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Safety Regulation Evolution: A New Paradigm?  
presented by  
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Introduction

Good afternoon, ladies and gentlemen.

This afternoon I want to call your attention to a number of current activities within the NRC and suggest that all of these, taken together, provide a new paradigm for safety regulation of nuclear power plants. I will talk about the regulatory environment and how it has changed over the years, and also about the regulatory process, and how it has changed. I want to emphasize the commitment of the Commission to make the regulatory process as clear, open and efficient as we can possibly make it. Finally, I will share with you some of my thoughts on the major obstacles to moving in that direction.

The Atomic Energy Commission

The industry's first regulator, of course, was the Atomic Energy Commission.(1) The five person Commission was created by the Atomic Energy Act of 1946, and was responsible for the management of the nation's atomic energy programs, which were primarily military. Eight years later, the Atomic Energy Act of 1954 directed the AEC to encourage widespread participation in the development of atomic energy for peaceful applications, and gave the AEC responsibility for protecting the public health and safety from the hazards of nuclear power.

The AEC had to write regulations and develop licensing procedures that were strict enough to assure safety, but were sufficiently flexible to accommodate new insights and new technology. The

regulatory structure and process that we have today still bear the imprint of decisions that were made 40 years ago.

The role of the AEC as both regulator and promoter of commercial nuclear power became the subject of controversy very early. By the '60s, there was increasing public concern about the safety of nuclear technology and the health effects of low level radiation. The AEC's handling of safety and environmental concerns such as emergency core cooling systems, thermal pollution, and high-level waste disposal eroded public support for reactor technology and for the AEC itself. Ultimately, the AEC was unable to recover the public's trust, and in 1974 Congress divided the agency into the Energy Research and Development Administration and the Nuclear Regulatory Commission.

### The Nuclear Regulatory Commission

The NRC began operation in January 1975. From the standpoint of regulatory structure and process, the early years of the NRC were not significantly different from the last years of the AEC. The change was simply that the agency was now unambiguously concerned with the safety aspects of nuclear power, and was not distracted by a promotional responsibility.

The early 1970s had already seen a significant number of regulatory changes compared with the 1960s. By 1974, changes to Title 10, Regulatory Guides, Generic Letters and other regulatory requirements were being issued by the AEC at the rate of about 70 per year. That rate continued during the first four years of the NRC.

An early event that had the potential to change the regulatory process was the publication of the Reactor Safety Study, WASH-1400, which had been commissioned by the AEC. The changes to the approach to reactor safety suggested by this work would be unrealized for a number of years.

The accident at TMI-2 in March of 1979, had an immediate and profound impact on the NRC and on the industry. The focus of the regulatory process up to that time was on design. If the designs were fundamentally sound, sufficiently robust and in compliance with all the wisdom represented by the accumulated rules, if the plants were constructed in accordance with the design, and if they were operated within the design basis, then the health and safety of the public should be adequately protected. As a result of TMI, the equal, or perhaps greater, importance of operations became apparent.

The NRC's post TMI-2 accident activities took several paths. The first was a short term re-examination of the adequacy of designs in light of the events that occurred. The second was to provide

the same level of attention to operations and human reliability that had been applied to the regulation of design and construction. Finally, the NRC embarked on a program of severe accident research that would lead to a better understanding of severe accidents.

The industry set up the Institute of Nuclear Power Operations (INPO) to foster excellence in the operation of nuclear power plants. INPO's initiatives and success in training, accreditation, and information exchange obviated the need for NRC to accomplish the same ends by regulatory mandate.

Although the new focus on operations was a significant change, it did not reduce the attention paid to design and construction, and in some ways the approach to operational safety was not philosophically different from the approach to design and construction safety. The emphasis was still on identifying rules or requirements judged to be important to safety, and then assuring compliance with those rules and requirements. The rate of issuance of changes to Title 10, Regulatory Guides, Generic Letters, and I&E Bulletins increased from about 70 per year to about 140 per year from 1979 through 1984.

The post-TMI view of successful regulation of plant operations was to ensure in every plant the establishment of a safety culture that put safety issues ahead of production concerns. This safety culture was process driven, and was based on the view that, in a nuclear power plant, every activity should be regarded as important to the overall safety culture. Attention to detail, so important to safety, became automatically extended to every aspect of the plant, including physical appearance and operability of systems and components having little or no safety significance.

### The Economic Environment

It is worth noting that during the 1960s and 1970s, when the AEC, and later the NRC, were learning how to regulate, there was also a great deal of change in the technological and economic environment in which the electric utilities were operating.

In the early 1970s, even before the 1973 oil embargo, the unit cost of electric generation was starting to increase. After the oil embargo it increased even more. Fuel costs skyrocketed, as did interest rates. The state and federal economic regulatory mechanisms were ill-equipped to handle the nature of and rate of change.

New capital projects, including nuclear units, were deferred to conserve economic resources or to convert oil fired plants to coal. In the meantime, construction costs were going up at a

terrific rate. Load growth projections, which were the basis for the industry having ordered new nuclear plants, turned out to be wildly optimistic, and economic difficulties were compounded by a slowdown in load growth. In addition to dealing with a changing nuclear safety regulatory environment, the utilities were dealing with equal or greater challenges in their economic environment.

### The Regulatory Environment

The regulatory environment for the electric utilities remains today quite chaotic. Of course, one element of the regulatory environment, the regulation of electric rates by the states, is inseparable from the economic environment. That element was even further complicated by federal moves toward deregulation and competition within the electric power business. The Public Utilities Regulatory Policy Act was passed in 1978. Conservation, cogeneration, independent power producers and demand side management all had to be factored into a utility's management strategy.

In addition to the NRC and the state public utility commissions, the utilities have had to deal with other regulators at the federal level, most notably EPA for air quality issues (coal fired generation) and FERC (hydroelectric generation). In some cases, any one of several federal agencies could give a firm "no" to a project or action, but none could give an unqualified "yes." With each of the agencies constrained by their own mandate, issues that required a balancing of considerations across agency lines were handled poorly or in some instances not at all. The challenge for the utilities was to get rational decisions on a timely basis. The challenge for the regulators was to avoid having their "single issue" mandate result in actions that were counter productive to the broad interest of the public.

### The Old Paradigm

In the decade following the days of the Atomic Energy Commission, one can identify some changes in the regulatory paradigm, but they were more shifts in emphasis than fundamental changes in approach. The initial rules and regulations were intended to provide adequate protection for the public health and safety, while still providing enough flexibility for the successful development of the technology. As the market narrowed to BWR and PWR technologies, it became possible to deal more specifically with the characteristics of those systems, and safety regulations became less flexible and more prescriptive. This trend was reinforced by the steady accumulation of experimental data, design knowledge and experience, and technical judgement on the part of the regulatory staff. Additional rules were written as the knowledge became available to support them and as they were

needed to resolve specific problems. Adequate safety was presumed to be assured by compliance with the rules.

Even the abrupt attention shift to plant operations and operator training caused by the TMI accident did not diminish the emphasis on rules and compliance. The regulatory imperative was to assure the establishment and maintenance of a safety culture that would govern all decisions, but the day-to-day measurement of success by the regulators was still largely compliance with the rules. The combined effect of the safety culture and compliance with requirements was that there was little differentiation among activities based on their importance to safety. The culture required that everything be done in the best possible way, regardless of its safety significance.

From a plant safety standpoint, I think it is fair to say that the post-TMI era has been a success. Plant performance and plant safety have improved since 1979. All of the performance indicators, from unplanned scrams to collective radiation exposure to thermal performance, are better than they were in 1980, and in some cases have exceeded the industry performance goals for 1995.

With this kind of success, why change? The answer is simply that through changes which we now know how to make, the public interest can be better served.

### The New Paradigm

The old paradigm was "identify the requirements for safe design, safe construction, safe operation, and then comply with those requirements." Its weakness (at least one of them) is that there are no intrinsic means to deal with the question of "how safe is safe enough." And there are many in the industry that would argue that, as a result, the cost has been too high.

The new paradigm, which has been developing for a number of years, is built around a recognition that resources are finite. They should be devoted to those things that have the most safety significance and payback, and they should not be misdirected to activities with minimal or no safety benefit.

Now let's look at the things that contributed to its development.

I mentioned the publication of WASH-1400 earlier as a significant event in this context, and its use of risk analysis clearly provided a framework for prioritizing design and reliability concerns, but how to use that capability in regulation was not immediately clear. WASH-1400 was, in any event, a stepping stone, and an important one, on the path to differentiating

between what is important from a safety standpoint and what is not.

The next significant stepping stone was the development of quantitative safety goals and their endorsement in a Commission policy statement. This was a direct outgrowth of the work that produced WASH-1400, and addressed, although at a very high level, the question of "how safe is safe enough?" The Policy Statement, however, also emphasizes the continuation of the defense-in-depth approach, and concludes, "These safety goals . . . are not meant as a substitute for NRC's regulations and do not relieve . . . licensees from complying with regulations." A 1990 Commission Staff Requirements Memorandum to the staff states, "Safety goals are to be used in a more generic sense, and not to make specific licensing decisions." The safety goals did little to mitigate the impact of the NRC's imposition of requirements on the licensees.

Contrary to the belief of many in the licensee community, the NRC did not go about its business with total disregard for the costs of its actions. I think it is arguably true, however, that for a long time we were not successful in institutionalizing appropriate cost/benefit considerations. Regulatory analyses, whose intent is to ensure that the NRC's imposition of regulatory burdens on licensees are soundly based and achieve a safety objective commensurate with the burden, have been performed by the NRC since 1976. The process was revised to comply with the intent of President Reagan's Executive Order 12291, issued in February 1981. This order directed the preparation of Regulatory Impact Analyses, and, in addition, required that actions taken have a net positive benefit to society. As an independent regulatory agency the NRC is not directly affected by Executive Orders, although we attempt to conduct our business at a level which matches or exceeds the objectives of such Executive Orders. In deciding how to respond, the agency's responsibility for safety regulation remains paramount. In this case, the order reinforced a direction that had already been established. The Regulatory Analysis Guidelines and supporting Regulatory Analysis Technical Evaluation Handbook that were put into place in 1983-84 are currently going through another major revision and update.

The Committee to Review Generic Requirements was created in 1981 to bring under control some of the excessive changes that resulted from TMI. The need for such a committee was identified as a result of a "regulatory impact survey" conducted of our licensees. We concluded that by asking for too much too fast we were actually having an adverse impact on safety. A few years later, the control of changes was strengthened by Commission approval of the Backfit Rule, which, using the CRGR charter as a basis, extended the controls on new requirements to plant specific issues. In retrospect, one of the important ideas

implicit in creating the CRGR is that requirements not tempered by consideration of resource limitations may have outcomes counter to what is intended.

A regulatory impact survey done in 1989 still showed that, collectively, licensees believed that they were acquiescing to NRC requests with little safety significance to avoid poor SALP ratings, and that responding to NRC requirements dominated their resource allocations.

As a result of this survey, we identified a number of ways we could improve our performance. Most of these were aimed at reducing unnecessary impact of our activities on licensee resources. Concurrently but independently, the "Marginal to Safety" program was initiated to identify those requirements that could be eliminated with little impact on safety.

A broad statement in support of the new paradigm is contained in the "Principles of Good Regulation" adopted by the Commission in January of 1991. These principles articulate the Commission's requirements for independence, openness, efficiency, clarity and reliability in its decisions which carry out its regulatory mandate. In particular, the principle of clarity requires a nexus between regulations and agency goals, and the principle of efficiency requires that regulatory activities be consistent with the degree of risk reduction they achieve and should minimize the use of resources.

Shortly after the Clinton Administration took office, it initiated the National Performance Review to look for ways to provide a "government that works better and costs less." As a result of its examination of the Federal Government's regulatory activities, President Clinton issued Executive Order 12866 in September 1993 on "Regulatory Planning and Review." The order states that the regulatory system should protect and improve "health, safety, environment and well being," and improve "performance of the economy without imposing unacceptable or unreasonable costs on society . . . ." The order goes on to direct agencies to "assess all costs and benefits of . . . alternatives, including the alternative of not regulating." The NRC's principles of good regulation and the new regulatory paradigm are clearly consistent with this Executive Order. The Regulatory Review Group, whose activities have been discussed earlier at this conference, fortuitously anticipated the intent of this Order when it was established in January of 1993.

Currently, there are a number of things going on within the agency that are intended to reduce the regulatory burden without reducing the health and safety of the public. Among the most important are continuation of the Marginal to Safety program, the implementation of the Regulatory Review Group recommendations,

the initiative for a Graded Approach to QA, and the Cost Beneficial Licensing Action initiative. All these activities share the idea that issues should be prioritized with respect to safety significance, resources should be allocated where they have the most safety impact, and resources should not be directed, certainly not by the NRC, to issues of little safety impact.

The primary decision tool in establishing safety significance undoubtedly will be probabilistic risk assessment. It provides a useful means of establishing the relative safety impacts of alternatives, and it also provides a way of estimating how we are doing relative to the safety goals. The NRC is devoting a great deal of effort to steadily improving its use of PRA in the regulatory decision making process. But it seems clear that the implementation of "risk based regulation" will be evolutionary rather than revolutionary.

Also embedded in many of the initiatives is an effort to replace compliance based rules with performance based rules. Some performance based rules can be formulated and justified in terms of risk, but others are not easily so structured. Inevitably, the establishment of, and inspection against, performance based rules can be more difficult than for compliance based rules. If an adequate performance based objective can be defined and met, such rules will have the advantage of moving the NRC one further step back from managing the licensee's resources.

### Conclusion

I believe that the trends implicit in the NRC's current programs to improve its own performance and effectiveness are correct. That is, we must keep firmly committed to providing for adequate protection of the public health and safety, but remain convinced that maximizing this protection is not accomplished by merely adding layer upon layer of additional prescriptive regulatory requirements. If everything is emphasized, nothing gets sufficient attention.

The history I have briefly recounted here reflects significant efforts to limit or reduce the regulatory burden without compromising the NRC's mandate to protect public health and safety. How do we assure future progress in this direction, and, assuming progress has been made, how do we hold on to it? One element in assuring future progress is the staff proposal now being considered to institutionalize the regulatory improvement process. This proposal includes policies, objectives and an administrative framework for implementation.

It is worth noting that one of the intrinsic characteristics of a "single issue regulator" such as the NRC, is that there are no

inherent limits on regulatory requirements. There will continually be new issues or new concerns where the public health and safety might appear to benefit from a new rule or requirement. The competing effect of optimum allocation of resources is not built into the mandate. One can expect progress in this respect will be maintained only by a determined effort on the part of the industry and the regulator.

In closing, I will share with you some cautions and concerns. The first is that we should not lose sight of the fact that regulation is essentially a political (but I hope non-partisan) process. It can be successful, and in turn the regulated industry can succeed, only if the process and its results are accepted by the public and by their elected representatives who mandate the regulation. I think we all intellectually agree that public trust requires that the regulatory process be open and understandable. We must not forget that the choices we talk about making, optimum allocation of resources, and decision processes using probabilistic risk assessment, are neither simple nor easily understood. We must do whatever is necessary to ensure public trust in the process and its results.

The second caution is related to the first. In choosing to allocate resources to a problem, or in choosing not to do so, we must recognize that the public perception of safety or lack of it can be as important as the reality of safety. Thus, a high visibility failure at a nuclear site with little safety significance may cause unacceptable damage to the credibility of the regulator and the industry. We should not forget that it was lack of public trust that caused the demise of the AEC as a regulator. We should allocate adequate resources to issues that are of high visibility, even if technically we rate their safety significance as low.

My third caution is that, in the process of further developing this new paradigm, we must not undermine the safety culture. It has, in my opinion, been an essential element in achieving an acceptable level of safety. Successful extension of the new paradigm will not diminish the importance of thoughtful plant design, operation and maintenance, where the first question that suggests itself is, "How does this action impact safety?" The new paradigm suggests that we can sometimes answer that question by saying, "This action is not important to safety." But we must continue to be sure to ask the question.

Finally, I think that one of the important reasons that the industry has been successful in improving reactor safety since TMI is the effectiveness of communication within the industry. Operating experiences, safety significant problems, successes and failures are shared freely within the industry. That did not happen by chance. The NRC has worked at it, INPO has worked at

it, and most importantly the plant owners and operators have worked at it. My concern is that the electric utilities are entering a new era of competition with independent power producers and with each other. It may, I fear, be difficult to maintain that kind of free flow of information in an environment where competitive advantage and economic survival could depend to a degree on others not knowing too much about your business. We must make sure that the lines of communication so important to the safety of the public stay open.

Thank you for your attention. I will be happy to take a few questions or comments.

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(1) The discussion of the regulatory history of the AEC relies heavily on "A Short History of Nuclear Regulation, 1946-1990," by J. Samuel Walker, the Historian of the Nuclear Regulatory Commission.