

Risk-Informed Regulation - Move Toward Realism  
Ashok Thadani  
PSAM

**Introduction**

Thank you for inviting me to discuss with you today the NRC's progress in implementing a risk-informed approach that brings better focus on issues of greater safety in our regulatory activities, and the opportunities that still exist to help us develop a more realistic view of nuclear safety issues. In the course of this discussion, I would like to focus in particular on the way in which this move toward realism is affected and influenced by consideration of uncertainties in the evaluation of risk. This has led to the concept of "realistic conservatism," which is the term that has come to embody our current initiatives in risk-informed regulation, and one which I will discuss in a moment.

I hope I will be able to give you an appreciation for those areas in which our risk-informed regulatory approach has been highly successful, as well as those areas in which challenges have arisen that will require further effort to reach our goals. I will also elaborate on how the integration of a realistic view of risk with traditional considerations of conservatism and defense-in-depth follows logically from our progress to date, to serve as a foundation for our regulatory philosophy.

Our regulatory philosophy is to integrate the best scientific and technical knowledge, the lessons-learned from operating experiences, and the best methods and practices, in our regulatory activities. I will begin with a brief discussion of the status of our implementation of the risk-informed initiatives.

**Implementation of Risk-Informed Regulation**

We have proceeded along several tracks in parallel towards more risk-informed and, where appropriate, performance-based, considerations in the agency's actions. The first track involves application of a risk-informed approach with regard to various day-to-day regulatory activities, such as consideration of license amendment requests for changes in areas such as technical specifications, quality assurance requirements, and in-service testing and inspection.

A second track involves implementation of a new reactor oversight process, or ROP, for operating plants, which was implemented in 2000. The ROP employs objective performance indicators for key plant systems, structures, and components, along with a baseline inspection program. Inspection findings are put through a risk-informed significance determination process to assess their safety impact, which is also the basis for further NRC action. The ROP is generally considered to be a substantial improvement over prior approaches; however, we continue to study the development of new performance indicators that may provide an even better risk-informed picture of a plant's operation.

The third track is a more comprehensive examination of the body of reactor regulations in 10 CFR Part 50 and in other related parts of Title 10. Since most of our regulations were developed 30 to 40 years ago, using the knowledge then available, we can now exploit more recent research results and mine operating experience to develop risk insights, and use those insights to bring better safety focus to our regulations. We have essentially completed a risk-informed revision of the combustible gas rule (10 CFR 50.44), and we are proposing to amend the regulations to provide an alternative approach for establishing the requirements for treatment of structures, systems and components (SSCs) for nuclear power reactors using a

risk-informed method of categorizing SSCs according to their safety significance (Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors (RIN 3150-AG42)). Additionally, we are making progress on our regulations on pressurized thermal shock and ECCS acceptance criteria.

We have initiated a program to develop an integrated, risk-informed, technology neutral regulatory framework for advanced reactors such that we have high-level regulatory requirements that will be the same regardless of the details of the reactor design – coolant, fuel, neutron energy spectrum, and so forth. A paper discussing the staff’s progress in defining the framework is being provided to the Commission this month. If the staff’s approach is ultimately approved by the Commission, implementation of these regulations on a design-specific basis will be described in regulatory guides, which are not regulations as such, but describe a methodology which the NRC has determined to be acceptable. Clearly this is a major challenge and we have much to do, but we have made good progress in defining what the framework will look like and what we must do to develop the technical infrastructure to support its development.

We are also developing consensus standards for PRAs in collaboration with the industry, working through various standards development organizations. A standard for full-power PRAs, developed in cooperation with the American Society of Mechanical Engineers (ASME), and a standard on external events, which is being handled by the American Nuclear Society, have been finalized. Progress continues on a standard for PRAs covering low-power and shutdown operations. The objective of these efforts is to ensure that risk assessment models and methods are high-quality, reliable, and technically sound. The Commission recently approved a phased approach for improving PRA quality, reflecting both the progress in developing standards and the use of those standards by licensees in developing PRAs. The ultimate objective of this approach is to reach a point where the quality of licensee PRAs will be at a sufficiently high level to support a wide range of applications.

### The Move to Realism

Up to this point, I have not explicitly addressed the issue of realism in the development of a risk-informed regulatory approach. But if you think about it, the concept of realism is implicitly embodied in the use of risk assessment as a tool in regulatory decision-making. If we are going to use risk as an element of our regulatory approach, then it follows that we must have the tools to make a realistic estimate of that risk. At the same time, we must be able to understand the nature of the uncertainties in risk estimates, and to take a conservative approach to ensure an adequate margin to safety. This philosophy was dubbed “realistic conservatism” in 2002 by then-Commissioner Diaz, shortly before he became NRC Chairman.

Simply put, “realistic conservatism” means that decisions are informed by the real world of advancing scientific knowledge, technological capabilities, and experience, in order to preserve appropriate and prudent safety margins, to regulate in a manner that corresponds to the actual risk presented and not to worst case assumptions. Being realistically conservative is in the best interest of the public safety and the environment, by ensuring that we maintain the right balance between under-regulating -- which puts the public safety and the licensees’ investment at risk -- and over-regulating, which could divert resources from important safety issues while increasing costs to licensees and thus to consumers, without a matching safety or security benefit. Such an approach is also essential if we are to understand the real margins to safety that exist in our nuclear facilities.

Our traditional practices are embodied in regulations such as our emergency core cooling system rule, 10 CFR 50.46, and the associated Appendix K, which utilized the concept

of design basis accidents and analytical methodologies using prescribed models with known conservatisms to show that large safety margins existed, even in the face of substantial – but largely unquantified – uncertainties. But we also know that Appendix K models do not account for known phenomena that can affect a nuclear plant's accident response. Thus, it is difficult, if not impossible, to determine the real margins. A realistic approach, based on improved phenomenological modeling and with consideration of the risk-significance of various accident scenarios and sequences, can help us to understand those real margins, and can indicate where appropriate conservatism in regulatory requirements should be applied to provide real enhancement of safety.

Let me discuss briefly the ramifications and challenges associated with this approach, and what we are doing to address them.

As the Commission recognized in its Safety Goal Policy Statement, and again in the PRA Policy Statement, a risk-informed – and realistic – approach to safety must take into account the uncertainties inherent in the quantitative assessment of risk. Understanding the nature and magnitude of these uncertainties, and finding ways to reduce them, have been among the most important objectives of the NRC's research programs over past 20 years.

Much of our research in this area initially grew out of post-Three Mile Island assessments. It was clear at that time that the use of quantitative risk assessment techniques in regulatory decision-making would require both the improvement of PRA methodology and better understanding of severe accident phenomenology to reduce uncertainties and improve the realism of severe accident and risk analyses. Consequently, an extensive Severe Accident Research Program was undertaken in the 1980s to provide the technical data needed to develop improved analytical models. The NRC also undertook, in 1986, an update of the Reactor Safety Study to incorporate the experience gained in the preceding decade, and to incorporate new information on source terms and on containment performance. This study, released as NUREG-1150, was published in 1991. That report was peer-reviewed by a committee chaired by Dr. Herb Kouts, which found NUREG-1150 to be a major step forward in risk assessment. Yet, while NUREG-1150 represented a significant improvement in the application of PRA to reactor safety assessment, there were substantial conservatisms embedded in the analyses.

For example, NUREG-1150 allowed the so-called "alpha-mode" containment failure scenario to exist, in which core melt and relocation produced catastrophic steam explosion, and resulted in a very large, early release of fission products to the environment. Further research has demonstrated that this scenario is not credible because the melt masses and energy conversion efficiencies necessary to produce the assumed chain of events are extremely unlikely to occur.

A similar story can be told concerning our analyses of spent fuel pool safety, a topic that has gotten much attention over the past few years. Early analyses of this issue were based on highly conservative or bounding assumptions related to areas such as spent fuel heatup, potential for a zirconium fire, fission product releases, and credit for operator action in consideration of the very long times over which these scenarios develop. Recent analyses have made use of improved models, such as those in our MELCOR code, along with detailed computational fluid dynamics methods, and show that the spent fuel is more easily cooled than predicted in the conservative studies, more time is available to restore cooling and prevent fuel damage, and that even if the fuel is damaged, the consequences are less severe than predicted in the earlier analyses.

Our continuing severe accident research has contributed to the achievement of significant progress in our ability to perform more realistic accident progression analyses and source term characterization for severe core damage events. We have also gained valuable insights on containment failure modes and associated behavior. Ongoing work continues to address important phenomena in accident progression and consequence analysis, such as fission product release, transport, and deposition. The NRC has also continued to support the development and improvement of PRA methodology. Some of the areas in which we continue to work include improving the equipment reliability database, assessment of containment performance, modeling of human performance and human factors, fire risk, external events, and low-power and shutdown events. Combined with our programs in thermal-hydraulics, severe accidents, and other aspects of reactor system behavior, we continue to make progress toward our goals of reducing uncertainties, quantifying safety margins, and ultimately, a realistically conservative view of reactor safety.

It is important to recognize, though, that there are limitations to quantitative risk assessment, and while we can improve our understanding of the origins of uncertainties and, in many cases, reduce their magnitude, we can never eliminate them completely. We must have a healthy respect for those things we do not know and carefully integrate defense-in-depth and engineering judgment with quantitative results.

We must also continue to “poke and probe” – to learn from experience and to apply what we have learned to the identification of any new safety issues. In the U.S., for example, we are now faced with trying to anticipate what we may see as we operate our plants for up to 60 years. Recent experience with materials degradation, such as at Davis-Besse, indicates that we must develop the capability to foresee problems and proactively address them before they can potentially threaten plant safety. These are just a few of the challenges that we must face as we continue to improve our knowledge base and continue along the path to risk-informed, realistically conservative regulation.

### Summary and Conclusions

My objective in this presentation has been to illuminate the progress that we have made in improving both PRA technology and our phenomenological understanding of reactor accident response, and in convolving these elements into a logical, consistent, risk-informed approach to reactor regulation—one that allow us to understand expected plant responses and real safety margins, so that we may establish the desired margins to support our safety decisions. I have also discussed those areas in which we continue to perform research to understand and characterize uncertainties, and to deal comprehensively with new challenges, to ensure that our regulatory approach is both realistic and conservative, and can identify and address the most important safety issues. Our responsibilities to protect the health and safety of the public demand no less.

Thank you for your attention.