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RISK BASED REGULATION AND THE NEED FOR RELIABILITY DATA COLLECTION

Presented by
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Good evening. It is a great pleasure to be in Toronto this evening and to have the opportunity to share some thoughts with you on the subject of reliability data collection. The call for papers for this international workshop identified: support of probabilistic safety assessment, plant maintenance, and life assurance programs as the primary reasons for reliability data collection. As a scientist, I have a great appreciation for the importance of having good, solid data available to provide technical insights and to help direct the further development of technical knowledge. As a nuclear safety regulator, I consider the applications identified: PSA, maintenance and life-assurance, to be among the top priority items for virtually every nuclear power program in the world.

For the last two days you have been discussing the technical aspects of data: how to collect it, how to evaluate it, how to store and retrieve it, how to share it and how to use it. I would like to divert your thoughts for a few minutes this evening to a different aspect of data; the regulatory and public policy aspect. Certainly, the lack of good data has shaped the regulatory process in the past, and the availability of good data will shape the regulatory process in the future. We need to realize, however, that data are not free. It costs time and money to collect and validate data, and sound policy requires that those costs result in some benefit. It is also unfortunately true that data can be misused, and misuse, or steps taken to prevent misuse, can result in costs being incurred.

These policy issues of costs and benefits are not truly separable from the technical issues. As a result, the entire data collection, evaluation and application process ultimately is influenced by both technical and regulatory policy considerations. The degree to which each of these factors influences the collection and sharing of data will vary from one country to another, just as the regulatory structures and nuclear power enterprises vary from one country to another. Be assured, however, that both factors have an impact.

When I accepted the invitation to speak here this evening, I had no way of knowing that the issue of collection of reliability data in the United States would be in front of the Nuclear Regulatory Commission at this very moment. The issue has been presented to the Commission in the form of a proposed rule requiring the collection and reporting of certain reliability data from our power reactor licensees. The rule is strongly supported by the NRC staff, opposed by the industry, and, as yet, undecided by the Commission. Because the Commission has made no determination on the proposed rule, I will pose more questions than I intend to answer this evening.

The regulatory structure and process in the United States evolved in parallel with the technical development of the nuclear power industry. The initial rules and regulations had to provide adequate protection for the public health and safety, while still allowing enough flexibility for the successful development of the technology. Rules were written as they were needed to resolve specific problems. Design conservatism was used to compensate for the lack of performance and operating reliability data. The fundamental design and regulatory philosophy was "defense in depth." The accident at TMI-2 focussed industry and regulatory attention on the crucial importance of operations, but the emphasis was still on identifying rules or requirements judged to be important to safety, and then assuring compliance with those rules and requirements.

This prescriptive approach to regulation is now changing. The new philosophy is based on the recognition that resources are finite. They should be devoted to those things that have the most safety significance, and they should not be misdirected to activities with minimal or no safety benefit. It is important to note that the new philosophy requires that we have the ability to quantify both the safety impact of a proposed regulatory action, and its cost.

The two relevant major areas of regulatory development are performance based rules and risk based regulation. These two concepts are closely related but they are not identical. Performance based rules focus on the end result to be achieved, and are usually based on risk insights. The rule does not

specify the process, but establishes the goals to be reached and how the achievement of those goals is to be judged. The inspection and enforcement activity is based on whether or not the goals have been met. The success of performance based rules ultimately depends on having sufficient performance data to provide assurance that goals have been achieved.

Risk based regulation is the broad term used for a regulatory process which characterizes alternatives in terms of their impact on risk. Our ability to distinguish one alternative from another based on safety significance depends on having two things: models, which describe the alternatives in probabilistic terms; and reliability data, which allow us to quantify the overall probability of an event occurring or not occurring. Without this ability to quantify, risk based regulation cannot work, and the successful application of risk based regulation necessarily had to wait for the development of good models and the availability of good data.

Probabilistic risk assessment methodology has now developed to the point where both the NRC and the licensees are comfortable using it to establish the relative safety significance of a variety of issues. The NRC is devoting a great deal of effort to improving its use of PRA in the regulatory decision making process. It will be used to make decisions with respect to which NRC requirements or licensee commitments can be changed or eliminated with little effect on safety. It will also continue to be used to identify new issues with high safety significance which require corrective action.

The NRC's PRA implementation plan includes a number of elements: developing applications in reactor regulation, developing improved modeling techniques, and analysis of plant operating data from a risk perspective. Common to all these elements is the need for data on the reliability, availability, and failure characteristics of the plant systems and components we are trying to model. All of our performance based rules and risk based decisions must ultimately be validated. We need to know if performance goals are being met. We need to know if component failure rates assumed in the design process are consistent with failure rates observed in the field. We need to know if failures observed in the field are consistent with the assumptions made in the regulatory decision process.

In the best of all possible worlds, there would be no divergence between the regulators and the industry on what data are needed or on the feasibility of providing them. Unfortunately, there is some divergence, and here is where the public policy issues come into play. There is no question that a great deal of momentum has built up for increased use of risk based regulation. The industry seems to be convinced that it

will help save money in the long run, and the regulators are convinced that it will give us a more objective basis for regulation.

The NRC staff has been negotiating with the industry through the Nuclear Energy Institute and the Institute of Nuclear Power Operations since 1991 in an attempt to reach agreement on what data are needed, how they should be reported, and whether or not plant specific reliability data would be routinely made available to the public. Agreement has seemed close on a number of occasions, but so far it has not been reached. The NRC staff, feeling that it cannot move forward with risk based regulation unless it has access to better reliability data, has asked the Commission to approve publishing a reliability data rule for public comment. The Commission, in turn, has asked the staff to make sure that the proposed rule can be justified in the context of the NRC's regulatory authority. Since the Commission has not acted on the proposed rule, I obviously cannot predict the outcome. The Commission's judgment clearly will depend on the information currently being assembled by the staff. Nonetheless, the coincidence of Commission consideration of the proposed rule and the availability of this audience provides an opportunity to explore some of the public policy implications I mentioned earlier.

From a technical and regulatory standpoint, there is no question in my mind that the availability of the data requested by the staff will ultimately benefit the plant owners, the NRC and the public health and safety. The proposed rule has been considered by the NRC's Advisory Committee for Reactor Safeguards, and the Committee has recommended that the rule be published for comment. The ACRS letter to the Chairman of the Commission states, in part, "We believe that high-quality, plant-specific reliability and availability data are needed if risk-based regulation is to reach its full potential for both improving safety and reducing burdens on licensees."

That is a significant endorsement, but as a Commissioner I have to ask if it is sufficient justification for promulgating a rule. In the United States, the authorizing legislation for the Nuclear Regulatory Commission requires that the Commission ensure that licensed activities be conducted so as not to result in "undue risk" to the public health and safety. As a result, the Commission has considered that there is a level of protection to the public, referred to as "adequate protection," that must be maintained in licensed activities regardless of cost. Beyond this level of "adequate protection," the NRC can, by its own rules, establish requirements that result in "substantial improvements" in safety, as long as the benefits of such requirements outweigh the costs. In the case of the proposed

reliability data rule, a majority of the Commissioners must conclude that benefits will ultimately exceed the costs.

What is the industry's view? I mentioned earlier that industry opposes the rule as proposed, yet industry stands to reap large benefits from performance based rules and risk based regulation. Based on the Nuclear Energy Institute's presentation to the ACRS, the industry acknowledges that it stands to benefit, and further states that it is anxious to come to closure with the NRC staff. At the March 9, 1995 ACRS meeting, the NEI representative stated, "We're pushing the risk-based and performance based approach. . . . [W]e can't move forward unless the data question is resolved."

What are industry's concerns, then? Let me see if I can summarize them. First, they believe that agreement on data to be collected and reported should be coupled with a mutual understanding of how the data will be used to implement performance based and risk based regulation so as to reduce regulatory burden. Without that understanding, they are concerned that the result will be a new layer of risk based requirements on top of the existing deterministic, compliance based requirements. Second, they are concerned that the data being requested will not meet everybody's needs, and that additional work needs to be done on defining the collection and reporting scope. They are reluctant to sign on to a major, continuing data collection effort that may turn out to be either too much or not enough. Finally, many in the industry are concerned about the staff's position that the reported, plant specific data must be made publicly available. The stated concern is over possible misuse of the plant specific data.

The industry has a dilemma; it would like the benefits of risk based and performance based regulation, but it is concerned about the staff's commitment to providing those benefits on a timely basis. The staff has a dilemma; it would like industry's cooperation, but it is not in a position to promise specific, quantifiable benefits in return for that cooperation. As a result, the Commission has a dilemma; is there sufficient justification for a rulemaking?

Clearly, the proposed rule is not required to meet the standard of adequate protection. I think the industry and the NRC agree that significant gains have been made in operational safety over the past 15 years, and those gains have been sufficient to provide adequate protection. On the other hand, can the rule be justified on the basis that it will provide a substantial improvement in safety, and that the benefits will outweigh the costs? We don't know the answer to that yet, but I suspect the benefits, both in terms of reduced risk and in terms of reduced cost of regulation will be very difficult to quantify.

Can the Commission approve the rule in the absence of an immediate safety need? Yes, the Commission can decide that the information is needed to support generic regulatory actions, such as rulemaking, revisions to regulatory guides and the resolution of generic safety issues. Will we approve it? I don't know.

One of the tenets of risk based regulation is that resources should be focussed on those things that are risk significant. If we cannot clearly establish how this rule would allow us to divert resources from less risk significant activities to more risk significant activities, how do we justify the rule? I think all parties agree that the potential benefits are great, but we have to recognize that specific benefits are beyond the reach of this particular rule. The rule only contains the hope of benefits, it does not include the promise.

This lack of clear and immediate safety need is particularly troublesome to the Commission at a time when both the Administration and the Congress are emphasizing reduction of regulatory burden. There is no mandate, at the moment, to promulgate rules that simply seem like a good idea.

Having said that, let's look at the other side for the moment. The greatest beneficiary of risk based regulation will, in all likelihood, be the licensee community. They appear to acknowledge that, and they further acknowledge that, without the data, risk based regulation can not go forward. From a regulatory standpoint, the benefit to industry is entirely consistent with our mandate to protect public health and safety. Resources that are not spent on issues of little safety significance can be diverted to issues of high safety significance. Perhaps, in this case, the Commission should take the position that this rule is the up-front price industry has to pay to realize the benefits we all agree are there.

In a speech at the Nuclear Energy Institute conference in Washington last week, Chairman Selin challenged the industry to do a better job of recognizing when its self-interest coincided with that of the NRC. There have been instances in the past where industry resisted NRC's attempts to identify and solve problems, and the industry would have been better served to work with the NRC from the beginning. The proposed reliability data rule could possibly be such a case.

So where does that leave us? The Commission basically has three options, I believe. Let me add parenthetically, if there were other Commissioners present here they might identify different options. First, the Commission could approve the rule as proposed. Our arguments for doing so would be rooted in the belief that ultimately it will provide a net benefit to the public, in terms of reduced risk, and to the industry, in terms

of reduced regulatory burden. The industry would simply have to live with the down side consequences of having plant specific reliability data available to both the NRC and the public.

The second option would be for the Commission to disapprove publication of the rule, and instruct the staff to not pursue it any further. The rationale for this outcome would be simply that the rule is not needed for any clear public health and safety reason. In this case, the burden would shift to the industry to pursue the benefits of performance based and risk based regulation. Each time a licensee or group of licensees wanted a change in a requirement, it would be incumbent upon them to provide enough data to allow the staff to conclude that the requested action could be defended from a safety perspective.

The third option would be for the Commission to direct the staff to go back to the industry, negotiate the best agreement they can short of imposing a rule, and bring that agreement back to the Commission for consideration. It is quite possible that with a little more pressure on both sides, the need for a rule could be avoided.

There is in fact a fourth option: the Commission could sidestep the issue for the time being by approving the rule for publication for comment in an attempt to get a better articulation of the industry position and concerns. I discount this option for the moment because it doesn't add anything to the current discussion.

How will this all turn out? As I said before, I don't know. I am intellectually convinced of several things. First, further development of risk based and performance based regulation will ultimately benefit the public, in terms of reduced risk; the industry, in terms of reduced regulatory burden; the NRC, in terms of a more rational regulatory process; and all parties in terms of reduced generation costs. Second, the availability of good, solid reliability data is critical to the beneficial use of risk based regulation. Finally, there will be a resolution to this problem that will benefit both the NRC and industry.

In a moment, I will be happy to respond to a few questions, but I want to leave you with some closing thoughts. Do not lose sight of the fact that one of the important reasons that the industry has been successful in improving reactor safety 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 regulators have worked at it and, most importantly, the plant owners and operators have worked at it. We must continue to expand that free flow of information within the world community of nuclear power plant operators.

My next point is that in the process of developing regulations that address the most safety significant issues and are cost effective, we must not undermine the safety culture. It has been an essential element in achieving an acceptable level of safety. Performance based rules and risk based regulation will not diminish the importance of thoughtful plant design, operation and maintenance. I challenge you practitioners of the arcane art of probabilistic risk assessment to work especially hard on human performance modeling and the collection and evaluation of the necessary human reliability data. I think some arguments can be made that, in spite of our limitations, the hardware is good enough and that the significant safety improvements will be found on the human reliability side.

Finally, 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.

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