and their acceptability
 - Better food
 - Security issues the extent to which it can be presented
 - Latest in thermal-hydraulics code
 - Latest in severe accident phenomena
 - RIS-ISI -- What is it? What are the issues?
 - RI TS initiatives -- What is it? What are the issues?
 - Maintenance Rule implementation B What is it? What are the issues?
 - SDP -- What is it? What are the issues?
 - How is risk information used in NOED decisions?
 - More handouts
 - Add performance-based PRA B how to use performance-based criteria in relief requests
 - 50.69
 - RMTS
 - 50.46
 - Allow the presenter to finish his (her) presentation. Then take questions. Try to discourage people's questions are purely motivated by Show off his (her) personal knowledge which does not benefit to general audiences.
 - Slide presentation not visible to all and not enough copies of presentation

Responses to Brown Bag #3

1. How did you hear about this brown bag?
- Email (10)
 - Have I Got News For You
 - Risk e-Business (2)
 - Notice board
 - Staff meeting
 - Branch calendar

2. What motivated you to attend this event?
 - Of vital interest in my work
 - Relevant to RMTS
 - Trying to get smart on risk during all plant ops
 - To hear about shutdown risks
 - New job assignment of Junior Risk Analyst
 - PRA activities in regulatory decisions
 - General interest
 - Interest in topic
 - It's an interesting area of risk which is not as well represented in risk studies
 - Learn more about the factors that impact shutdown risk
 - Need to keep up to date
 - Topic
 - Interest in learning about this topic
 - Past experience as utility PSA engineer

3. What did you like about the presentation?
 - Thoroughness, good communication!
 - Good comprehensive overview
 - Good work, well covered.
 - Open format allowed for discussion during presentation
 - Important information provided about significance of shutdown risk
 - Good overview.
 - Level of presentation
 - Good general coverage of the issues that are relevant to risk, clearly presented
 - Real life examples/demonstrated points! Made presentation more effective.
 - Historical perspective, numerical risk results
 - Pointed out that staff reviews are not integrated. How a requirement in one area, containment isolated while in shutdown, may be negated by an item taken in another area, allowance of personal air locks or equipment hatches to be open.
 - Good presentation -- geared for average reviewer -- plain English
 - Good historical perspective

4. What did you dislike?
 - Reflected only NRC state of knowledge. Industry has gone farther than NRC seems to realize.

5. Do you have any suggestions for future brown bags?
 - I couldn't stay the entire time. But I think the brown bags are a great idea.
 - Don't call it brown bag since, as scheduled, it really isn't.
 - SDP
 - External Events Risk (may need RES person)
 - Uncertainty and decision making
 - Great job Marie!
 - Transition risk B how to decide if a shutdown is less risky than staying at power.
 - Repeat Gareth's on PRA quality/use
 - Industry representative presents brown bag

Appendix C

Operability Workshop Evaluation Summary

On Thursday, August 14 WPI assisted NRC staff in facilitating a workshop discussing operability guidance. Approximately 120 people from NRC headquarters, industry, and various stakeholder groups attended the meeting. Most of the participants heard about the meeting through the NRC Web Page or the NRC mailing list. Several others heard about it through other communication channels including word of mouth and internal notifications.

1. How did you hear about this meeting?	#
NRC Web Page	7
NRC Mailing List	8
Newspaper	0
Radio/TV	0
No Response	1
Other (see below)	21

Other Responses:

- Plant's Reg Affairs Staff
- NEI
- Reg Affairs Mailing
- Sent by supervisor
- STARS telecon
- Licensing Mgr.
- Contact with Kerri Kavanaugh
- Licensing Dept.
- NEI Notification
- My supervisor
- NRC mailing via internal company distribution
- Industry
- Coworker
- WG
- Company distribution
- Utility
- Discussion with NRC personnel
- Internal organizational correspondence
- Coworker
- Regional management notification
- Company management

	Yes	No	Somewhat
2. Were you able to find supporting information prior to the meeting?	30	0	5
3. Did the meeting achieve its stated purpose?	21	2	12
4. Has this meeting helped you with your understanding of the topic?	27	1	7
5. Were the meeting starting time, duration, and location reasonably	33	1	1
6. Were you given sufficient opportunity to ask questions or express your views?	33	0	2
7. Are you satisfied overall with the NRC staff who participated in the meeting?	27	1	7

Total	171	5	34
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Comments

The discussion about why the use of Alternate Source Term under 91-18 is different from use of other methodologies under 91-18 left the participants confused. The use of the AST has been used under 91-18 when a license amendment for use of AST was in the NRC approval process. Although an isolated case, it was allowed because a complete control room dose analysis had already been performed by the licensee, but not yet NRC approved.

Branch Chief -- Containment systems (B) response to use of AH . Source term for GL91-18 operability indicates he did not understand the questions nor does he understand GL19-18 Rev. I.

Some time set aside to discuss operability issues with reps from regions would have been helpful even if extra 2 day was needed. This would help with interim expectations. Good facilitation.

Another workshop would be good if comments on draft R.2 of GL91-18 are major.

When revision is done some inspector training, even if informal, would be beneficial. Several questions from industry seem to have resulted from inspector misunderstanding of operability.

More dialogue oriented meeting would have helped rather than a panel Q&A session.

While early in the process, little information was given out by the NRC on what their expectations/plans are. What are the NRC's issues?

We were able to provide input but were not able to get answers. Provide another workshop where specific answers to questions on changes can be addressed or NRC experts can answer specific implementation questions.

The meeting's purpose included 'discuss,' in addition to 'receive input.' The sessions tended to be a one-way collection of issues and concerns that the NRC staff needed. This is a laudable goal which I support. However, the NRC staff provided little or no feedback. I think NEI should play a role in reviewing the draft GL and helping the staff sift through the input they received today. NEI seems perfectly positioned to perform this role. Overall, I am satisfied with the meeting.

My expectation (possibly perceived) was that the 'draft rev' would be discussed, and questions/clarifications discussed. I also had hoped for more peer interaction to address industry questions regarding understanding/implementing GL91-18. Then, hopefully, the staff would provide existing expectations. What I feel is that the meeting was more directed in the staff gathering comments to assist the NRC in drafting a rev. Hopefully after the rev is drafted, there will be an opportunity to meet again to go over it.

Agenda for the meeting was different then the one originally published. Hence, I came with slightly different expectations. I expected more NRC input during breakout sessions.

Overall, the meeting went well. I expected a slightly different format.

My initial impression was that this was going to provide info and background on implementing/using GL91-18 B NOT on providing input to revision process. Holding workshop in auditorium was not conducive to interaction. Final note B good to have meeting and solicit feedback.

I believe we had some expectations of greater NRC interaction. However, it seems that the actual

purpose was to get input and questions on the table. That is fine, but we did not appreciate that ahead of time. Otherwise, once we understood the purpose it worked fine. Good facilitators.

Purpose of mtg was to obtain input/no clarification was provided: any ambiguities that existed, still exist until GL is revised. Having breakout in other building caused 15 minute delay which caused breakout to go 15 minutes long. Not big deal, but slightly impacted discussion.

I had the impression that there would be information shared with us about the staff's position. Instead, it was only a solicitation of questions and recommendations for the revision to the GL.

Looked for information on meeting during June and early July and could not find information on the meeting. Facilitators worked good.

Not all answers (written) to topical questions were provided prior to the meeting. The meeting lacked input from NRC. The NRC staff should have a better developed goal and purpose for the GL 91-18 revision. More input and a clear NRC position would help.

Good venue. However, we did not learn very much about the NRC progress in resolving the issue. We provided input to you, but I didn't get a sense of your intent with respect to resolving the issues that were already submitted in writing. There were no Anew drafts of any NRC guidance documents to review.

Good meeting such that public was able to provide questions, comments, etc., that could be incorporated into future revisions to 91-18. Once draft is available or out, another workshop to get industry input would be good.

Depends on what enhanced guidance is issued [Q3]. Since the meeting focused on questions and not answers, the meeting did provide an idea of what troubles people [Q4]..

The interaction between the industry and NRC was very beneficial. The breakout sessions provided a good forum for the exchange of ideas. Good coordination of events/breakout sessions.

That starting point was too wide-open to bring so many people in. If you draft new guidance from this you will feel like you are on square 1. Would have been better if you had a straw man encompassing NRC's known problems with current guidance and let that be the platform from which to connect.

Perhaps the NRC could hold a workshop on how it will enforce regulations rather than coaching the nuclear industry on how to avoid compliance with the CFR. How does allowing reactors to operate in degraded conditions enhance safety? How can NRC justify allowing a reactor to restart in a degraded condition when safety is supposedly NRC's priority? If an average member of the public were to witness this workshop, public confidence in the agency as a legitimate regulatory authority would be even lower than it currently is..if that is possible.

Could have had better answers to panel questions. Facility problems: Lights in auditorium too low, Door to room 10D4 needs to be fixed. Thanks for doing this. This was invaluable for me!

It is very good to have a meeting of this type before issuing the draft for comment.

Excellent activity that greatly enhanced my understanding of the issues.

The workshop breakouts that were round-table discussions seemed to be much more productive.

Excellent coordination with meeting and breakouts. Excellent NRC participation and dialogue. Great NRC preparation for [communication with] industry with long standing 91-18 issues.

Difficult dealing with NRC HQ security. A better venue would be a hotel conference room.

Appreciate the early involvement, but comes at the cost of answers. Good organization and topics. Look forward to receiving draft.

Great dialogue, many issues discussed. Facilitation kept meeting focused. Suggestion: Provide drinking water for meetings.

Initial breakout in auditorium was stilted because we were supposed to use microphones to ask questions. Suggest rearranging chairs to a classroom format. I'm glad we had the internal meeting ahead of time. A helpful approach to gathering NRC input.

Use of facilitators worked very well. Pre-registration worked well. Use of guards for security ease was good.

The agenda was not received prior to the meeting.

Appendix D

Interview Excerpts from RES Risk Communication Guidelines project related to RIE

We aren't aligned with external stakeholder needs. We say we want to maintain safety. We say risk-informed/performance based enhances safety, efficiency, effectiveness. To increase public confidence, look at the real benefit of safe operation. If we allowed changes of LOCA standards would that make us safer? Public confidence doesn't equal safety or levels of risk and consequence. Public confidence is something else than managing risk.

In the Different Professional View process, there are problems with internal risk communication. Inspectors don't feel like they are heard. The systems in plants are so redundant, that if an engineer finds a problem, the risk value may still come back green (no risk) due to the redundancies. Before, everything was deterministic vs. probabilistic risk assessment, so the person who pounded his fist loudest on the table got attention. Now, the engineers' concerns seldom come up as important. They are told that their findings are not key things. I try to convey to them that their value is in preparing for an inspection and asking risk-informed questions in an inspection, not getting risk values changed to red or white. The inspections staff is now bigger than the operations staff, so you have a large portion of the staff frustrated because they feel like they are finding things that they are told don't matter.

Internal risk problems in reactor space include: risk-informed, PRA policy statement, integrated plant evals, etc. Yet the percent of staff comfortable with PRA is still small. I'm not even totally comfortable with it. PRAs are a useful tool but we've never required high quality. That undermines us when plants have low quality. We need to get over that hump - get a larger percent of staff comfortable with using it and applying it at some plants and not others.

We have to overcome our name. PRAs in Europe ' PSAs -- probabilistic safety assessments, they are safety focused not risk-informed.

Internally: we're far too risk-based. We tend to counter that by saying we're risk-informed, but if you look at the process, it is based on risk.

Internally -- staff activities, can't cover risk. When a PRA public briefing is held, there are always a few slides about risk. There's a sense that there is still a competition within NRC that is deterministic, doesn't believe risk-informed is a good idea. Tremendous progress, but even the latest ROP summary shows some decrease in confidence in how well we can regulate effectively using risk (because of Davis Besse, probably).

Doing inspections/licensing in a risk-informed manner is fuzzy which makes it harder. You can't go down a checklist and say did you check that valve and did it work, you have to ask how relevant is that valve to safety.

There would be less disagreement on safety issues internally, less confusion, a more consistent point of view on safety significance. There would be more alignment about risk-informed regulation. Now it means different things to different people. We'd all come together on these concepts. I don't know if we can get there. We need to deal on a fundamental level with these issues B for example, what do you mean when you say 'risk' -- a fatality? property damage? core damage frequency? system failure? What's the relationship among these? Which is most risky?

First, we need to have shared understanding of issues within agency. We need shared understanding of risk-informed approaches. We still have culture change that is needed but have made major improvements. Throughout the agencies there are different levels of comfort with the use of risk. We should spend more effort with the culture change to reduce mixed messages to public. But it has gotten

better. HLW have brought in risk analysis. Need risk analysis to try to understand the long-term timeframe. This is easier for risk analysts than for operational people. Human reliability, for example, is a difficult area. There are different challenges across agency that need risk communication.

Hard to think of risk-informed example of successful risk communication. We are making progress in open communication but still aren't there with risk-informed activities and regulation.

The challenge is using risk-informed approach and communicating the degree to which we now regulate to the right issues. NRC culture change is necessary for success.

Questions about quality or precision of risk answers - People don't believe we or anyone can estimate probabilities correctly/accurately. For instance with scenario calculators B we get asked did you consider x event at y plant -- if the answer isn't yes they don't trust our answer. There are two groups: 1. Engineers -- mechanistic/deterministic/empirical; and 2. Probability types -- probability of states, of knowledge, subjective probabilities -- not empirical. They are perspective/subjective based, less clearly relatable to empirical data.

The internal treatment of risk as absolutes without characterizing uncertainty. Especially the deterministic folks -- they tend to hang on to a number as if it's the gospel. Same with stakeholders but they are very diverse. Our critics jump on point value, using one number to characterize something that is very uncertain. They use that number like it's the gospel, just like we do.

When we develop a risk analysis or risk argument, we argue for or against using certain factors in calculating the risk. Other factors should also have weight such as deterministic and observational factors.

In the Different Professional View process, there are problems with internal risk communication. Inspectors don't feel like they are heard. The systems in plants are so redundant, that if an engineer finds a problem, the risk value may still come back green (no risk) due to the redundancies. Before, everything was deterministic vs. probabilistic risk assessment, so the person who pounded his fist loudest on the table got attention. Now, the engineers' concerns seldom come up as important. They are told that their findings are not key things. I try to convey to them that their value is in preparing for an inspection and asking risk-informed questions in an inspection, not getting risk values changed to red or white. The inspections staff is now bigger than the operations staff, so you have a large portion of the staff frustrated because they feel like they are finding things that they are told don't matter.

"I'm risk-informed." "I'm performance based." People say this inside NRC all the time (no scale to measure how much). People say "The risk-informed thing to do is _____" but then they say something deterministic. They don't have the risk info, they have engineering values.

Internal --we have too many organizational conflicts/silos. Silos cause poor communication. NRR risk vs. RES risk vs. NMSS risk -- all are different perceptions and definitions. Too many terms: risk-informed, risk based, design based, deterministic etc. None of this is English. It's either risky or not period.

Bad example -- Davis Besse -Design basis didn't account for not having the carb and steel layers -- the stainless steel just happened to have been there. That layer turned out also to have scratches on it. But the calculations didn't account for it not being in the design or the scratches, so they came up with no event, they just did a mechanistic calculation. That's a function of ROP process. Once they changed their application of it and identified the scratches on the stainless steel layer they came up with a red. Concern in NRR that it would look like manipulation of a process to do this, they would lose credibility and go back to the older way, when they used to manipulate the process. It took us a year to determine it was red under ROP -- because we're a slave to our process, which is risk based not risk-informed. Our 1st analysis didn't account for the fact that the stainless steel layer was for preventing internal spread, not

for protection from the top down. All senior management said it had to be red. But ROP said you must do xyz process and we ended up with yellow. We acted as if it was red from beginning -- but we couldn't document it for a year. In more routine things we do a good job. At least we're trying to communicate risk significance. We need to do a better job at being timely, and not be a slave to the process. Our intuitive analysis told us it's a red, but we had to prove it. Davis Besse is the worst thing since TMI. We should be asking why it took so long to get to red.

People feel we're too risk-based because of our dependence on specific numbers without realizing that there are huge uncertainties and a lot of sensitivities factors. If you don't understand that, then you tend to take the risk number and use it as if it has reality. I often see that inside the agency. All engineers grab numbers and use them for a decision basis. They need to use other factors such as current performance and other non-risk factors.

In 1995-1996, NRC was writing guidance on how to do risk-informed regulations. I was part of the team that wrote that guidance. I thought it was a success because it set the tone of the agency to go down a risk-informed path. We involved stakeholders at the beginning. The team included the technical community, licensees, the public, and intervenor groups. We had public meetings over the course of 2-3 months. By the end of the process, everyone had input. It was an open process. Everyone understands that the guidance is not risk-based, but it is risk-informed. People who had doubts about going that way realize that there are backstops (i.e., safety margins), and that addresses their concerns.

There is some resistance to change to decisions being done on a risk-informed basis. They've been doing engineering for 25 years. I've been doing regulations and engineering for 25 years. We've always depended on certain parameters. How do you change when someone says that what you've done for 25 years is no longer the case? We're fighting against personal beliefs. Some blame the resistance on people's fear for job security. I don't agree. The staff believes that what they're doing is important, and no amount of education and training will change their perception.

Uncertainty with models and engineering inputs. We tend to end up in risk-based approach (crunching the numbers) and don't consider levels of uncertainty while doing it. We also use engineering judgment. For example, if we have a degraded bearing, will a pump fail? We have to use judgment if operability is in question. Using that judgment leads to delays, and the numbers come across as more exact than they are. We could answer risk quickly if engineering operability is intact.

We had an inspection issue at a plant, and there was significant disagreement on how to characterize an event. You have the risk side and the engineering side. Issues of disagreement in the risk arena usually are not in determining or calculating the risk. It is in agreeing to the underlying engineering issues. The engineering drives the risk calculations. Once you reach agreement on the engineering, the risk calculations are relatively easy. Risk determinations hinge on fundamental engineering. We hadn't anticipated that in the reactor oversight program. We thought we would just proceed through risk calculations. But, if a licensee says something won't fail, and NRC says it will Y It took about a year to resolve that issue regarding the reliability of the equipment.

If we don't have good communication internally how can we have it externally? Levels of understanding are inconsistent. Not improving much in this area. I have not had training in this area. I was given a book about Understanding Risk...that was supposed to explain it all to me, but I found it impenetrable.

The staff is frustrated because they feel they have done a good job technically and then are frustrated that communication doesn't get through. They are obligated to follow regulations. If they have done this, then feel they are doing their job. Frustrated that message is not getting out. There is often a risk communication issue when we grant exemptions. Hard for public to grasp why we would grant an exemption. Throws in engineering judgment. Doesn't satisfy external stakeholders. Most staff does not

communicate with public personally. Just through documents.

That's a big answer. A major barrier is that we don't have independent assessments of risk. We have no peer review. We calculate the numbers or do determinations, and our answer is final. The solution would be to have our calculations peer reviewed. We should seek other opportunities or stakeholders to review what to determining. We need an independent/unbiased third party. A mediator.

The most common concern is that there is no standard for PRA models. Decision makers don't understand the weaknesses. One model may be good, but at another plant, the model may not work as well (or the model may not work well at different areas within the same plant). PRA models without standards are easy to manipulate. Licensees can make a valid change in the model and something may appear less significant than it should. Some licensees don't know how to use PRA very well, and others may manipulate the models on purpose because they do know how to use PRA. As a result, PRA benefits those with poor models and is harder on people with better models.

Empower staff with knowledge they need. Most of concerns and questions have been dealt with in the past. Train staff in these. Do not need to recreate the wheel. Also increase consistency so different part of organization will have the same message and approach.