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Transitioning to Risk-Informed Regulation: The Role of Research

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Introduction

Good morning, ladies and gentlemen. I am pleased to join you at this opening session of the 26th Annual Water Reactor Safety Meeting. Given the agenda discussion topics, I believe this will be a very informative meeting, and I encourage each of you to contribute your insights and ideas to the dialogue. To begin the dialogue this morning, I would like to discuss with you a significant transition taking place at the Nuclear Regulatory Commission (NRC)–the move toward "risk-informed regulation"–and, in particular, the role of research in achieving this goal.

I believe that the acquisition of valid risk information, and the prudent use of that information in decision-making related to nuclear safety matters, are achievements essential to the continued effectiveness of the NRC and the industries it licenses and regulates. For this reason, I have made the theme of risk-informed regulation central to my tenure as the NRC Chairman. In fact, the Commission is committed to the goal of using risk information and risk analysis as part of a policy framework that applies to all phases of our nuclear regulatory oversight, including rulemaking, licensing, inspection, assessment, and enforcement.

Just as a sound policy framework clearly is the key to making prudent decisions, a vigorous, focused safety research program is fundamental to achieving a robust foundation for risk-informed regulation. Therefore, in my remarks today, I want to answer a series of questions that will place into context the role of research in risk-informed regulation: (1) Why is it so important that the NRC make the transition to risk-informed regulation? (2) Why is research key to the transition? (3) What has been accomplished to date–both by the NRC and by the nuclear industry? (4) What are our areas of current focus? and (5) What initiatives are being planned for the future?

I. Why Is It So Important for the NRC To Make the Transition To Risk-Informed Regulation?

Before answering this question directly, let me set the stage with a brief acknowledgment of the more far-reaching and global changes that are facing the nuclear power industry and the NRC today. The deregulation of the electricity generation market to allow and to encourage competition is expected to lead to new ownership arrangements, and to an increased focus on the control and reduction of facility operating costs. Faced with this changing environment, nuclear power licensees must decide whether to complete the existing terms of their licensed nuclear plant operations, to decommission early, or to apply for a 20-year renewal of their operating licenses. Some already have chosen to decommission prior to the end of the license term. Two licensees, Baltimore Gas and Electric Company and Duke Power, have submitted applications for license renewal–for Calvert Cliffs and Oconee, respectively. For those licensees who choose to continue operation under either the current or a renewed license, the reduction of operating costs clearly will be a primary objective. Licensee efforts to eliminate unnecessary burdens or to achieve greater flexibility will, in many cases, involve interactions with and oversight decisions by the NRC. But these decisions will not be easy to make. As you all are aware, nuclear technology is very complex, not only from the standpoint of the complexity and diversity of plant design features, but also in terms of operational factors such as the human-machine interface, aging effects, and potential accident sequences. The challenge of deciding how, and when, it is appropriate to reduce design margins, to enhance flexibility, and to relieve unnecessary regulatory burden without allowing an undue risk to public health and safety is a significant one.

Given this background, the importance of the NRC transition to risk-informed decision-making in regulatory matters quickly becomes evident. Essentially all Commission and NRC staff decisions can be made more effectively, if they can be based on valid information about the risk importance of the decision. For each rulemaking, regulatory guide, or generic letter we issue, the Commission conducts a regulatory analysis to weigh the costs associated with the action against the risk reduction and safety enhancement to be achieved. For nuclear power reactors, the Commission also has adopted the backfit rule which requires that, with the exception of cases involving compliance or adequate protection, the proposed action must provide substantial additional protection before it will be taken. In a number of instances, a significant volume of risk information and risk analysis has been developed to support these decisions. However, in other cases, we have had only <u>qualitative</u> information available about the risk reduction potential of a rule change, whereas quite specific <u>quantitative</u> information has been available concerning the potential costs. Clearly, the quality of our decisions on generic regulatory matters will improve as the breadth, scope and generic applicability of available risk information improves.

In addition to decisions on generic issues, each year we make numerous plant-specific decisions–on the appropriateness of a particular license modification, on what aspects of a given facility or licensed activity should be inspected, or, in a given case, on whether a civil penalty should be issued for a violation of NRC requirements. Once again, it is obvious that these plant-specific judgments will better ensure the protection of public health and safety if we can base them on a solid foundation of plant-specific or site-specific risk information.

The Commission has formally documented its position on the importance of using valid risk information in its deliberations and actions. In our Principles of Good Regulation, we state that "Regulatory activities should be consistent with the degree of risk reduction they achieve." Under the principle of "Reliability," we further state that, "Regulations should be based on the best available knowledge from research and operational experience. Systems interactions, technological uncertainties, and the diversity of licensees and regulatory activities must all be taken into account so that risks are maintained at an acceptably low level." In the 1995 Commission Probabilistic Risk Assessment (PRA) Policy Statement, to which I will refer again later in these remarks, we also note that PRA and associated analyses should be used "to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices." These quotes summarize the general principles of the Commission regarding the use of risk information and risk analysis–that we should use these insights to increase our safety focus, to achieve appropriate risk reduction, and to eliminate unnecessary conservatism and any associated unnecessary burden on our licensees or the NRC staff.

When applied broadly, as a coherent approach to the full spectrum of regulatory activities, risk-informed regulation will allow us to maintain a clear sense of the primary NRC health and safety mission, while also being responsive and flexible in the face of change. When such an approach is not in place--even when a clear sense of mission exists--the organizational response to emerging issues can become a patch-work of quick fixes, knee-jerk reactions, and/or redundant programs that quickly balloon into overall inefficiency, ineffectiveness, and a lack of clear priorities. A risk-informed approach provides a structured, systematic, and defensible method that can be applied not only to rulemaking, but also to licensing, inspection, enforcement, and performance assessment--as well as providing a basis for prioritization in the establishment of programs and the allocation of resources.

2. Why Is Research a Key To This Transition?

Let me next provide my perspective on why research is such an important attribute in the pursuit of more risk-informed regulatory decision-making. Information from research programs can aid such decision-making in several ways: (1) by providing new information, (in the form of test results or detailed analysis), that sheds light on the likelihood, consequences, or mode of progression of a given accident; (2) by relating that risk information and analysis to the specific context of a rule, regulatory guide, or generic letter–even when that information leads to the closure of an issue or concern without new requirements; and (3) by providing a risk-informed context relevant to a plant-specific licensing, inspection, or enforcement action.

These enhancements to decision-making can occur in the NRC oversight of either reactor or materials licensees, and can take place independently of whether a formal PRA or partial PRA has been developed for the facility in question. However, when coupled with PRA information or folded into a PRA, research on system or human performance or on accident phenomena can be even more helpful in providing a directly relevant basis for regulatory decision-making. Additionally, research can advance the state-of-the-art of PRA, by reducing or quantifying uncertainties in risk estimates, allowing new phenomena to be incorporated into risk estimates, addressing previously unmodeled operating modes, or providing greater design detail for inclusion in a given risk model.

These aspects emphasize the role that research has played and will continue to play in this vital NRC transition to risk-informed regulation. Clearly, a great deal of work remains to make this transition complete and successful. However, before discussing the new initiatives we need to undertake to accomplish our goals, we should recognize what already has been accomplished and consider the efforts that currently are underway.

3. What Has Been Accomplished To Date–Both By the NRC and By the Nuclear Industry?

Clearly, one of the earliest milestones in advancing our understanding of nuclear safety risk was the publication of the WASH-1400 study, in 1975. WASH-1400 provided risk estimates for two plants–a Westinghouse-designed pressurized water reactor (PWR), and a General Electric-designed boiling water reactor (BWR). Although there were criticisms of WASH-1400 that limited its application in regulatory decision-making, it did represent a significant advance by demonstrating the potential benefit that a more fully developed PRA could have as a regulatory tool.

As time progressed, the NRC and the nuclear power industry continued to conduct risk studies, and PRA methods and insights gradually began to be seen as having direct application to regulatory activities, as a valuable complement to deterministic engineering approaches. In other words, the application of PRA has represented an extension and enhancement of traditional regulation, rather than a separate, different, stand-alone technology. PRA methods were used effectively during the anticipated transient without scram (ATWS) and station blackout rulemakings, and were incorporated into the generic issue prioritization and resolution process. Probabilistic analyses also were used in developing an approach to estimate the Safe Shutdown Earthquake Ground Motion for a reactor site, as part of the rule change to reactor siting criteria in 10 CFR Part 100.

In 1986, the Commission took a key action toward incorporating risk information and risk analysis into an overall framework for decision-making, by publishing the NRC “Policy Statement on Safety Goals for the Operation of Nuclear Power Plants.” These Commission Safety Goals set forth quantitative societal health effects objectives, based on the incremental risk of cancer arising from potential accidents at nuclear power plants. The Commission recognized that such goals could be implemented best through the continued maturation of PRA as the mechanism for performing quantitative safety assessments.

In early 1991, the NRC published NUREG-1150, “Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants,” after extensive peer review. In NUREG-1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants, including the WASH-1400 plants and adding an additional BWR and two PWRs, to examine a range of containment designs. This study was a significant turning point in the use of risk-informed concepts in the regulatory process, and enabled the Commission to improve greatly its methods for assessing containment performance and accident progression after core damage initiators. The methods developed for these studies, and the results that emerged, provided a valuable foundation in quantitative risk techniques.

With the increasing sophistication of PRA techniques, the NRC began to use PRA information in assessing the safety importance of operating reactor events, as well as making risk analysis an integral part of the design certification review process for advanced reactor designs. Some reactor licensees also began using risk-assessment methods to identify plant vulnerabilities–and with the initiation of the Individual Plant Examination (IPE) program and the Individual Plant Examination External Events (IPEEE) program, all reactor licensees began participating in this effort. I should note that all power reactor licensees have completed the IPE program, and to a large measure already have undertaken the plant changes judged to be appropriate based on a weighing of risk reduction versus cost. I also would point out that we are nearing the completion of IPEEEs by all licensees, which, with the resultant plant design and operational changes, will represent another significant milestone in risk-informed regulation.

Since the publication of NUREG-1150 and the continued work of the nuclear industry to enlarge and improve the PRA database, the Commission has continued to develop policies and guidelines on the use of PRA insights. In 1995 the Commission published a major revision of the NRC Regulatory Analysis Guidelines (NUREG/BR-0058, Revision 2). The Regulatory Analysis Guidelines included a formulation of screening criteria for using PRA information, in conjunction with the subsidiary safety goals, as part of regulatory decision-making on generic matters such as rulemaking and generic letter issuance. The guidelines relate the subsidiary safety goals to the criterion of substantial additional protection contained in the NRC Backfit Rule, 10 CFR 50.109. They also lay out criteria for the quality of the risk information needed for such safety goal evaluations.

Perhaps even more significantly, the Commission also published in 1995 the PRA Policy Statement, from which I quoted earlier, setting out the broad principles and goals that the Commission would pursue in the PRA Implementation Plan. With the publication of the PRA Policy Statement, the Commission consciously began to take a more holistic approach toward risk-informed regulation, with the goal of establishing an overall framework for risk-informed decisions in all regulatory functions, as well as on plant-specific licensing issues. The NRC PRA Implementation Plan was established to describe and monitor progress on Commission initiatives, including (1) the development of additional regulatory guidance on risk-informed plant-specific licensing decisions; (2) the incorporation of risk information and analysis into NRC rulemaking, inspection, licensing, and enforcement programs; and (3) the linkage between NRC and industry activities in this area.

Just this past July, the Commission published Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Bases." Whereas the Regulatory Analysis Guidelines provide a framework for generic decision-making <u>initiated</u> by the NRC, this Regulatory Guide provides a general framework for plant-specific NRC decisions that have been <u>requested</u> and <u>initiated</u> by licensees. It sets forth the Commission-approved principles for NRC staff evaluation of such proposals, including expectations for application of the Commission Safety Goal Policy, reliance on traditional defense-in-depth approaches, and maintenance of sufficient safety margins when initiating changes to the licensing bases. In addition, it provides criteria for the scope, level of detail, and quality of the PRA supporting the licensee submittal.

The publication of Regulatory Guide 1.174, while critical, was only a partial step toward the overall use of PRA information for plant-specific decisions. Regulatory guides and standard review plans also have been published that outline risk-informed approaches for in-service testing programs, technical specifications, and graded quality assurance programs. In addition, the staff has provided, for trial use, a regulatory guide on risk-informed in-service inspection.

The nuclear power industry has initiated pilot projects at several reactors that are expected to provide a basis for refining these risk-informed regulatory guides. These pilot applications have included proposed licensing changes such as (1) changes to allowable equipment outage times; (2) changes to equipment testing intervals; (3) changes to the types, locations, and frequency of piping inspections; and (4) reduced quality assurance measures on specified equipment. I will acknowledge that during the development of the PRA regulatory guides, there was insufficient acceleration of plant-specific pilot requests for changes to plant licensing bases. This has changed, especially since the guides now are complete (although still subject to revisions based on actual use). In addition to the pilots, the Nuclear Energy Institute is sponsoring a whole plant study to support the development of changes to 10 CFR Part 50. A significant effort also is underway to develop an industry consensus standard for conducting a PRA, coordinated by the American Society of Mechanical Engineers (ASME). Groups such as the Electric Power Research Institute have contributed greatly to these and other ongoing risk studies. The NRC staff is committed to working with the nuclear power industry to ensure that these efforts achieve the desired advances in risk-informed regulation.

I would like to point out that not all NRC regulatory activities lend themselves as readily to the use of risk analysis event trees and fault trees, found so useful for commercial power reactors. Although the NRC has developed probabilistic methods for performance assessment of waste disposal facilities and decommissioning, we are still evaluating approaches for applying risk analysis methods to medical and industrial uses of radioactive material. While our focus at this meeting is on water reactor safety, it is important to note that the NRC staff also has developed a plan for moving forward on risk-informed regulatory oversight of our materials licensees, and to the degree that resources permit, we intend to implement that plan.

4. What Are Our Areas of Current Focus, Relevant to Risk-Informed Regulation?

Clearly, many of the specific initiatives I have described so far are areas of ongoing activity, in which we have made significant progress but which will continue to evolve and mature. Most of these initiatives have related directly toward risk-informing NRC requirements–either through a risk-informed approach to rulemaking or through guidance on making risk-informed changes to the plant-specific licensing bases. In recent months, however, the Commission has accelerated the transition toward risk-informing NRC processes–that is, establishing a framework for NRC inspection, performance assessment, and enforcement that will more readily accommodate and incorporate risk information and risk analysis. These changes, for the most part, are still works-in-progress; however, the NRC staff has been working intensively in these areas, actively soliciting and receiving input from our stakeholders, and I would like to share briefly with you the general direction of the progress we have made.

Over the past three years, the Commission has placed increasing emphasis on risk-informing these processes. The 1996 Commission-directed Arthur Andersen study of the Senior Management Meeting process resulted in an increased emphasis on using objective, quantitative information as input to the assessment of reactor licensee performance. In addition to developing more objective performance indicators, the Commission directed a more systematic processing and comparison of regulatory performance data in the areas of human performance, enforcement, allegations, and risk. Inspection procedures and the NRC Enforcement Policy were revised to require the explicit consideration of risk information as part of evaluating the significance of problems identified. Senior reactor analysts, trained as PRA experts, were placed in each of the regions and in NRC Headquarters. Reactor inspectors were provided additional training on PRA and PRA applications. Taken together, these efforts helped to lay the groundwork for the increased incorporation of risk information and risk analysis into our reactor regulatory oversight processes.

Current efforts, however, are re-examining our inspection, assessment, and enforcement processes in much more fundamental, comprehensive terms. For example, the NRC staff has sought to answer the question: What is the “risk-informed baseline” level of inspection for reactor licensees? In other words, what is the baseline amount of inspection that the NRC must conduct–even at the best performing reactor sites, in order to have the requisite degree of confidence that licensee safety performance is being maintained?

The first step in answering this question, in keeping with the overall NRC mission of protecting public health and safety, has been to identify the "Cornerstones of Safety"–those fundamental objectives that characterize safe and appropriate reactor licensee performance and plant material condition. When considering light-water reactor safety, these cornerstones basically reduce to the following: (1) minimizing plant transients; (2) preventing accidents; and (3) being able to mitigate accidents, should they occur. Once these cornerstones have been established, we then can proceed (1) to define the inspectable population of facility equipment and activities; (2) to determine monitoring methods that will provide the desired level of confidence that no undue risk is presented by facility operation; and (3) within such a context, to establish and execute an inspection program that can be adapted as necessary to the characteristics and performance of specific licensees.

The NRC staff has been working with industry representatives and other stakeholders to determine how this sort of risk-informed program could be established most effectively. At a recent public workshop, members of the NRC staff worked with industry representatives to define these cornerstones of reactor safety, as well as to discuss how radiation safety and safeguards objectives could be integrated into such a program. In particular, the workshop focused on how a risk-informed NRC reactor performance assessment process could take its input from a combination of objective performance indicators, NRC inspection results, licensee reports, and other data sources. The NRC staff also has been working with our stakeholders to determine the appropriate role of enforcement as an integrated part of an overall risk-informed regulatory oversight framework.

Based on our current schedule, the NRC staff intends to brief the Commission next week on these proposed improvements–and in particular the proposed changes to the reactor assessment process. While the Commission has not yet determined the appropriateness of these changes or the exact features of the processes that will result, we have made clear our commitment toward achieving an overall framework for reactor oversight that is coherent, scrutable, defensible, and risk-informed. This will allow the NRC to apply <u>necessary</u> burden, but not <u>unnecessary</u> burden. Based on the continuing efforts by the NRC staff and the industry, we believe that we are making rapid progress toward that goal.

5. <u>What Initiatives Are Being Planned for the Future?</u>

So far I have described how WASH-1400, NUREG-1150, and industry efforts have provided a substantial body of risk information, how various Commission policies and guidance documents have established a framework for incorporating this information into regulatory decision-making, how we are seeking to reform our reactor oversight processes to be more risk-informed, and, in fact, how a number of risk-informed regulatory decisions have been made. Given the progress that we have made, should we be content with continuing to use existing tools–that is, continuing to rely on the current state-of-the-art in PRA methods?

In my opinion, the answer to that question is "no." Too many issues and decisions still face the NRC and the nuclear power industry that could benefit from advances in the state-of-the-art of PRA capability. A vigorous research program must be retained in order to achieve these advances. Consider some examples:

- Our ability to understand the risk effects of component and structural aging at nuclear power plants and other facilities will become increasingly important as facilities age, and as we assess the capability of licensees to manage those aging effects.

- ♦ Continued efforts to model the effects of human performance and reliability on risk would help to narrow the uncertainties persisting in this area.

- ♦ Licensees are continuing to replace analog circuitry with digital technology, including software, in the safety and control systems of power plants. Although we have in place some deterministic acceptance criteria for such replacements, we would benefit from the ability to quantify more accurately the reliability of these new systems through the use of probabilistic methods.

- ♦ Some stakeholders have expressed an interest in reducing the burden or providing greater flexibility in NRC fire protection and quality assurance requirements. The ability of the NRC to determine how to proceed would be facilitated by a better understanding of the risk significance of the various facets of these programs.

The NRC Office of Nuclear Regulatory Research has developed plans to advance our capability to analyze all these issues, using PRA methods. If the Congress provides sufficient funding, we intend to pursue those plans.

In addition to these initiatives, the NRC research program will continue to provide the technical bases, including improved calculational tools and data, to support more realistic analyses of safety margins in thermal hydraulics, fuel behavior, reactor physics, engineering, and materials. These efforts will lead to more accurate risk estimates, elimination of unnecessary conservatism, and improved decision-making.

We also are considering several new initiatives. The Commission is considering the issuance of a white paper on “Risk-Informed, Performance-Based Regulation” to facilitate a common understanding among our stakeholders of such key terms as “risk-informed,” “risk-based,” and “performance-based” regulation. Given that the NRC has been criticized for not having a real definition of safety, as we move to risk-informed, performance-based regulation, a common understanding of fundamental terms is of paramount importance. The NRC staff also is reviewing the possible benefits of a revision to the existing Safety Goal Policy, to add a quantitative safety goal for core damage frequency. We are considering, both internally and in joint efforts with the nuclear power industry, how we could make our reactor regulations in 10 CFR Part 50 more risk-informed, with particular emphasis on developing a more risk-informed 10 CFR 50.59 process. Throughout all of these actions, we are pursuing active interaction with our stakeholders, to ensure that this transition to risk-informed, and, where appropriate, performance-based regulation is completed in a deliberate, sensible, safety-conscious, and scientifically sound manner.

Conclusion

This completes my overview of the ongoing NRC transition to risk-informed regulation, and of the vital role that research must play in that transition. In conclusion, I would note that some members of industry have expressed concerns that the NRC focus continues to be on developing the risk-informed framework, and that as yet our licensees have not realized any substantial positive impact or relief from NRC efforts. In addition to continued development of foundational elements, we are accelerating our efforts to achieve definite, measurable outcomes in all license-initiated requests. Let me assure you, without ambiguity, that the Commission metric for success in this area is not simply the completion of a framework–but in fact is the implementation of that framework, and the use of associated guidance documents. In short, we will not be content simply by having published "outputs." Rather, we will measure success by our achievement of the desired "outcomes." Your discussions and deliberations here will help both to achieve and to measure those outcomes.

I hope that I have given you a clear sense of the strong Commission commitment to developing a risk-informed regulatory framework that will encompass all NRC regulatory oversight functions, and that will underlie and provide a defensible, coherent basis for future decision-making. I hope that I have given you additional perspective on how far we have come, and on where we are headed. I also hope that you understand more fully the value of previous and future research accomplishments as part of this overall effort. The Commission will continue to make every effort to assure that NRC activities, including our research program, are focused on providing the information needed to support risk-informed decision-making. Thank you.