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Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Final policy statement.

SUMMARY: This statement presents the policy that the Nuclear Regulatory Commission (NRC) will follow in the use of probabilistic risk assessment (PRA) methods in nuclear regulatory matters. The Commission believes that an overall policy on the use of PRA methods in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that would promote regulatory stability and efficiency. In addition, the Commission believes that the use of PRA technology in NRC regulatory activities should be increased to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's

deterministic approach. The pertinent comments received from the published draft policy statement are reflected in this final policy statement. This policy statement will be implemented through the execution of the NRC's PRA Implementation Plan.

EFFECTIVE DATE: August 16, 1995.

ADDRESSES: The proposed policy statement and the comments received may be examined at: NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

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SUPPLEMENTARY INFORMATION:

I. Background

The NRC has generally regulated the use of nuclear material based on deterministic approaches. Deterministic approaches to regulation consider a set of challenges to safety and determine how those challenges should be mitigated. A probabilistic approach to regulation enhances and extends this traditional, deterministic approach, by: (1) Allowing consideration of a broader set of potential challenges to safety, (2) providing a logical means for prioritizing these challenges based on risk significance, and (3) allowing consideration of a broader set of resources to defend against these challenges.

Until the accident at Three Mile Island (TMI) in 1979, the Atomic Energy Commission (now the NRC), only used probabilistic criteria in certain specialized areas of licensing reviews. For example, human-made hazards (e.g., nearby hazardous materials and aircraft) and natural hazards (e.g., tornadoes, floods, and earthquakes) were typically addressed in terms of probabilistic arguments and initiating frequencies to assess site suitability. The Standard Review Plan (NUREG–0800) for licensing reactors and some of the Regulatory Guides supporting NUREG–0800 provided review and evaluation guidance with respect to these probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. In addition, both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional nonprobabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (NUREG–1050) that addressed the state-of-the-art in risk analysis techniques.

In early 1991, the NRC published NUREG–1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In NUREG–1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants. This study was a significant turning point in the use of risk-based concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance after core damage and accident progression. The methods developed for and results from these studies provided a valuable foundation in quantitative risk techniques.

PRA methods have been applied successfully in several regulatory activities and have proved to be a valuable complement to deterministic engineering approaches. This application of PRA represents an extension and enhancement of traditional regulation rather than a separate and different technology. Several recent Commission policies or regulations have been based, in part, on PRA methods and insights. These include the Backfit Rule (§ 50.109, "Backfitting"), the Policy Statement on "Safety Goals for the Operation of Nuclear Power Plants," (51 FR 30028; August 21, 1986), the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138; August 8, 1985), and the Commission's "Final Policy Statement on Technical Specifications Improvement for Nuclear Power Reactors" (58 FR 39132; July 22, 1993). PRA methods also were used effectively during the anticipated transient without scram (ATWS) and station blackout (SBO) rulemaking, and supported the generic issue prioritization and resolution process. Additional benefits have been found in the use of risk-based inspection guides to focus NRC inspector efforts and make more efficient use of NRC inspection resources. Probabilistic analyses were extensively used in the development of the recently proposed rule change to reactor siting criteria in 10 CFR Part 100 (59 FR 52255; October 17, 1994). The proposed rule change invoked the use of a probabilistic approach to estimate the Safe Shutdown Earthquake Ground Motion for a nuclear reactor site, instead of the purely deterministic method currently specified in Appendix A to 10 CFR Part 100.

Currently, the NRC is using PRA techniques to assess the safety importance of operating reactor events and is using these techniques as an integral part of the design certification review process for advanced reactor designs. In addition, the Individual Plant Examination (IPE) program and the Individual Plant Examination—External Events (IPEEE) program (an effort resulting from the implementation of the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants") have resulted in commercial reactor licensees using risk-assessment methods to identify any vulnerabilities needing attention.

The Commission has been developing performance assessment methods for low-level and high-level waste since the mid-1970s and these activities intensified using performance assessments techniques in the late 1980s and early 1990s. This has involved the development of conceptual models and computer codes to model the disposal of waste. Because waste-disposal systems are passive, certain analysis methods used for active systems in PRA studies for power reactors had to be adapted to provide scenario analysis for the performance assessment of the potential geologic repository at Yucca Mountain, Nevada. In regard to high-level waste, the NRC staff participates in a variety of international activities (e.g., the Performance Assessment Advisory Group of the Organization for Economic Cooperation and Development, Nuclear Energy Agency) to ensure that consistent performance assessment methods are used to the degree appropriate.

The Commission believes that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA methodology can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency and enhances safety. In May 1994, the NRC staff forwarded a draft PRA policy statement to the Advisory Committee on Reactor Safeguards (ACRS) for review and briefed ACRS on the same subject. On August 18, 1994, the NRC staff proposed a PRA policy statement to the Commission in SECY–94–218, "Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities." In that Commission paper, the staff proposed that an overall policy on the use of probabilistic risk

assessment (PRA) methods in nuclear regulatory activities should be established and that the use of PRA technology in NRC regulatory activities should be increased. Comments from the ACRS regarding the policy statement as documented in a letter dated May 11, 1994, were incorporated. On August 19, 1994, the staff forwarded SECY–94–219, "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)," to the Commission. On August 30, 1994, the staff discussed the PRA policy statement and the PRA implementation plan in a public meeting with the Commission. On September 13 and October 4, 1994, the Secretary issued two staff requirements memoranda (SRMs) providing Commission guidance regarding the draft policy statement. In these SRMs, the Commission directed the staff to revise the proposed PRA policy statement, publish the policy statement for public comment in the **Federal Register**, and conduct a public workshop on the PRA implementation plan.

As directed by the Commission, the staff conducted a public workshop on December 2, 1994, to discuss the PRA implementation plan. The purpose of the workshop was to inform the public of NRC activities related to increasing the use of PRA methods and techniques in regulatory applications and to receive public comments on these activities. After the staff incorporated the comments from the SRMs, the proposed policy statement "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" was published in the **Federal Register** on December 8, 1994 (59 FR 63389). The public comment period expired on February 7, 1995.

II. Summary of Public Comments and NRC Responses

In January and February 1995, the NRC received 17 letters commenting on the proposed policy statement on "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities". These comments were from the following organizations: Six utilities—PECO Energy Company, Detroit Edison, Washington Public Power Supply System, Carolina Power and Light Company, Virginia Power Company, and Centerior Energy; three State regulatory agencies—State of Illinois Department of Nuclear Safety, State of New Jersey Department of Environmental Protection, State of Nevada Agency for Nuclear Projects; two industry groups—Nuclear Energy Institute and Westinghouse Owners Group; two engineering firms—PLG, Inc. and ICF Kaiser Engineers, Inc.; University of California at Los Angeles; Ohio Citizens For Responsible Energy; Winston and Strawn, Counsel to the Nuclear Utility Backfitting and Reform Group; and the Department of Energy. Copies of the letters may be examined at the NRC Public Document Room at 2120 L Street., NW. (Lower Level), Washington, DC.

General Comments

Twelve commenters explicitly supported the basic tenet of the policy to increase the use of PRA technology in NRC's regulatory activities. The other commenters did not object to the policy statement but provided recommendations for the NRC to modify and improve the policy statement and/or the PRA implementation plan. Five commenters indicated that they agreed with the NEI comments on the proposed PRA policy statement. The NRC staff has reviewed the comments and summarized them in the following areas. The staff response to the comments are also included in this final policy statement.

Use of PRA in Regulatory Decisions

Several comments dealt with the scope of the PRA applications (where can PRA be used) and the implementation of the policy statement (how can PRA be used).

One commenter felt that neither the policy statement nor the PRA implementation plan provided consistent decision criteria for accepting PRA results as part of the justification for licensing decisions. The commenter was concerned that the short term effect of the policy statement would likely be an increased burden on the licensees. For the long term, the commenter recommended a systematic review of the rules and regulations to identify opportunities for elimination of unnecessary regulations. The proposed policy statement directed the staff to use PRA and associated analyses, where appropriate, as part of the justification for licensing decisions. The PRA implementation plan describes how the stated policy is to be implemented. Appropriate decision criteria will be developed and documented as part of the PRA implementation plan. The Commission has already performed a systematic review of the many current rules and regulations to identify opportunities for the elimination of unnecessary regulations. In 1993, the NRC established the Regulatory Review Group (RRG) to conduct a structured review of power reactor regulations with special attention on the opportunity to reduce unnecessary regulatory burdens. The RRG recommendations to reduce the regulatory burden included the suggestion to use more risk-based approaches in quality assurance, inservice inspection and testing, and the concept of a PRA plan. The RRG recommendations were documented in SECY–94–003. To better focus the NRC's effort on the PRA related activities recommended by the RRG, the PRA Working Group, and the Regulatory Analysis Steering Group, the PRA implementation plan was developed in 1994. The implementation plan included a task to develop guidelines for determining when it is practical to use PRA technology and results in regulatory activities. The NRC has had discussions with volunteer licensees regarding the pilot applications of risk-based regulatory initiatives. Results from the pilot applications will be incorporated in the NRC's guidance for PRA applications in regulatory activities. A number of current regulatory requirements are being considered as part of the PRA implementation plan to determine if alternative risk-based approaches are practical. Over time, the Commission would expect some streamlining and refocusing of its rules and regulations as part of this process. The Commission has implemented a continuing regulatory improvement program which is responsive to the commenter's recommendation of a systematic examination of marginal regulatory requirements.

Another commenter recommended that the policy statement be amended to state that when backfitting analyses are performed, mean risk levels be the exclusive basis of regulatory decision-making when comparisons are made against the $1000/person-rem criterion. The Commission does not feel this policy statement needs to address the issue regarding the use of mean risk level as the exclusive basis for applying the $1000/person-rem criterion because the Commission's safety goal policy statement has already spoken to the use of mean values of risk in connection with the cost-benefit analyses. Furthermore, this issue is addressed in the proposed Revision 2 of NUREG/BR–0058, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission, Draft Report for Comment." This commenter also recommended that the policy statement should direct the staff to use the relevant plant specific PRA in assessing the need for any backfitting action at that plant. For generic backfits, this commenter recommended that the policy should allow licensees to take

credit for plant specific information to justify relief from NRC imposed action. The Commission believes that the use of the plant specific PRA in the backfit analysis to evaluate whether there is a substantial increase in the overall protection or to justify relief from NRC imposed action is acceptable when combined with other relevant deterministic considerations, as appropriate.

Regarding the use of safety goals, one commenter recommended retention of the language in SECY–94–218 to effect that safety goals could be used in granting relief from unnecessary requirements. Another commenter recommended that the safety goals should be used as a minimum goal, rather than the maximum level of safety. As stated in the proposed PRA policy statement published on December 8, 1994, the Commission's safety goals are "* * * intended to be generically applied by the NRC as opposed to plant specific applications," and "* * * to be used with appropriate consideration of uncertainties in making regulatory judgements in the context of backfitting new generic requirements on nuclear power plant licensees." In the Staff Requirement Memorandum (SRM) dated June 15, 1990, regarding the implementation of safety goals, the Commission directed that "Safety goals are to be used in a more generic sense and not to make specific licensing decisions." Therefore, at this time, the NRC would use the safety goals in making regulatory decisions regarding backfitting new generic requirements but not to make specific licensing decisions including granting relief from unnecessary requirements. Any changes to the safety goal policy are outside the scope of the PRA policy statement and would, therefore, need to be pursued independently.

Referring to paragraphs 1 and 2 of the proposed policy statement, a commenter suggested that it should include the application to NRC enforcement decisions, including the severity levels. As noted in NUREG–1525, "Assessment of the NRC Enforcement Program," the Commission does not support defining severity levels using PRA results. The NRC's basis for severity level categorization clearly is safety significance. In judging safety significance, the NRC considers (1) Actual consequences, (2) potential consequences, and (3) regulatory significance. It is recognized that PRA results may be helpful to provide risk insights on the likelihood and significance of potential consequences. The NRC plans to continue to consider the use of PRA results where relevant as part of the integrated process considering all facets surrounding the violation in support of enforcement decisions.

Several commenters discussed the role of PRA in reducing the unnecessary conservatisms in regulations and to support additional regulatory requirements. One commenter's concern was that the proposed policy statement appeared to be biased in the direction of using PRA to support deregulation. Another commenter was concerned with the implication that PRA could result in an additional layer of regulation. The policy statement addressed the need to remove unnecessary conservatism associated with regulatory requirements. It is not the Commission's intent to replace traditional defense-in-depth concepts with PRA, but rather to exploit the use of PRA insights to further understand the risk and improve risk-effective safety decision-making in regulatory matters. In doing so, the Commission is focusing its attention and resource allocation to areas of true safety significance. Where appropriate, PRA should be used to support additional regulatory requirements, according to 10 CFR 50.109 (Backfit Rule).

One commenter recommended that the policy statement should explicitly state that the use of PRA by licensees in regulatory matters is at the discretion of each licensee. The commenter also believed that the NRC should not prescribe how and when PRA methods should be used by licensees in regulatory matters, but should address the potential impact the expanded use of PRA may have on regulatory interactions with licensees. The Commission's PRA policy statement is intended only to encourage the NRC staff and industry to use probabilistic risk assessment methods in regulatory matters. It is not intended to prescribe or require any of the many potential PRA applications. Any requirements for licensees to perform PRA analyses would be expected to occur through formal rulemaking.

One commenter's concern was that there was a wide range of applications for which PRA was being applied without consistency and standards. This commenter urged the NRC to insist on quality PRAs commensurate with the intended applications and to develop standards which require rigorous and living PRAs by regulation for nuclear power plant applications. The commenter also questioned whether the PRA analyses for the IPE may be used for other applications because of a lack of PRA standards. Another commenter expressed the concern that strict conformance to detailed PRA standards would not be desirable, and recommended that flexibility in PRA models should be allowed. The Commission issued Generic Letter (GL) 88–20 with the primary purpose of generating IPEs to identify severe accident vulnerabilities. The PRAs which supported the IPE efforts may be useful for other applications, however, this would have to be evaluated on a case-by-case basis under well-defined objectives. After the Commission briefing on the IPE program, the Commission recognized, as stated in the SRM dated April 28, 1995, that current industry IPE results do not provide a complete basis for supporting risk-based regulatory decision-making. The SRM suggested that "* * * the industry should, in coordination with the staff, initiate the actions necessary to develop PRAs that are acceptable for risk-based regulatory use (i.e., standardized methods, assumptions, level of detail)." The industry is encouraged to formulate a general approach for performing PRAs acceptable for regulatory use. This approach should include guidance on standardizing approaches for use of PRA techniques for specific applications, narrowing some of the variability in the IPE results, and strengthening its usefulness in the regulatory and safety decision-making process. The Commission is currently considering the quality level and scope of assessment necessary to justify use of specific PRAs for specific regulatory applications. The Commission will require PRA quality commensurate with the proposed application.

PRA Methodology

One commenter agreed with the NRC that the probabilistic approach should be used to complement the deterministic approach and that PRA numbers alone should not be used to make regulatory decisions. The commenter also believed that uncertainties should not prevent or delay the implementation of PRA in regulatory activities. The Commission understands that uncertainties exist in any regulatory approach. These uncertainties are derived from knowledge limitations that are not created by PRA, but are often exposed by it. The PRA implementation plan has provided a framework to assess the significance of potential uncertainties and to develop a strategy to accommodate them in the regulatory process.

One commenter stated that probabilistic analysis is simply an extension of deterministic analysis. They are not separate and distinctive

concepts. The Commission agrees with this concept as the proposed policy statement stated that "The probabilistic approach to regulation is, therefore, considered an extension and enhancement of traditional regulation by considering risk in a more coherent and complete manner." The Commission believes that the PRA method plays a complementary role in relationship to the deterministic method. This was reflected in the policy statement that "Deterministic-based regulations have been successful in protecting the public health and safety and PRA techniques are most valuable when they serve to focus the traditional, deterministic-based, regulations and support the defense-in-depth philosophy."

One commenter recommended that the most efficient use of NRC resources should be to enhance or improve the existing methods, but not to develop new ones. The Commission's principal focus will be on improving the existing methods, but some new methods development may also be useful.

Another commenter recommended that the PRA policy statement should seek a uniform and standard application of PRA within the NRC, and begin with a commitment to ensure that PRA is used consistently and is not ignored when required by those unfamiliar or reluctant to apply it. The Commission's PRA policy statement specifically emphasizes the need for consistent and predictable application of PRA within the Commission to promote regulatory stability and efficiency. The Commission believes that this goal can be achieved through the implementation plan which will ensure that the appropriate use of PRA is implemented by the staff.

Schedule of PRA Activities

Two letters commented that the activities discussed in the PRA implementation plan appeared to be on a protracted schedule and recommended that priority and urgency be stressed and reflected in the plan, including the use of PRA and PRA insights in the near term. The Commission's PRA implementation plan showed the target completion dates for all the tasks. The Commission fully realizes the need for near term PRA applications and has included them in the implementation plan wherever possible. These milestones include examples such as pilot applications for risk-based initiatives and transfer of IPE insights to NRC staff members for use in regulatory matters in the near term. The Commission plans to periodically review the progress of the "living" PRA implementation plan and, as appropriate, to adjust the priorities.

One letter commented that the NRC review and approval of licensing actions that are based on PRA insights should not be contingent upon the schedule for implementation of the plan. The plan should not be an impediment to moving forward toward the goals outlined in the policy statement. The Commission's implementation plan had been developed to effectively and expeditiously establish a framework for increasing the use of PRA technology inside the Commission. Since it is a "living" plan, new tasks could be added and existing tasks could be modified, as the plan progresses. The Commission agrees that the plan should not be an impediment to moving forward to achieve the goals stated in the policy. The Commission welcomes risk-based regulatory initiatives from the industry as the plan is being carried out and will adjust resources, as appropriate.

One commenter asked how the NRC will propose to control the utilities' application of PRA and the timeframe to implement the consistent use of PRA within the NRC. The Commission's PRA implementation plan describes the activities and schedule to effect a coherent and consistent PRA application within the agency. As the plan is implemented, the NRC expects to interact with licensees and publish guidelines for the application of PRA in their submittal to the NRC.

PRA Training

Two commenters advocated PRA training for appropriate NRC and licensee staff as soon as possible to ensure proper application of PRA in regulatory matters. A PRA training program has been in place for the NRC staff for a number of years. As part of the PRA implementation plan, the existing training program is being enhanced. The existing PRA training curriculum serves as the basis on which to build a more comprehensive staff PRA training program. Six new courses have been incorporated in the training program to address the short term needs from the increasing use of PRA in regulatory activities. As a result of the PRA implementation plan, the number of NRC staff participating in the training program has increased significantly during the first half of fiscal year 1995.

One commenter recommended that NRC's PRA training should be extended to State agencies that can justify attendance. Historically, attendance at NRC courses has been routinely available on a space-available, no-cost basis to State personnel as well as for other non-NRC personnel (such as foreign regulators, EPA, DOE, and other Federal personnel). This has included training in the PRA area for a limited number of State regulators. In courses that were under-subscribed by NRC personnel, many had sufficient available space to allow acceptance of outside personnel. Logistics for these arrangements are handled by the NRC office responsible for interactions with the outside group (i.e., Office of State Programs for States or Office of International Programs for foreign personnel). NRC training currently is not available to NRC licensees. Because of recent budgetary constraints, as described in SECY-95-017 "Reinventing NRC Fee Policies," full cost reimbursements from States for NRC training is expected in future years. However, NRC will continue its space-available policy for all courses, including PRA courses.

Data Collection

Several commenters expressed concerns about the potential data collection implications of the proposed PRA policy. They are summarized as follows:

One commenter stated that the desire to collect detailed data related to equipment and human reliability should not prohibit the use of PRA for applications or support for decision-making. The collection of plant-specific data must be commensurate with the benefit that specific information might have on the quality or insight from the PRA. Plant-specific information may not be statistically significant. Furthermore, requiring all plants to collect the same information without a focus based on plant performance, is counter to the concept behind the Maintenance Rule.

Another commenter stated that the discussion of uncertainties in Part II.(B) of the proposed policy statement is appropriate. However, in the implementation of this part of the policy, care must be exercised to restrain from requiring or implying the need for massive plant-specific component level failure rate data collection programs. Several commenters expressed concerns that a new or expanded nuclear power plant experience data collection rulemaking could further burden the licensees and the resulting benefit may well be marginal.

The Commission agrees that it should make every effort to avoid any unnecessary regulatory burdens in connection with collecting reliability and availability data. Specific comments on the types of data that should or should not be collected will be addressed in connection with proposed

data collection requirements when they are published for comment.

Radiation Medicine

One commenter recommended that NRC should abandon the use of the linear hypothesis in estimating radiation-induced cancer and mutation risk. The commenter further stated that the NRC's PRA implementation plan refers to risk analysis to analyze nuclear medical devices and that, "* * * there are no nuclear medicine devices that have risk to be analyzed."

The International Commission on Radiation Protection, the United Nations Scientific Committee on the Effects of Atomic Radiation, and the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation believe that, in the absence of convincing evidence that there is a dose threshold or that low levels of radiation are beneficial, the assumptions regarding a linear nonthreshold dose-effect model for cancers and genetic effects and the existence of thresholds only for certain nonstochastic effects remain appropriate for formulating radiation protection standards. NRC follows their guidelines. Although some data suggest the possible use of other models, there are still many scientists who believe there are insufficient data to deviate from the "linear" hypothesis. The issue of realism involved in continuing the use of the "linear" hypothesis is expected to be a matter of debate over the coming years.

The NRC regulates radiation medicine, which includes both nuclear medicine and radiation oncology. The intent of the policy statement concerning medical applications is to refer to medical devices containing byproduct material, in particular, those used in radiation oncology. The term "nuclear medical device" was revised in the recent status update on the PRA implementation plan (SECY–95–079) and clarified in the policy statement.

Nuclear Waste

One commenter recommended that the NRC expand its use of PRA to other areas such as radiological dose assessment during the site decommissioning process. The NRC intends to consider expansion of PRA techniques into additional areas with the proviso that the application of these techniques to these facilities should be tempered according to the complexity of the disposal system, its uncertainties and the estimated risk.

One commenter provided comments on several aspects of the proposed policy statement in the nuclear waste area. Regarding the scope of the policy statement, the commenter recommended that the policy statement be amended to include risk assessment applications other than power reactors. The Commission agrees with that comment. The use of PRA should be considered for those applications that involve projecting system performance for very long time periods, such as hundreds or thousands of years. The policy statement stated that the use of PRA technology should be increased in all regulatory matters. Another recommendation was to temper the commitment to PRA to reflect inherent risk differences associated with different waste management facilities. Because of inherent differences in the regulations and practices associated with the licensing of waste management facilities, the application of performance assessment (PRA is called performance assessment for waste management systems) techniques to these facilities should be tempered according to the complexity of the disposal system, uncertainties surrounding the system performance, and the estimated risk. The Commission also agrees with the comments regarding uncertainties in projecting repository performance and the use of technical expert judgment in assessing these uncertainties, but feels the PRA policy statement is not the appropriate forum to discuss these items applicable only to waste management.

Regarding the suggestion of describing the reasons for using the PRA and the application of PRA in regulatory activities, the Commission included the reasons for using PRA in Section III of the policy statement and added a description of the impact of PRA on the rule changes to 10 CFR Part 100 in the background discussion.

Another commenter expressed concern that the proposed policy statement inappropriately encouraged the use of PRA in the licensing and regulation of nuclear waste disposal facilities. The Commission disagrees with this comment since PRA techniques are acceptable in a performance assessment for the geologic repository, but are only part of the requirements for a license. The commenter was also concerned that any new regulations proposed by the Environmental Protection Agency (EPA) and the NRC's 10 CFR Part 60 for a high-level waste (HLW) disposal facility proposed for Yucca Mountain will probably prohibit use of PRA for these facilities because of Type I faults at this site. The Commission anticipates that both probabilistic and deterministic hazard assessment methodologies will be applied to assess the significance of faulting at Yucca Mountain. Furthermore, the Commission does not interpret 10 CFR Part 60 so as to preclude the use of PRA as a basis for licensing a proposed repository at Yucca Mountain. The commenter did not agree with NRC's characterization of the waste disposal system as passive and believed that, at this time, there is no alternative to the use of deterministic techniques for waste disposal application because PRA techniques are in the embryonic stage. The "Fault Tree Handbook" (NUREG–0492, January 1981) refers to "passive" as a "* * * mechanism (e.g., wire) whereby the output of one 'active' component becomes the input to a second 'active' component." "Passive" is generally used for "engineered" components that have no moving parts. Since there are no "engineered" components that are "active" (or causing motion in another engineered component) in the post-closure phase of the potential geologic repository at Yucca Mountain, the NRC has applied the traditional PRA concept to the waste disposal system and referred to it as a "passive system." The remanded 1985 EPA Standard, 40 CFR 190, required a probabilistic analysis for a geologic repository. The NRC has developed this type of analysis since 1970 and has attained a state of maturity for these analyses that is accepted by internationally-known organizations (e.g., Organization for Economic Cooperation and Development (OECD)/ Nuclear Energy Agency (NEA)).

A number of editorial comments were received on the role of PRAs in the licensing of waste disposal facilities. The NRC has incorporated the appropriate comments in this final PRA policy statement.

III. Deterministic and Probabilistic Approaches to Regulation

(A) Extension und Enhancement of Traditional Regulation

The NRC established its regulatory requirements to ensure that a licensed facility is designed, constructed, and operated without undue risk to the health and safety of the public. These requirements are largely based on deterministic engineering criteria. Simply stated this deterministic approach establishes requirements for engineering margin and for quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist (e.g., equipment failures and human errors) and establishes a specific set of design-basis events. It then requires that the licensed facility design include safety systems capable of preventing and/or

mitigating the consequences of those design-basis events to protect the public health and safety.

The deterministic approach contains implied elements of probability (qualitative risk considerations), from the selection of accidents to be analyzed as design-basis accidents (e.g., reactor vessel rupture is considered too improbable to be included) to the requirements for emergency core cooling (e.g., safety train redundancy and protection against single failure). The approach by the Commission for the use of performance assessment to implement its regulations for disposal of radioactive nuclear waste (10 CFR Part 60 for high-level waste disposal and 10 CFR Part 61 for low-level waste disposal) also contains implied elements of probability. The results of the numerous calculations obtained from a performance assessment for a given performance measure and for a particular type of facility (e.g., a spectrum of values for ground-water travel time or individual dose) are expressed in terms of statistical distributions that express the probability that a given measure of performance will be attained. When this distribution is compared to the appropriate deterministic standard in the Commission's regulations, the probability of not exceeding the standard can be obtained from the part of the distribution that falls below this standard.

PRA addresses a broad spectrum of initiating events by assessing the event frequency. Mitigating system reliability is then assessed, including the potential for multiple and common cause failures. The treatment therefore goes beyond the single failure requirements in the deterministic approach. The probabilistic approach to regulation is, therefore, considered an extension and enhancement of traditional regulation by considering risk in a more coherent and complete manner. A natural result of the increased use of PRA methods and techniques would be the focusing of regulations on those items most important to safety. Where appropriate, PRA can be used to eliminate unnecessary conservatism and to support additional regulatory requirements. Deterministic-based regulations have been successful in protecting the public health and safety and PRA techniques are most valuable when they serve to focus the traditional, deterministic-based, regulations and support the defense-in-depth philosophy. In addition, PRA techniques are appropriately used when considering regulations defined in probabilistic terms, and for estimating safety of systems with very large uncertainties such as waste disposal systems (Note that PRA is called performance assessment for these waste disposal systems).

Beyond its deterministic criteria, the NRC has formulated guidance, as in the safety goal policy statement, that utilizes quantitative, probabilistic risk measures. The safety goal policy statement establishes top-level objectives to help assure safe operation of nuclear power plants. The safety goals are intended to be applied generically and are not for plant-specific applications. For the purpose of implementation of the safety goals, subsidiary numerical objectives on core damage frequency and containment performance have been established. The safety goals provide guidance on where plant risk is sufficiently low that further regulatory action is not necessary. Also, as noted above, the Commission has been using PRA in performing regulatory analysis for the proposed backfit of cost-beneficial safety improvements at operating reactors (as required by 10 CFR 50.109) for a number of years.

(B) Uncertainties and Limitations of Deterministic and Probabilistic Approaches

The treatment of uncertainties is an important issue for regulatory decisions. Uncertainties exist in any regulatory approach and these uncertainties are derived from knowledge limitations. These uncertainties and limitations existed during the development of deterministic regulations and attempts were made to accommodate these limitations by imposing prescriptive, and what was hoped to be, conservative regulatory requirements. A probabilistic approach has exposed some of these limitations and provided a framework to assess their significance and assist in developing a strategy to accommodate them in the regulatory process.

Human performance is an important consideration in both deterministic and probabilistic approaches. Assessing the influence of errors of commission and organizational and management issues on human reliability is an example that illustrates where current PRA methods are not fully developed. While this lack of knowledge contributes to the uncertainty in estimated risks, the PRA framework offers a powerful tool for logically and systematically evaluating the sensitivity and importance to risk of these uncertainties. Improved PRA techniques and models to address errors of commission and the influence of organizational factors on human reliability are currently being developed.

It is important to note that not all of the Commission's regulatory activities lend themselves to a risk analysis approach that utilizes fault tree methods. In general, a fault tree method is best suited for power reactor events that typically involve complex systems. Events associated with industrial and medical uses of nuclear materials generally involve a simple system, involve radiation overexposures, and result from human error, not equipment failure. Because of the characteristics of medical and industrial events, as discussed above, analysis of these events using relatively simple techniques can yield meaningful results. Power reactor events, however, generally involve complex systems and human interactions, can potentially involve more than one adverse consequence, and often result from equipment failures. Therefore, power reactor events can require greater use of more complex risk analysis techniques, such as fault tree analysis, to yield meaningful insights. PRA methods need to be adapted for waste disposal systems because they are passive systems subjected to interlocking natural and man-made processes and events that are dominated by complex phenomenology.

Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decision-making.

(C) Defense-in-Depth Philosophy

In the defense-in-depth philosophy, the Commission recognizes that complete reliance for safety cannot be placed on any single element of the design, maintenance, or operation of a nuclear power plant. Thus, the expanded use of PRA technology will continue to support the NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements applicable to the nuclear industry. Defense-in-depth is a philosophy used by NRC to provide redundancy for facilities with "active" safety systems, e.g., a commercial nuclear power, as well as the philosophy of a multiple-barrier approach against fission product

releases. Such barrier principles are mandated by the Nuclear Waste Policy Act of 1982, which provides redundancy for a geologic repository to contain and isolate nuclear waste from the human environment.

IV. The Commission Policy

Although PRA methods and information have thus far been used successfully in nuclear regulatory activities, there have been concerns that PRA methods are not consistently applied throughout the agency, that sufficient agency PRA/statistics expertise is not available, and that the Commission is not deriving full benefit from the large agency and industry investment in the developed risk assessment methods. Therefore, the Commission believes that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency. This policy statement sets forth the Commission's intention to encourage the use of PRA and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the-art in terms of methods and data. Implementation of the policy statement will improve the regulatory process in three areas: Foremost, through safety decision making enhanced by the use of PRA insights; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees.

Therefore, the Commission adopts the following policy statement regarding the expanded NRC use of PRA:

(1) The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

(2) PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal for additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

(3) PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

(4) The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

Policy Implications

There are several important regulatory or resource implications that follow from the goal of increased use of PRA techniques in regulatory activities. First, the NRC staff, licensees, license applicants, and Commission must be prepared to consider changes to regulations, to guidance documents, to the licensing process, and to the inspection program. Second, the NRC staff and Commission must be committed to a shift in the application of resources over a period of time based on risk findings. Third, the NRC staff must undertake a training and development program, which may include recruiting personnel with PRA experience, to significantly enhance the PRA expertise necessary to implement these goals. Additionally, the NRC staff must continue to develop new and improved PRA methods and regulatory decision-making tools and must significantly enhance the collection of equipment and human reliability data for all of the agency's risk assessment applications, including those associated with the use, transportation, and storage of nuclear materials. However, it is recognized that there may be situations with material users where it may not be cost-effective to use PRA in their specific regulatory applications.

This policy statement affirms the Commission's belief that PRA methods can be used to derive valuable insights, perspective, and general conclusions as a result of an integrated and comprehensive examination of the design of nuclear facilities, facility response to initiating events, the expected interactions among facility structures, systems, and components, and between the facility and its operating staff.

The Commission also recognizes, and encourages, continuation of industry initiatives to improve PRA methods, applications and data collection to support increased use of PRA techniques in regulatory activities.

V. Availability of Documents

Copies of documents cited in this section are available for inspection and/or for reproduction for a fee in the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington, DC 20037. Copies of NUREGs cited in this document may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013–7082. Copies are also available for purchase from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

In addition, copies of (1) SECY–94–218, "Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," (2) SECY–94–219, "Proposed Agency-Wide Implementation Plan for Probabilistic Risk Assessment (PRA)," (3) the Commission's Staff Requirements Memorandum of September 13, 1994, concerning the August 30, 1994, Commission meeting on SECY–94–218 and SECY–94–219, and (4) the Commission's Staff Requirements Memorandum of October 4, 1994, on SECY–94–218 can be obtained electronically by accessing the NRC electronic bulletin board system (BBS) Tech Specs Plus. These four WordPerfect® 5.1 documents are located in the BBS MISC library directory under the single filename "PRAPLAN.ZIP". The WordPerfect® 5.1 file for the final policy statement on the "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," is located in the BBS MISC library directory under the filename "PRPOLICY.ZIP". The BBS operates 24 hours a day and can be accessed through a toll-free number, 1–800–679–5784, at modem speeds up to 9600 baud with communication parameters set at 8 data bits, no parity, 1 stop bit, full duplex, and using ANSI terminal emulation.

Dated at Rockville, Maryland, this 10th day of August, 1995.

For the Nuclear Regulatory Commission.

Andrew L. Bates,

Acting Secretary of the Commission.