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NUCLEAR REGULATORY COMMISSION

Strategy Needed to Develop a Risk-Informed Safety Approach

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Mr. Chairman and Members of the Subcommittee:

We are here to testify about the actions that the Nuclear Regulatory Commission (NRC) has taken to move from its traditional regulatory approach to an approach that considers risk in conjunction with engineering analyses and operating experience—termed risk-informed regulation. NRC believes that a risk-informed approach would reduce unnecessary regulatory burden and costs, without reducing safety.

Our testimony today is based on ongoing work we are conducting for Senators Lieberman and Biden. Specifically, our testimony discusses the (1) issues that NRC needs to resolve to implement a risk-informed regulatory approach and (2) status of NRC's efforts to make two of its oversight programs—overall plant safety assessments and enforcement—risk-informed. In addition, in January 1999, we provided the Congress with our views on the major management challenges that NRC faces.¹ Our testimony discusses these challenges and their relationship to NRC's efforts to consider risk in its regulatory activities.

In summary, we are finding that:

- Since July 1998, NRC has accelerated some activities needed to implement a risk-informed regulatory approach and has established and set milestones for others. However, NRC has not resolved the most basic of issues; that is, that some utilities do not have current and accurate design information for their nuclear power plants, which is needed for a risk-informed approach. Also, neither NRC nor the nuclear utility industry have standards or guidance that define the quality or adequacy of the risk assessments that utilities use to identify and measure the risks to public health and the environment.² Furthermore, NRC has not determined if compliance with risk-informed regulations will be voluntary or mandatory for the nuclear utility industry. More fundamentally, NRC has not developed a comprehensive strategy that would move its regulation of the safety of nuclear power plants from its traditional approach to an approach that considers risk.
- In January 1999, NRC released for comment a proposed process to assess the overall safety of nuclear power plants. The process would establish

¹Performance and Accountability Series: Major Management Challenges and Program Risks: Nuclear Regulatory Commission (GAO/OCG-99-19, Jan. 1999).

²Risk assessments systematically examine complex technical systems to attempt to quantify the probabilities that a potential accident will occur and the resulting consequences. By their nature, risk assessments are statements of uncertainty that identify and assign probabilities to events that rarely occur.

generic and plant-specific safety thresholds and indicators to help NRC assess overall plant safety. NRC expects to phase in the new process over the next 2 years and evaluate it by June 2001, at which time NRC would propose any adjustments or modifications needed. In addition, NRC has been examining the changes needed to its enforcement program to make it consistent with, among other things, the proposed plant safety assessment process. For many years, the nuclear industry and public interest groups have criticized the enforcement program as subjective. In the spring of 1999, NRC staff expect to provide the Commission recommendations for revising the enforcement program.

- In January 1999, we identified major management challenges that limit NRC's effectiveness. The challenges include the lack of a definition of safety and lack of aggressiveness in requiring utilities to comply with safety regulations. NRC's revised plant safety assessment and enforcement initiatives may ultimately help the agency address these management challenges and carry out its safety mission more effectively and efficiently.

Background

NRC is responsible for ensuring that the nation's 103 operating commercial nuclear power plants pose no undue risk to public health and safety. Now, however, the electric utility industry is faced with an unprecedented, overarching development: the economic restructuring of the nation's electric power system, from a regulated industry to one driven by competition. According to one study, as many as 26 of the nation's nuclear power plant sites are vulnerable to shutdown because production costs are higher than the projected market prices of electricity.³ As the electric utility industry is deregulated, operating and maintenance costs will affect the competitiveness of nuclear power plants. NRC acknowledges that competition will challenge it to reduce unnecessary regulatory burden while ensuring that safety margins are not compromised by utilities' cost-cutting measures.

Since the early 1980s, NRC has been considering the role of risk in the regulatory process, and in August 1995, NRC issued a policy statement that advocated certain changes in the development and implementation of its regulations through an approach more focused on risk assessment. Under such an approach, NRC and the utilities would give more emphasis to those structures, systems, and components deemed more significant to safety. The following example illustrates the difference between NRC's existing and a risk-informed approach. One particular nuclear plant has about 635 valves and 33 pumps that the utility must operate, maintain, and

³World Energy Service: U.S. Outlook (Standard & Poor's, Apr. 1998).

periodically replace according to NRC's existing regulations. Under a risk-informed approach, the utility found that about 515 valves and 12 pumps presented a low safety risk. The utility identified 25 components that were a high risk but would have been treated the same as other components under the existing regulations. If the utility concentrated on the 120 valves, 21 pumps, and 25 components that have been identified as having a high safety risk, it could reduce its regulatory compliance burden and costs.

NRC Has Not Resolved Many Issues Needed to Implement a Risk-Informed Regulatory Approach

NRC staff estimate that it could take 4 to 8 years to implement a risk-informed regulatory approach and are working to resolve many issues to ensure that the new approach does not endanger public health and safety. Although NRC has issued guidance for utilities to use risk assessments to meet regulatory requirements for specific activities and has undertaken many activities to implement a risk-informed approach, more is needed to

- ensure that utilities have current and accurate documentation on the design of the plant and structures, systems, and components within it and final safety analysis reports that reflect changes to the design and other analyses conducted after NRC issued the operating license.
- ensure that utilities make changes to their plants based on complete and accurate design and final safety analysis information.
- determine whether, how, and what aspects of NRC's regulations to change.
- develop standards on the scope and detail of the risk assessments needed for utilities to determine that changes to their plants' design will not negatively effect safety.
- determine whether compliance with risk-informed regulations should be mandatory or voluntary.

Furthermore, NRC has not developed a comprehensive strategy that would move its regulation of nuclear plant safety from its traditional approach to an approach that considers risk.

Utilities Do Not Have Accurate and Reliable Design Information for Some Plants

Design information provides one of the basis for NRC's safety regulation. Yet, for more than 10 years, NRC has questioned whether utilities had accurate design information for their plants. Inspections of 26 plants that NRC completed early in fiscal year 1999 confirmed that for some plants (1) utilities had not maintained accurate design documentation, (2) NRC did not have assurance that safety systems would perform as intended at all

times, and (3) NRC needed to clarify what constitutes design information subject to NRC's regulations. As of November 1998, NRC had taken escalated enforcement actions for violations found at five plants—Three Mile Island, Perry, H.B. Robinson, Vermont Yankee, and D.C. Cook. NRC took these actions because it did not have assurance that the plants' safety systems would perform as intended. One utility, American Electric Power, shut down its D.C. Cook plant as a result of the inspection findings.

NRC does not plan additional design team inspections because it concluded that the industry did not have serious safety problems. NRC's Chairman disagreed with this broad conclusion, noting that (1) the inspection results for the five plants indicate the importance of maintaining current and accurate design and facility configuration information, (2) the inspections did not apply to the industry as a whole but to only certain utilities and plants within the industry, and (3) other NRC inspections identified design problems at other such nuclear power plants as Crystal River 3, Millstone, Haddam Neck, and Maine Yankee. The Commissioners and staff agreed that NRC would oversee design information issues using such tools as safety system engineering inspections.

The 26 inspections also identified a need for NRC to better define the elements of a plant's design that are subject to NRC's regulations. NRC staff acknowledge that the existing regulation is a very broad, general statement that has been interpreted differently among NRC staff and among utility and industry officials. According to NRC staff, it is very difficult to develop guidance describing what constitutes adequate design information. Therefore, NRC has agreed that the Nuclear Energy Institute (NEI) would provide explicit examples of what falls within design parameters.⁴ NEI plans to draft guidance that will include examples of design information and provide it to NRC in January 1999. Concurrently, NRC is developing regulatory guidance on design information. NRC staff expect to recommend to the Commission in February 1999 that it endorse either NRC's or NEI's guidance and seek approval to obtain public comments in March or April 1999. NRC staff could not estimate when the agency would complete this effort.

⁴NEI has members from all utilities licensed to operate commercial nuclear plants in the United States as well as nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry. NEI establishes unified nuclear industry policy on such matters as generic operational and technical issues.

NRC Does Not Have Confidence That Safety Analysis Reports Reflect Current Plant Designs

At the time NRC licenses a plant, the utility prepares a safety analysis report; NRC regulations require the utility to update the report to reflect changes to the plant design and the results of analyses that support modifying the plants without prior NRC approval. As such, the report provides one of the foundations to support a risk-informed approach. Yet, NRC does not have confidence that utilities make the required updates, which results in poor documentation of the safety basis for the plants.

NRC published guidance for the organization and contents of safety analysis reports in June 1966 and updated the guidance in December 1980. NRC acknowledges that the guidance is limited, resulting in poorly articulated staff comments on the quality of the safety analysis reports and a lack of understanding among utilities about the specific aspects of the safety analysis reports that should be updated. On June 30, 1998, NRC directed its staff to continue working with NEI to finalize the industry's guidelines on safety analysis report updates, which NRC could then endorse. Once the agency endorses the guidelines, it will obtain public comments and revise them, if appropriate. NRC expects to issue final guidelines in September 1999.

Erroneous Evaluations Can Erode Design and Safety Margins

According to NRC documents, if a utility does not have complete and accurate design information, the evaluations conducted to determine whether it can modify a plant without prior NRC approval can lead to erroneous conclusions and jeopardize safety. For more than 30 years, NRC's regulations have provided a set of criteria that utilities must use to determine whether they may change their facilities (as described in the final safety analysis report) or procedures or conduct tests and experiments without NRC's prior review and approval.

However, in 1993, NRC became aware that Northeast Nuclear Energy Company had refueled Millstone Unit 1 in a manner contrary to that allowed in the updated final safety analysis and its operating license. This led NRC to question the regulatory framework that allows licensees to change their facilities without prior NRC approval. As a result, NRC staff initiated a review to identify the short- and long-term actions needed to improve the process. For example, in October 1998, NRC published a proposed regulation regarding plant changes in the Federal Register for comment; the comment period ended on December 21, 1998. NRC requested comments on criteria for identifying changes that require a license amendment and on a range of options, several of which would allow utilities to make changes without prior NRC approval despite a

potential increase in the probability or consequences of an accident. NRC expects to issue a final regulation in June 1999.

In addition, in February 1999, NRC staff expect to provide their views to the Commission on changing the scope of the regulation to consider risk. NRC's memorandum that tracks the various tasks related to a risk-informed approach and other initiatives did not show when NRC would resolve this issue.

Making Its Regulations Risk-Informed Will Be a Challenge to NRC and the Industry

Until recently, NRC did not consider whether and to what extent the agency should revise all its regulations pertaining to commercial nuclear plants to make them risk-informed. Revising the regulations will be a formidable task because, according to NRC staff, inconsistencies exist among the regulations and because a risk-informed approach focuses on the potential risk of structures, systems, or components, regardless of whether they are located in the plant's primary (radiological) or secondary (electricity-producing) systems. With one exception, NRC has not attempted to extend its regulatory authority to the secondary systems.

NRC staff and NEI officials agree that the first priority in revising the regulations will be to define their scope as well as the meaning of such concepts as "important to safety" and "risk significant" and integrating the traditional and risk-informed approaches into a cohesive regulatory context. In October 1998, NEI proposed a phased approach to revise the regulations. Under the proposal, by the end of 1999, NRC would define "important to safety" and "risk significant." By the end of 2000, NRC would use the definitions in proposed rulemakings for such regulations as definition of design information and environmental qualification for electrical equipment. By the end of 2003, NEI proposes that NRC address other regulatory issues, such as the change process, the content of technical specifications, and license amendments. After 2003, NEI proposes that NRC would address other regulations on a case-by-case basis.

NRC staff agreed that the agency must take a phased approach when revising its regulations. The Director, Office of Nuclear Regulatory Research, said that, if NRC attempted to revise all provisions of the regulations simultaneously, it is conceivable that the agency would accomplish very little. The Director said that NRC needs to address one issue at a time while concurrently working on longer-term actions. He cautioned, however, that once NRC starts, it should be committed to completing the process. At a January 1999 meeting, NRC's Chairman

suggested a more aggressive approach that would entail risk informing all regulations across the board. NRC's memorandum that tracks the various tasks related to a risk-informed approach and other initiatives did not show when the agency would resolve this issue.

NRC Does Not Have a Standard for the Content of Risk Assessments

NRC and the industry view risk assessments as one of the main tools to be used to identify and focus on those structures, systems, or components of nuclear plant operations having the greatest risk. Yet, neither NRC nor the industry has a standard or guidance that defines the quality, scope, or adequacy of risk assessments. NRC staff are working with the American Society of Mechanical Engineers to develop such a standard.

However, this issue is far from being resolved. The Society is developing the standard for risk assessments in two phases (internal events and emergency preparedness). NRC staff estimate that the agency would have a final standard on the first phase by June 2000 but could not estimate when the second phase would be complete. To ensure consistency with other initiatives, in December 1998, NRC staff requested the Commission's direction on the quality of risk assessments needed to implement a risk-informed approach. Since it may be several years until NRC has a standard, the Commission should also consider the effect that the lack of a standard could have on its efforts to implement a risk-informed regulatory approach.

NRC Has Not Determined Whether Compliance With Risk-Informed Regulations Would Be Mandatory or Voluntary

NRC has not determined whether compliance with revised risk-informed regulations would be mandatory or voluntary for utilities. In December 1998, NRC's staff provided its recommendations to the Commission. The staff recommended that implementation be voluntary, noting that it would be very difficult to show that requiring mandatory compliance will increase public health and safety and could create the impression that current plants are less safe. In its analysis, the staff did not provide the Commission with information on the number of plants that would be interested in such an approach. In January 1999, the Commissioners expressed concern about a voluntary approach, believing that it would create two classes of plants operating under two different sets of regulations.

Utilities may be reluctant to shift to a risk-informed regulatory approach for various reasons. First, the number of years remaining on a plant's operating license is likely to influence the utility's views. NRC

acknowledged that if a plant's license is due to expire in 10 years or less, then the utility may not have anything to gain by changing from the traditional approach. Second, the costs to comply may outweigh the benefits of doing so. Considering the investment that will be needed to develop risk-informed procedures and operations and identify safety-significant structures, systems, or components, utilities question whether a switch will be worth the reduction in regulatory burden and cost savings that may result. Third, design differences and age disparities among plants make it difficult for NRC and the industry to determine how, or to what extent, a standardized risk-informed approach can be implemented across the industry. Although utilities built one of two types of plants—boiling water or pressurized water—each has design and operational differences. Thus, each plant is unique, and a risk-informed approach would require plant-specific tailoring.

NRC Has Not Developed a Strategic Plan to Implement a Risk-Informed Approach

Since the early 1980s, NRC has considered applying risk to the regulatory process. NRC staff estimate that it will be at least 4 to 8 years before the agency implements a risk-informed approach. However, NRC has not developed a strategic plan that includes objectives, time lines, and performance measures for such an approach.

Rather, NRC has developed an implementation plan, in conjunction with its policy statement on considering risk, that is a catalog of about 150 separate tasks and milestones for their completion. It has also developed guidance for some activities, such as pilot projects in the four areas where the industry wanted to test the application of a risk-informed approach. In one case, NRC approved a pilot project for Houston Lighting and Power Company at its South Texas plant, and the utility found that it could not implement it because the pilot project would conflict with other NRC regulations.

Given the complexity and interdependence of NRC's requirements, such as regulations, plant design, and safety documents and the results of ongoing activities, it is critical that NRC clearly articulate how the various initiatives will help achieve the goals set out in the 1995 policy statement. Although NRC's implementation plan sets out tasks and expected completion dates, it does not ensure that short-term efforts are building toward NRC's longer-term goals; does not link the various ongoing initiatives; does not help the agency determine appropriate staff levels, training, skills, and technology needed and the timing of those activities to implement a risk-informed approach; does not provide a link between the day-to-day

activities of program managers and staff and the objectives set out in the policy statement; and does not address the manner in which it would establish baseline information about the plants to assess the safety impact of a risk-informed approach.

In a December 1998 memorandum, NRC staff said that once the Commission provides direction on whether and how to risk-inform the regulations and guidance on the quality of risk assessments to support their decisions for specific regulations, they would develop a plan to implement the direction provided. The staff did not provide an estimated time frame for completing the plan.

The Status of NRC's Assessment and Enforcement Processes: Many Unanswered Issues Remain

For many years, the nuclear industry and public interest groups have criticized NRC's plant assessment and enforcement processes because they lacked objectivity, consistency, and predictability. In January 1999, NRC proposed a new process to assess overall plant performance based on generic and plant-specific safety thresholds and performance indicators. NRC is also reviewing its enforcement process to ensure consistency with the staff's recommended direction for the assessment process and other programs.

NRC Is Trying to Make Its Plant Assessment Process More Objective and Transparent

In 1997 and 1998, we noted that NRC's process to focus attention on plants with declining safety performance needed substantial revisions to achieve its purpose as an early warning tool and that NRC did not consistently apply the process across the industry.⁵ We also noted that this inconsistency has been attributed, in part, to the lack of specific criteria, the subjective nature of the process, and the confusion of some NRC managers about their role in the process. NRC acknowledged that it should do a better job of identifying plants deserving increased regulatory attention and said that it was developing a new process that would be predictable, nonredundant, efficient, and risk-informed.

In January 1999, NRC proposed a new plant assessment process that includes seven "cornerstones."⁶ For each cornerstone, NRC will identify the desired result, important attributes that contribute to achieving the desired result, areas to be measured, and the various ways that exist to measure

⁵Nuclear Regulation: Preventing Problem Plants Requires More Effective NRC Action (GAO/RCED-97-145, May 30, 1997) and Nuclear Regulatory Commission: Preventing Problem Plants Requires More Effective Action by NRC (GAO/T-RCED-98-252, July 30, 1998).

⁶The seven cornerstones are: initiating events, mitigation systems, barrier integrity, emergency preparedness, and public, occupational, and physical protection.

the identified areas. Three issues cut across the seven cornerstones: human performance, safety conscious work environment, and problem identification and resolution. As proposed, NRC's plant assessment process would use performance indicators, inspection results, other such information as utility self-assessments, and clearly defined, objective decision thresholds. The process is anchored in a number of principles, including that: (1) a level of safety performance exists that could warrant decreased NRC oversight, (2) performance thresholds should be set high enough to permit NRC to arrest declining performance, (3) NRC must assess both performance indicators and inspection findings, and (4) NRC will establish a minimum level of inspections for all plants (regardless of performance). Although some performance indicators would be generic to the industry, others would be plant-specific based, in part, on the results that utilities derive from their risk assessments. However, the quality of risk assessments and number of staff devoted to maintain them vary considerably among utilities.

NRC expects to use a phased approach to implement the revised plant assessment process. Beginning in June 1999, NRC expects to pilot test the use of risk-informed performance indicators at eight plants, by January 2000 to fully implement the process, and by June 2001 to complete an evaluation and propose any adjustments or modifications needed. Between January 1999 and January 2001, NRC expects to work with the industry and other stakeholders to develop a comprehensive set of performance indicators to more directly assess plant performance relative to the cornerstones. For those cornerstones or aspects of cornerstones where it is impractical or impossible to develop performance indicators, NRC would use its inspections and utilities' self assessments to reach a conclusion about plant performance. NRC's proposed process illustrates an effort by the current Chairman and other Commissioners to improve NRC's ability to help ensure safe operations of the nation's nuclear plants as well as address industry concerns regarding excessive regulation. NRC's ensuring consistent implementation of the process ultimately established would further illustrate the Commissioners' commitment.

NRC's Enforcement Process Continues to Be in a State of Flux

NRC has revised its enforcement policy more than 30 times since its implementation in 1980. Although NRC has attempted to make the policy more equitable, the industry has had longstanding problems with it. Specifically, NEI believes that the policy is not safety-related, timely, or objective. Among the more contentious issues are NRC's practice of

aggregating lesser violations into an enforcement action that results in civil penalties and its use of the term “regulatory significance.”

To facilitate a discussion about the enforcement program, including the use of regulatory significance and the practice of aggregating lesser violations, at NRC’s request, NEI and the Union of Concerned Scientists reviewed 56 enforcement actions taken by the agency during fiscal year 1998. For example, NEI reviewed the escalated enforcement actions based on specific criteria, such as whether the violation that resulted in an enforcement action could cause an offsite release of radiation, onsite or offsite radiation exposures, or core damage. From an overall perspective, the Union concluded that NRC’s actions are neither consistent nor repeatable and that the enforcement actions did not always reflect the severity of the offense. According to NRC staff, they plan to meet with various stakeholders in January and February 1999 to discuss issues related to the enforcement program.

Another issue is the use of the term “regulatory significance” by NRC inspectors. NRC, according to NEI and the Union of Concerned Scientists, uses “regulatory significance” when inspectors cannot define the safety significance of violations. However, when the use of regulatory significance results in financial penalties, neither NRC nor the utility can explain to the public the reasons for the violation. As a result, the public cannot determine whether the violation presented a safety concern.

NEI has proposed a revised enforcement process. NRC is reviewing the proposal as well as other changes to the enforcement process to ensure consistency with the draft plant safety assessment process and other changes being proposed as NRC moves to risk-informed regulation. NRC’s memorandum of tasks shows that the staff expect to provide recommendations to the Commission in March 1999 that address the use of the term regulatory significance and in May 1999 on considering risk in the enforcement process.

Major Management Challenges and Program Risks

In January 1999, we provided the Congress with our views on the major management challenges that NRC faces. We believe that the management challenges we identified have limited NRC’s effectiveness. In summary, we reported that:

- NRC lacks assurance that its current regulatory approach ensures safety. NRC assumes that plants are safe if they operate as designed and follow

NRC's regulations. However, NRC's regulations and other guidance do not define, for either a licensee or the public, the conditions necessary for a plant's safety; therefore, determining a plant's safety is subjective.

- NRC's oversight has been inadequate and slow. Although NRC's indicators show that conditions throughout the nuclear energy industry have generally improved, they also show that some nuclear plants are chronically poor performers. At three nuclear plants with long-standing safety problems that we reviewed, NRC did not take aggressive action to ensure that the utilities corrected the problems. As a result of NRC's inaction, the conditions at the plants worsened, reducing safety margins.
- NRC's culture and organizational structure have made the process of addressing concerns with the agency's regulatory approach slow and ineffective. Since 1979, various reviews have concluded that NRC's organizational structure, inadequate management control, and inability to oversee itself have impeded its effectiveness.

Some of the initiatives that NRC has underway have the potential to address the first two management challenges. However, the need to ensure that NRC's regulatory programs work as effectively as possible is extremely important, particularly in light of major changes taking place in the electric utility industry and in NRC. Yet changing NRC's culture will not be easy. In a June 1998 report, the Office of the Inspector General noted that NRC's staff had a strong commitment to protecting public health and safety. However, the staff expressed high levels of uncertainty and confusion about the new directions in regulatory practices and challenges facing the agency. The employees said that, in their view, they spend too much time on paperwork that may not contribute to NRC's safety mission. The Inspector General concluded that without significant and meaningful improvement in management's leadership, employees' involvement, and communication, NRC's current climate could eventually erode the employees' outlook and commitment to doing their job. This climate could also erode NRC's progress in moving forward with a risk-informed regulatory approach. According to staff, NRC recognizes the need to effectively communicate with its staff and other stakeholders and is developing plans to do so.

Mr. Chairman and Members of the Subcommittee, this concludes our statement. We would be pleased to respond to any questions you may have.

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