



# **NRC NEWS**

## **U.S. NUCLEAR REGULATORY COMMISSION**

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No. S-00-19

September 13, 2000

**NRC's Regulatory Approach: OIG's Role in a Time of Change**  
**Keynote Address**  
**by**  
**Richard A. Meserve, Chairman**  
**OIG Annual Information and Planning Conference**  
**September 12, 2000**

### Introduction

Good morning. Thank you for inviting me to your Annual Planning Conference. I am pleased to have this opportunity to talk with you about the theme for this conference, "NRC's Regulatory Approach," and the important role that OIG can play in assuring the integrity of our implementation of that approach.

As you know, we are in a dynamic period in the NRC, as we move from a prescriptive, deterministic regulatory framework to performance-based rules that are informed by assessments of relative risk. We are early in this transition and we face a daunting task because the transition will involve a fundamental change in our approach. And we must accomplish this evolution without compromising our fundamental mission of protecting the health and safety of the public.

OIG plays an essential part in the NRC's regulatory processes, and OIG's contributions will prove even more important in this time of change. Traditionally, an Inspector General audits agency programs and operations to look for instances of waste, fraud, and abuse, thereby promoting the most effective and efficient use of an agency's resources. This function is fundamentally important because we must be good stewards of the financial resources available to us.

Even more important from my perspective, however, is OIG's role in assuring that the NRC conducts its business according to principles of regulatory best practice. The Commission and its staff must make independent, objective decisions based on technically competent, unbiased assessments. Our decisions must be reached through open processes. And we must conduct inspection and enforcement activities in a manner that is efficient, impartial, and fair. OIG's reviews of our performance against these standards helps to assure that we as an agency are always improving, even as we meet our statutory and regulatory responsibilities.

This role is singularly important in this period of transition. I will return to this aspect of OIG's role later in my remarks.

First, though, I would like to provide an overview of the fundamental change in the NRC's regulatory philosophy. I will focus for the most part on power reactor regulation, but we should not lose sight of the fact that our regulatory purview extends well beyond that area and that the change to risk-informed regulation stretches across the entire range of NRC's regulatory responsibilities.

### Where We Were: Deterministic, Prescriptive Regulation

The foundation of the nuclear reactor regulations was developed, for the most part, in the early days of the civilian use of nuclear power by the Atomic Energy Commission. With little operating experience, the regulatory structure focused to a large extent on plant design, reflecting the perception that a conservative approach to plant engineering would provide large margins of safety. The philosophy of "defense in depth" – many layers of diverse and redundant systems designed to prevent accidents, if possible, and mitigate the consequences of any events that did occur – became a fundamental precept of our regulatory requirements. Assumptions were made about the threats posed by various types of events, such as large-break loss-of-coolant accidents. The regulations resulting from these beliefs and assumptions mandated specific types of analyses and established quantitative acceptance criteria for the results of those deterministic analyses. The acceptance criteria were prescribed so as to ensure, as much as possible, large safety margins.

The goal of this process was to assure plant safety. But our knowledge was not so extensive as to provide a firm understanding of which plant systems and processes were truly significant for safety. As a result, a conservative engineering approach was applied across the board. When a serious event occurred, such as the Browns Ferry fire, the response was to develop additional, prescriptive regulations to deal with the causes and effects of the problem. While this approach was not inappropriate in its time given the state of technical knowledge of these complex systems, it could create two problems. First, it could lead to rules requiring actions that imposed costs that were not always commensurate with the benefits of improved safety. Second, an attitude developed that severe accidents, with consequences beyond those with which the plant was designed to cope, were almost impossible.

The incident at Three Mile Island in 1979 shattered that confidence. The NRC, however, followed previous practice and developed an extensive list of new prescriptive regulations, related largely to the course of events at TMI.

Beginning in the middle 1980s, several factors combined to set the stage for the current change in regulatory approach. First, for several reasons, utilities stopped placing new plant orders, and even canceled previously ordered plants, so that by the late 1980s, design and construction of nuclear power plants was coming to a stop with little prospect for new projects in the near term. As a result, the NRC's focus shifted from design and construction of new plants to safe operation of the existing fleet. Second, based on the growing body of operating experience, both we and the industry began to accumulate important insights to distinguish those aspects of plant design and operation that are truly significant for safety from those that are not. Third, the techniques of quantitative risk assessment improved, and the community became more familiar with these techniques. Fourth, a general recognition arose in academic and government circles, not just in the

NRC, that prescriptive, deterministic regulation was economically inefficient and that performance-based regulation could achieve the desired results at lower cost to society as a whole.

### Where We Are: Moving into Risk-Informed Regulation

From much of what has been written and said about risk-informed regulation at the NRC, you might think that this is a relatively recent idea. In fact, the concept has been with us almost since the NRC's creation as regulatory successor to the AEC in 1975. In that year, the Reactor Safety Study, better known as WASH-1400, was published by the NRC. This was the first attempt in the U.S. to apply the technique of quantitative probabilistic risk assessment, PRA, to the evaluation of reactor safety. The report generated a great deal of controversy, particularly over the resulting estimates of risks of nuclear accidents and the associated uncertainties in those estimates. Despite the controversy, however, the potential value of PRA as a tool for gaining insights into reactor safety was widely recognized.

As I noted, the Three Mile Island accident served as a rude awakening for both the industry and the NRC. The accident, however, lent credence to some of the results of WASH-1400, which predicted that events such as the one that occurred at TMI were more likely, and could pose more of a challenge to overall plant safety, than the lower-probability design-basis accidents. Both of the major post-mortem studies of the TMI event -- one sponsored by the NRC, the other commissioned by President Carter -- recommended the use of probabilistic risk assessment where appropriate in helping to focus regulatory attention on risk-significant issues.

The NRC responded, gradually, in a number of ways. For example, the Office of Research funded further development and refinement of risk assessment techniques, and eventually undertook a follow-up study of reactor risk, published as NUREG-1150. The Office of Analysis and Evaluation of Operational Data, established after TMI to help develop regulatory insights from plant operation, used risk assessment techniques to assess the significance of events at operating plants for safety. And the Commission published major policy statements on severe accidents and safety goals based in part on risk insights. In 1988, the NRC requested that operating plants perform assessments of their vulnerabilities to severe accidents, assessments that were called "individual plant examinations." While licensees were not required to use risk assessment techniques in these examinations, their use was strongly encouraged. The increasing familiarity with and confidence in probabilistic risk assessment techniques ultimately led, in the mid-90s, to a determination by the Commission that the agency should begin to evolve toward a risk-informed regulatory approach.

As I indicated previously, and want to emphasize again, "risk-informed" does not mean that risk is the only factor to be used in regulatory decision-making. Rather, it is one of the factors that should be considered in our deliberations. We need to be fully cognizant of the fact that risk assessment techniques are subject to significant limitations, such as in the area of modeling human performance. While risk assessment ideally takes account of uncertainties in our knowledge base, we still employ conservative approaches to account for the practical limitations in the techniques. The concept of defense in depth, with redundancy and diversity in safety systems, and a balance between accident prevention and mitigation of consequences remain central to our regulatory approach. In these aspects, too, risk assessment can help by shining light on areas with the greatest significance for safety.

Currently, we have what effectively is a hybrid regulatory structure. Risk-informed decision-making is employed by the staff in assessing license amendments, in assessing inspection results, and in dealing with specific regulatory requirements, such as technical specifications and in-service inspection. The deterministic foundation still exists, however, and in many areas the body of regulation remains relatively prescriptive. We are now examining how to update these regulations in an evolutionary process. That process is likely to be a long one, requiring continuous adaptation and improvement.

I'd like to take a moment now to speculate on what we may have when that process is complete.

### Where We Are Going

As you know, the NRC has adopted a strategic plan that articulates four primary objectives: to maintain safety; to improve public confidence; to make our regulatory processes more effective, efficient and realistic; and to reduce unnecessary regulatory burden. Our efforts to risk-inform our regulations need to reflect these objectives.

Our focus must always be on safety, first and foremost. As a result, the risk-informing process will be a two-edged sword. As we apply risk insights to our regulatory structure, we will undoubtedly find rules that are unnecessarily prescriptive and requirements that do not significantly affect plant safety. In these areas, regulatory requirements can be modified, reduced, or made more performance-based and less prescriptive, increasing the efficiency and effectiveness of both licensees and the NRC. However, we may also find areas in which risk-significant systems or processes currently are not adequately addressed by our regulations, and we will need to develop new rules to cover these areas. We must be open to both possibilities and be prepared to act on both.

In addition to the task of looking at individual rules, the risk-informing process gives us the opportunity to take a fresh look at the ways in which our regulations relate to one another. Given the way in which our regulatory structure and processes have evolved since the early days of the AEC, it should not be surprising if we found that the requirements in one rule may overlap with the requirements in other rules. Our efforts should include evaluations of these sorts of regulatory interactions, so that our final products are clear, consistent, and stable. Moreover, as we inform the technical bases of our rules with better understanding of risks, we should look at requirements that are based on technology that has been improved or superseded. If the technology basis cannot be replaced by performance specifications, then at least the technical bases should be updated to reflect the state of the art.

Our oversight process is well on its way to becoming more risk-informed. For example, in addition to inspections, the new reactor oversight process includes the use of objective performance indicators to evaluate plant operations. Findings from inspections and performance indicators are processed to determine their significance for safety, the results of which are then used to guide future oversight activities and, if necessary, enforcement actions. Work is in progress to develop new performance indicators that are clearly focused on risk and are leading indicators of emerging problems.

My vision for the final product of this complex process is a regulatory structure that is more aligned with safety, more internally consistent, and easier for our licensees to understand and our staff to implement. I believe that the overall regulatory burden will, in fact, be reduced without sacrificing safety. I want to emphasize again, however, that while consideration of risk is an important element of the NRC's work, it is not the only factor. Mindful of the limitations of current risk assessment methods, we do not strive for a risk-based regulatory environment. Informed by insights into risk, the concepts of defense in depth and a conservative approach to design and operation will continue to be part of our regulatory paradigm, as long as they are needed to assure safety.

### The Role of OIG

I now want to turn to my view of the role of the Inspector General's office in the process of transition to a new regulatory approach.

As I mentioned at the start of this talk, OIG fulfills two roles. The first, concerned with discovery of instances of waste, fraud, and abuse, is clearly an important one. We cannot and should not tolerate inappropriate conduct by NRC employees. I am convinced, however, that the vast majority of the NRC staff undertake their jobs with the highest regard for personal and professional integrity, and that cases of intentional wrongdoing are few and far between. Nonetheless, we welcome OIG's vigilance.

The second role of OIG is to monitor the performance of our regulatory responsibilities. I want to stress that I do not see this as a means to determine who should be blamed when problems arise. Rather, it is an acknowledgment of the fact that, as humans, we do not always do our jobs as well as we might, that mistakes occasionally are made despite our best efforts, and that constructive analysis can only be beneficial to us all. There will always be room for improving performance. OIG's reviews can provide important insights into ways to improve our regulatory processes, ensuring that they are conducted in accordance with our principles and policies. This willingness to be self-critical is an essential element in improving the confidence of the public, including our stakeholders, in our performance.

Indeed, OIG scrutiny is an aspect of the fact that our regulatory processes must be performed, as much as possible, in the open. Our stakeholders comprise a broad and diverse group, including: the regulated industry; the public, which is often represented by various public-interest groups; the Congress; and the technical community. We must solicit from all input to our processes and carefully consider their views as we carry out our duties. This attention to conducting an open process may be time-consuming, but openness will lead to better decisions and is an essential factor in improving and maintaining public confidence in the NRC. Our encouragement of knowledgeable OIG scrutiny of our activities is part of a philosophy of openness that must be a core NRC operating principle.

In conclusion, I want to recognize that the evolution from prescriptive, deterministic standards to risk-informed performance-based regulation will be a challenging one for NRC staff and the regulated industries. Accomplishing this objective will take time and require us to learn new skills and approaches to our work. Complicating the task is the current dynamic environment of the nuclear power industry. While we cannot predict how that industry will change over the next decade in response to the economic deregulation, we must be adaptable to whatever changes occur. We cannot, however, modify our mission or slight our principles.

We depend on OIG to inform us on whether we are discharging our responsibilities correctly and to give us guidance on how continuously to improve.

Once again, thank you for the opportunity to share my views with you. I look forward to working with you as we strive to meet these important challenges.

Thank you.