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Institutional Implications of Establishing Safety Goals for Nuclear Power Plants

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FOREWORD

The analysis contained in this report was based on the NRC Policy Statement on Safety Goals for Nuclear Power Plants as originally proposed on February 17, 1982 (44Fed.Reg.7073). The final version of the Policy Statement, issued on March 14,1983 (48 Fed.Reg.10772), and the accompanying evaluation plan, were not included in the analysis contained herein.

ABSTRACT

The purpose of this project is to anticipate and address institutional problems that may arise from the adoption of NRC's proposed Policy Statement on Safety Goals for Nuclear Power Plants. The report emphasizes one particular category of institutional problems: the possible use of safety goals as a basis for legal challenges to NRC actions, and the resolution of such challenges by the courts.

Three types of legal issues are identified and analyzed. These are, first, general legal issues such as access to the legal system, burden of proof, and standard of proof. Second is the particular formulation of goals. Involved here are such questions as sustainable rationale, definitions, avoided issues, vagueness of time and space details, and degree of conservatism. Implementation brings up the third set of issues which include interpretation and application, linkage to probabilistic risk assessment, consequences as compared to events, and the use of results.

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EXECUTIVE SUMMARY

The purpose of this report is to anticipate and address institutional problems that may arise from the adoption of NRC's proposed Policy Statement on Safety Goals for Nuclear Power Plants. The report emphasizes one particular category of institutional problems: the possible use of safety goals as a basis for legal challenges to NRC actions, and the resolution of such challenges by the courts.

The report is organized as follows. Chapter 1 is an introduction. Chapter 2 briefly describes the current nuclear regulatory process, with particular attention to regulatory practices aimed at preventing nuclear plant accidents. Chapter 3 then describes NRC's safety goals and numerical guidelines, and their potential role in the nuclear regulatory process. Chapter 4 analyzes legal issues in safety goal implementation. Chapter 5 describes an alternative approach to the application of safety goals, based on the FAA experience with certification of commercial aircraft. Chapter 6 states general conclusions and possible recommendations for NRC action.

CURRENT REGULATORY FRAMEWORK

The current framework for nuclear safety regulation can be divided into five elements. The first element is NRC's safety philosophy, consisting of the principles governing acceptable risk and the role of safety cost tradeoffs in regulation. Perhaps because the Atomic Energy Act provides very little guidance on this score, with the exception of ALARA for routine emissions the Commission has never stated the principles governing what constitutes "adequate protection to the public health and safety." The second element involves the ways in which achievement of acceptable risk and cost effective safety steps are measured. For many years, NRC's general measure of safety has been no credible possibility of an accident that would release significant quantities of fission products. The third element is NRC approach to establishing general regulations governing nuclear reactor safety. Essentially, NRC's approach rests on promulgation of design and siting criteria, including pressure vessel standards, design objectives and guidance for meeting ALARA, seismic standards, ECCS criteria, and quality assurance standards. The fourth element concerns the application of such rules to licensing. Licensing decisions are mainly based on staff review involving ad hoc, subjective tradeoffs, using the applicant's accident analysis. The fifth element is backfitting, the imposition of new requirements on existing plants. At present, the basis for imposing backfits is primarily staff and Commission judgment in response to new information.

ROLE OF SAFETY GOALS

As contemplated in the proposed policy statement and the NRC staff's Action Plan to implement it, safety goals would fit within the current regulatory framework, and to some extent modify it. Qualitative safety goals would

provide an explicit statement of the Commission's safety philosophy: that no individual should bear a significant risk to life and health as a result of a possible nuclear power plant accident, and that societal risks to life and health from nuclear power plant accidents should be as low as reasonably achievable and comparable to or less than the risks of generating electricity by viable competing technologies. Provisional numerical guidelines would provide measures for achievement of the qualitative goals. The first two guidelines concern individual and societal mortality risks. According to the first, the risk of prompt fatality to an individual of the local population resulting from reactor accidents should not exceed 0.1% of the sum of prompt fatality risks resulting from all other accidents. According to the second guideline, the risk of cancer fatalities to an individual or a local population resulting from nuclear accident should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes. The third guideline concerns benefit-cost comparisons. It provides that the benefit of incremental risk reduction below the guidelines for societal mortality risks should be valued at \$1,000 per person-rem averted. The fourth performance guideline provides that the probability of an accident resulting in a large-scale core melt should be less than 10^{-4} per year of reactor operation.

Under present plans, the qualitative safety goals and provisional numerical guidelines would be used to assess the adequacy of existing regulations. However, they would not themselves become surrogates for design and siting criteria otherwise established by regulation. Licensing decisions would continue to be based on Commission regulations. The issuance of construction permits and operating licenses would not be conditioned on demonstrated compliance with numerical guidelines. However, the numerical guidelines in conjunction with PRAs may be used to provide a "perspective" for possible improvement in case work reviews, where a PRA clearly demonstrates a potential need for additional safety measures. Finally, the numerical benefit-cost guideline applied in conjunction with plant-specific PRAs may be used as at least a consideration in assessing the need to backfit new safety requirements.

LEGAL ISSUES

Three types of legal issues could arise in implementation of safety goals. First are those issues stemming from NRC's adoption of any general scheme of safety goals and numerical guidelines, to be verified by some analytic methodology such as probabilistic risk assessment. Second are those issues arising from the particular formulation of goals and guidelines set forth in the proposed policy statement. Third are those issues involving the particular plan for implementation that NRC has tentatively developed.

General Legal Issues

General legal issues have to do with access to the legal system, burden of proof, standard of proof, and an analogy between safety goals and NEPA.

Access to the legal system. To mount a legal challenge, a party must first gain access to the legal system, either to administrative proceedings or to judicial review. In general, both the APA and the Atomic Energy Act grant interested parties broad rights of participation in nuclear regulatory decisionmaking. Means of access include the right to intervene in administrative proceedings, the right to compel administrative proceedings, and the right to obtain judicial review of agency action. Although in principle NRC's Rules of Practice require interested parties to meet certain preconditions in order to exercise these rights, in practice reviewing courts, the commission, the Atomic Safety and Licensing Appeal Board, and individual licensing boards have made such requirements easy to meet. As a result, parties desiring to place safety goals at issue should have little trouble at least receiving a hearing.

NRC's procedural rules as applied in practice provide significant opportunity for parties desiring to place safety goals and PRAs at issue in NRC proceedings. To keep the introduction of PRA-related issues within reasonable bounds, NRC may wish to develop guidance on these matters.

Burden of proof. Burden of proof allocates both the responsibility for producing evidence and the responsibility for convincing the finder of fact as to the truth of key issues. In a construction permit or operating license proceeding, the license applicant must produce evidence showing that it is entitled to the license; anyone opposing the license must produce evidence at least "sufficient to require reasonable minds to inquire further;" and the license applicant must prove its entitlement to the license by showing that the facility complies with all applicable NRC requirements and by rebutting staff or intervenor evidence to the contrary. In a proceeding to modify, suspend, or revoke a license, NRC staff or an interested party would first have to make out a prima facie case. Then the licensee would have the burden of persuading NRC that license suspension, modification, or revocation were inappropriate. Safety goals could afford an opportunity for interested parties to exploit these rules. For example, in a construction permit or operating license proceeding, intervenors could produce rather minimal evidence (such as a cursory PRA) purporting to show that the plant would not comply with goals or guidelines. If such evidence cast sufficient doubt on the plant's safety to require reasonable minds to inquire further, the license applicant might then have to conduct a PRA to rebut the evidence and thereby demonstrate the plant's safety. To avoid unnecessary and protracted exercises along these lines, NRC may wish to consider setting more explicit standards for the evidence that would establish a prima facie case in this context.

Standard of proof. While burden of proof refers to who is responsible for producing relevant facts, standard of proof refers to what level of certainty is required. The standard of proof for NRC licensing boards is "preponderance of the evidence," meaning the board must decide according to which version of the facts is more probable than not. Because applicants or licensees have the burden of persuasion, it is they who must meet this standard of proof. If the applicant or licensee is in the posture of using probabilistic risk assessment to demonstrate compliance with the numerical guidelines, this standard could be difficult to meet because of the inherent uncertainty of PRA results.

NEPA analogy. In some respects, issuance of the policy statement on safety goals may be analogous to the enactment of NEPA. Just as NEPA introduced a new analytic procedure to government (the environmental impact statement), so does the policy statement (probabilistic risk assessment). Just as NEPA specified new decision criteria (environmental considerations), so does the policy statement (safety goals and guidelines). One may therefore expect intervenor groups and disgruntled utilities to compel NRC and/or the utilities to do PRAs (just as they seek to compel EISs). They may also challenge the adequacy of PRAs that have been done (just as they challenge the adequacy of EISs). And they may argue that particular PRAs have been wrongly interpreted in light of the goals and guidelines (just as they challenge NEPA decisions for failure to give enough weight to environmental values). NRC may be able to make this process go more smoothly by developing its own guidance as to when PRAs must be done and what constitutes an adequate PRA.

Issues Arising from the Proposed Policy Statement

A number of specific legal issues could arise, whether in a proceeding challenging the policy statement itself or (more likely) in the context of a rulemaking or licensing proceeding. Most involve NRC's failure to explain or justify certain aspects of the goals and guidelines. While many of these issues are at least partially addressed by OPE's discussion paper, it would seem preferable to address these issues expressly in any final policy statement, or at a minimum, to be prepared to address them in any subsequent regulatory action based on the goals and guidelines.

Rationales needed. Prevailing standards of judicial review require that regulatory decisions be based on a sustainable rationale. Future regulations or licensing decisions based on the goals and guidelines may be found defective if the goals and guidelines themselves lack an identifiable rationale, as expressed either in a final policy statement or in the record of the regulatory decision. Several particular guidelines could benefit from more careful justification. These include the 0.1% incremental risk level in the first numerical guideline, the \$1,000 per person-rem averted in the second numerical guideline, the 10^{-4} per reactor year probability of large-scale core melt in the third numerical guideline, and the overall limitation of goals and guidelines to nuclear power plant accident risks. NRC should consider providing rationales for these choices either in any final policy statement or in subsequent regulatory decisions based on the goals and guidelines.

Definitions needed. Another weakness in the policy statement arises from its failure to define key terms. Definitional problems include ambiguity about measurement of the \$1,000, vagueness about the distinction between individual and societal risks, uncertainty about the meaning of "large-scale core melt," and ambiguity about the distinction between maximum total risk and maximum incremental risk. NRC should consider providing definitions of key terms in any final policy statement.

Issues avoided. The policy statement also avoids discussing several difficult issues. Under prevailing standards of judicial review for both rulemaking and licensing, NRC must state its assumptions and explain why it

has rejected alternative theories or courses of action. Therefore, if the goals and guidelines are used as a basis for rulemaking or licensing decisions, these issues will need to be addressed. Problems of this sort include the following. First, NRC does not describe the current risks from nuclear power plant accidents and from non-nuclear sources. Second, the policy statement does not establish a clear relationship between the qualitative goals and the second numerical guidelines (ALARA and benefit-cost value). Third, the policy statement does not discuss the advantages and disadvantages of the proposed approach compared with alternative regulatory strategies. Fourth, the policy statement does not specify the "utility function" embedded in NRC's safety philosophy. Fifth, the policy statement does not acknowledge the primitive state of probabilistic risk assessment and the high degree of uncertainty attached to the results. NRC need not address these issues definitively, but they should be acknowledged. A frank admission of uncertainties and imponderables, with a reasonable explanation of how NRC has chosen to resolve them, would help insulate the policy statement and subsequent regulatory actions from legal challenge.

Variations in time and space unspecified. Application of the goals and guidelines depends on a variety of facts external to the policy statement, such as background risk, the risks of other electricity-generating technologies, demographic conditions, the number of power reactors operating, and the geographic distribution of all of the above. These factual conditions are apt to vary from place to place and over time. Unless principles are established for addressing these variations, application is apt to be extremely difficult. NRC may find any regulations based on the goals and guidelines remanded for vagueness or it may discover that the courts or other bodies themselves supply such principles if the Commission has not itself done so.

Excess conservatism. Some of the goals and guidelines could also be challenged by utility or other groups on the grounds that they go beyond NRC's statutory mandate to protect the public health and safety. Examples include the second qualitative goal's requirement that risks from nuclear power plant accidents be comparable to or less than the risks from the operation of competing electricity-generating technologies, the \$1,000 per person-rem value for ALARA, and the first numerical guideline's requirement that reactor accident risks be no greater than 0.1% of the risks from all other accidents. NRC could defend such conservatism by expressly stating in any final policy statement or subsequent regulatory decisions that it is intended to balance the high uncertainty surrounding low-probability, high-consequence catastrophic accidents. In general, the courts will defer to the agency in determining the appropriate level of conservatism, provided the agency explains its choice and the choice is not irrational.

Insufficient conservatism. Others may challenge the policy statement or regulatory actions based on it as insufficiently conservative. For example, the large-scale core melt guideline could be considered too lenient if read to refer only to fatality-causing core melts involving large-scale fuel melting and large, uncontrolled releases of radioactivity. The need for NRC to anticipate and address charges of insufficient conservatism by express justification

is even more urgent than the need to justify extreme conservatism. While the federal courts have granted regulatory agencies substantial leeway to assess risks, they have also stressed the need to act with extreme caution in the face of high uncertainty and potentially disastrous consequences.

Issues of Implementation

A third set of issues arises from implementation. In the proposed policy statement, NRC is appropriately cautious about the ease of verifying compliance to goals and guidelines through PRA. However, implementation depends as much on how staff, licensing boards, utilities, and others respond as it does on NRC's initiative. To the extent there is disagreement or confusion, the courts could play at least some role in their resolution.

Interpretation and application. Two sources of legal issues complicate the implementation of almost any regulatory policy: interpretation and application. For example, as background for preparing the Action Plan to implement the policy statement, NRC staff have developed what they call "assumptions" about the statement. These assumptions may well be the most reasonable extrapolations from the text of the statement, but nonetheless they may be brought into question. Problems of interpretation are almost always accompanied by problems of application. The Commission itself, and the staff discussions, have suggested a number of limitations on the application of the proposed statement. However, these decisions are similarly subject to debate.

Linkage to PRA. No matter how careful the Commission, NRC staff, and others are on the point, it will be difficult to keep the policy statement and PRA separate. Many experts believe that PRA is most useful for such purposes as the identification of fault sequences and areas for concern. They consider PRA much less useful for developing bottom-line estimates of risk. However, the process of implementation itself will create very powerful pressures to concentrate on the bottom line. As a result, uncertainties inherent in PRA results may mean that the party with the burden of proof frequently loses.

Consequences versus events. The policy statement more often speaks in terms of consequence than in terms of events. This focus broadens the environment that NRC and parties involved with it must examine. Contrast the "harm to individuals" section of the policy statement with the "core melt" section. The second clearly involves a subject matter in which NRC is presumed to be expert. Harm to individuals, particularly when expressed in relative terms, shifts the debate more widely. For instance, will licensing boards eventually have to hear evidence on the background risks of cancer?

Use of results. In the meantime, the policy statement creates the possibility that PRAs done for purposes other than licensing and regulation may give rise to a variety of legal challenges. For example, if PRAs seem to demonstrate that existing regulations are more stringent than the goals or guidelines require, utilities or others in the nuclear industry may challenge regulations on that basis. Similarly, if PRAs seem to show that existing regulations are less stringent than the goals and guidelines require, they may

be subject to challenge by environmental interest groups. Analogous problems could arise at the level of an individual plant.

THE FAA EXPERIENCE

In addressing implementation issues, NRC may wish to consider the experience of other agencies. By far the closest analogy is the approach taken by the Federal Aviation Administration to the certification of new transport aircraft. While FAA's mission and activities differ in some respects from those of NRC, both regulate the safety of a complex technological system with the potential for catastrophic accidents. Equally important, FAA has actually adopted and applied a system of qualitative safety goals and numerical guidelines for use in transport aircraft certification. FAA's safety goals call for certain system performance failures to be either improbable or extremely improbable. FAA's numerical guidelines then define improbable to mean a frequency of occurrence in the range from approximately 1×10^{-5} to 1×10^{-9} per hour of flight time. Improbable events are not expected to occur during the total operational life of a single airplane of a particular type, but are expected to occur during the total operational life of all airplanes of a particular type. FAA's guidelines define extremely improbable to be a frequency of occurrence on the order of 1×10^{-9} or less per hour of flight. Extremely improbable events are so unlikely that for purposes of analysis they need not be considered, unless engineering judgment would require their consideration.

Thus the most striking difference between FAA and NRC safety goals is that the FAA goals focus on the performance of the system (i.e., the airplane) while the NRC goal focuses on the incremental risks to individuals and society as a result of living near a nuclear power plant. Clearly, a safety goal that addresses the performance of the system directly will pose fewer legal problems than a safety goal that addresses system performance indirectly through the potential consequences of system failure—for example, by eliminating the evidentiary problems posed by the necessity of estimating cancer risks.

CONCLUSIONS AND RECOMMENDATIONS

The overall conclusion of this report is that adoption of safety goals provide some opportunity for legal challenges. While these problems are not inevitable, and if they do arise are not likely to be insurmountable, NRC can take some steps to reduce their severity.

Legal rules concerning access to the legal system, burden of proof, standard of proof, and licensing board autonomy all provide intervenors with opportunities to exploit safety goals for their own purposes. To keep these opportunities within reasonable bounds, NRC should consider providing clear direction on the conduct and use of PRAs within the safety goal regime so that courts, licensing boards, and others will not make these decisions for themselves. Useful guidance could be supplied as to when PRAs must be done, when they may not be done, and when their use is discretionary. Guidance could also be provided as to how PRAs should be done and how the results should be interpreted.

In general, the policy statement itself is too elliptical. Legal controversy could be avoided by drafting a policy statement so that necessary rationales are supplied, definitions provided, and issues discussed. In addition, discussion could be added that explicitly justifies the level of safety provided by the goals and guidelines. Again, such discussion could help insulate the policy statement and regulatory actions based on it from legal challenge.

Finally, the safety goals' emphasis on risk to populations seems likely to make implementation particularly difficult. NRC could at least consider reformulation of the goals and guidelines to correspond to the FAA approach, which emphasizes limiting the probability of system performance failures, rather than limiting incremental risks.

1.0 INTRODUCTION

The purpose of this report is to anticipate and address institutional problems that may arise in the implementation of NRC safety goals. The report emphasizes one particular category of institutional problems: the possible use of safety goals as a basis for legal challenges to NRC actions, and the resolution of such challenges by the courts.

Safety goals and numerical guidelines express the interest of NRC, the nuclear industry, and others in developing an explicit and operational philosophy for nuclear power plant regulation and licensing.¹ This interest reached a critical juncture with publication for public comment of NRC's proposed policy statement on the subject in February, 1982.² Under the proposed policy, the Commission would adopt the following qualitative safety goals:

- Individual protection from nuclear power plant accidents such that no individual bears a significant additional risk to life and health
- Societal risks to life and health from nuclear power plant accidents that are as low as reasonably achievable and no greater than the risks from generating electricity by viable competing technologies³.

These goals would then be supported by provisional numerical guidelines:

- Individual or population risk of prompt fatalities from reactor accidents not more than 0.1% of the sum of prompt fatality risks from other accidents from which members of the U.S. population are generally exposed
- Individual or population risk of cancer fatalities from reactor accidents not more than 0.1% of the sum of cancer fatality risks from all other causes
- Benefit of incremental societal mortality risk reduction below numerical guidelines to be compared with associated costs on the basis of \$1,000 per man rem averted
- Less than 10^{-4} probability of large scale core melt per year of reactor operation⁴.

At present, the Commission does not plan to substitute the goals and guidelines for its regulations in 10 CFR Chapter 1. Rather, the goals and guidelines would be used by NRC staff in conjunction with probabilistic risk assessments (PRAs) as an aid to professional judgment, pursuant to an implementation plan now being developed.

Of course, the use of explicit safety goals could be taken further. The Atomic Industrial Forum's subcommittee on probabilistic risk assessment has proposed qualitative criteria and quantitative goals similar to the

Commission's goals and guidelines. The AIF subcommittee then goes on to suggest use of PRAs in examining present regulations to determine whether they meet or exceed quantitative safety goals. If so, licensees and license applicants that comply with these requirements would be presumed to meet safety goals. A licensee that did not meet the regulatory requirements could still demonstrate compliance with safety goals through performance of a plant specific PRA. In the longer term, the PRAs could be used to revise NRC regulations. And in proposing plant modifications, licensees would have the choice of complying with the regulations or using a PRA to demonstrate compliance with the safety goals.⁵

Whether in the NRC or AIF versions, such approaches to nuclear power plant regulation have undeniable attractions. In particular, they could encourage greater innovation in achieving power plant safety, while permitting more cost effective achievement of given levels of safety.⁶ They could also contribute to the integrity of the nuclear regulatory process by more clearly communicating to the public and industry the level of risks inherent in power plant operations and the basis of regulatory standards.⁷ Moreover, PRAs have additional value. They foster more systematic analysis of possible accident scenarios; they develop a basis for improving reactor operator qualification procedures; and they provide better data to use in establishing responses to reactor emergencies.

Nonetheless, a variety of factors could complicate the establishment and use of explicit safety goals.

First, while much progress has been made in the development of risk assessment methodology, the techniques are still young and subject to differing interpretations. Inherent limitations of PRAs include the lack of credibility in point estimates of risk, the limited data base available, the extreme uncertainty surrounding many estimates of probabilities and consequences, the difficulty of quantifying common cause failures, the difficulty of quantifying human adaptability during the course of an accident, and the conceptual impossibility of being mathematically complete in the construction of event trees and fault trees.⁸

Second, institutional factors may further complicate the implementation of safety goals. Nuclear power is heavily politicized. Critics of the industry and Commission may be expected to seize on any missteps in the adoption and implementation of safety goals as evidence of retreat from commitment to reactor safety.⁹ In addition, the complex analysis that makes up the PRA is inaccessible to the non-specialist.¹⁰ The "inscrutability," of PRA methodology places a heavy burden even on reviewing courts that limit their review to procedural regularity, and instill even greater burdens on those who seek to delve into substantive adequacy.¹¹ The lay public seems most likely to ignore the analysis altogether and concentrate on the bottom line estimates of risks that PRAs produce. This attention could stir political controversy, since there is great public ambivalence about acceptable risk. As Donald Kennedy has observed, "one does not resolve such doubts merely by stating the risks more precisely."¹² To the contrary, stating risks more precisely may serve to exacerbate such doubts. Indeed, there is some indication NRC's proposed policy

statement has already done so.¹³ PRAs are also likely to lay bare large bands of uncertainty. In the face of such explicit uncertainty, regulators and politicians are often tempted to defer decisions, pending better information that may never come.¹⁴

In the past, administrative and legal proceedings have been a central forum for the resolution of institutional issues surrounding nuclear energy regulation. Whatever doubts or disagreements about safety goals and their application arise seem likely to find their way into NRC's formal deliberations and the courts. Hence the emphasis of this report.

The analysis proceeds as follows. Following this introduction, Chapter 2 briefly describes the current nuclear regulatory process, with particular attention to regulatory practices aimed at prevented nuclear plant accidents. Chapter 3 then describes NRC's safety goals and numerical guidelines, and their role in the nuclear regulatory process, as contemplated in the NRC staff's Action Plan to Implement the Commission's Draft Safety Goal Policy Statement. Chapter 4 analyzes legal issues in safety goal implementation. Chapter 5 describes an alternative approach to the application of safety goals, based on the FAA experience with certification of commercial aircraft. Chapter 6 states general conclusions and possible recommendations for NRC action.

2.0 CURRENT FRAMEWORK FOR NUCLEAR SAFETY REGULATION

The current framework for nuclear safety regulation can be divided into five elements. The first is NRC's safety philosophy, the principles governing acceptable risk and the role of safety cost tradeoffs in regulation. The second element consists of how this philosophy is operationalized—that is, the ways in which achievement of acceptable risk and cost effective safety steps are measured. The third element is the process for establishing regulations, the basis of generalized rules governing nuclear reactor safety. The fourth element is the process for licensing, the application of general rules to the issuance of construction permits and operating licenses. The fifth element is backfitting, the process for imposing new requirements on existing plants, either through regulation or the suspension, revocation, or modification of existing licenses.

2.1 SAFETY PHILOSOPHY

In passing the Atomic Energy Act of 1946, Congress gave little attention to the acceptable level of risk and the role of safety cost tradeoffs in the management of nuclear energy. The Atomic Energy Act of 1954, which as amended still is the basis of the present regulatory framework, did not go much further. The Act contains such vague formulations as "no undue risk," and "adequate protection to the public health and safety." As a consequence, AEC was essentially left to develop its own safety philosophy. For many years, this task was not a central concern issue at AEC or its regulatory successor, NRC. However, in the early 1970s, the Commission began to place increasing emphasis on the concept of a comparative risk.¹⁵ However, with one exception this emphasis was not formalized. In 1971, the Commission announced the ALAP ("As Low As Practicable") principle for routine emissions. Under this principle, whose name was changed to ALARA ("As Low As Reasonably Achievable") in 1979, licensees are to make routine emissions "as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest."¹⁶ With the exception of ALARA for routine emissions, the Commission has never enunciated an explicit safety philosophy as to what constitutes "adequate protection to the public health and safety."

2.2 OPERATIONAL MEASURE

The operational measure for adequate protection has been only slightly more specific. For many years, the main general measure of safety has been no credible possibility of an accident that would release significant quantities of fission products—i.e., quantities beyond 10 CFR Part 20 limits.¹⁷ Known as the design basis accident approach, this measure is sometimes formulated as a requirement that the reactor design should withstand the maximum credible accident without release.¹⁸ For example, 10 CFR Part 50, Appendix A, Criterion 50 requires that containment be so designed to accommodate any loss of cooling accident without radiation leakage.

Rarely has a number been officially attached to the achievement of safety, although there have been at least two instances. One was an informal 1×10^{-7} probability of major accidents, stated by Commission officials in the early 1970s.¹⁹ The other has been use of the value \$1,000 per person-rem averted in the application of the ALAP/ALARA criterion.²⁰ This value is expressly made an "interim measure" pending establishment of better values or other appropriate criteria.²¹

2.3 REGULATIONS

In principle, the Commission could issue regulations establishing design and siting criteria that license applicants could use in designing their facilities to demonstrate adequate protection of the public health and safety. However, for a long period there was little systematic knowledge on which to base design and siting criteria.²² As one observer put it in 1958, "Nobody knows enough about the hazards to lay down reliable safety criteria. The Commission and the industry must feel their way."²³ More succinctly, "asking for design standards was asking the impossible."²⁴ Accordingly, throughout the 1950s, such criteria were very general, calling simply for remote siting and the use of containment.²⁵ In response to pleas for more explicit standards the Commission did establish some very general criteria in the 1960s.²⁶ Maturing technology, safety-oriented research, and various attempts to quantify risks including those contained in WASH-740 (1957), WASH-1250 (1973), WASH-1400 (1974), and NUREG/CR-0400 (1978) gradually improved the information base. As a result, more explicit design and siting criteria were established by regulation. These included pressure vessel standards, design objectives and guidance for meeting ALAP (1970, 1975), seismic standards (1973), ECCS criteria (1973), and quality assurance standards. Still, the Commission has been reluctant to base these regulations explicitly on the quantification of risks undertaken in WASH-1400 and similar reports. At present, the use of PRAs in regulation is essentially limited to "better understand the relative importance of various generic safety issues and proposed new requirements."²⁷

2.4 LICENSING

NRC's siting and design criteria are general. They essentially set forth "principal areas of consideration" for NRC staff in reviewing license applications, rather than establishing a formula that can be applied mechanically.²⁸ The staff review necessarily entails a process of ad hoc, subjective tradeoffs, based on the applicant's accident analysis.²⁹ Formally, this review is grounded on the design basis accident concept, mentioned above. A design is acceptable if it mitigates a group of postulated accidents.³⁰ This review focuses primarily on systems and equipment that are classified as "safety related." It employs the "single failure criterion," according to which a system or piece of equipment is judged safe if it is able to perform its mission despite the failure of a component within the system or a failure in an associated system.³¹ Particular emphasis is placed on "large scale" failures. The entire process relies heavily on engineering judgment, with limited use of PRAs. At present NRC requires that environmental impact statements prepared in connection with nuclear power plant licensing "shall include a reasoned

consideration of the environmental risks (impacts) attributable to accidents at the particular facility or facilities within the scope of each such statement."³² Otherwise, PRAs are only required for a few licensees and applicants at high population sites, except for post-construction permit PRAs relating to core containment heat removal systems and the post-operating license PRAs required as part of NREP.³³ In short, the review process for construction permits and operating licenses is based on conservative engineering judgment, with only implicit consideration of failure likelihoods.³⁴

2.5 BACKFITTING

NRC recognizes that new information about safety, such as that pertaining to risks, or the costs or benefits of risk reduction, may require modification in nuclear reactor design or the addition or deletion of specific items of equipment or systems, after a construction permit has been issued. Accordingly, NRC reserves the right to require backfitting, either by regulation or by modification, suspension, or revocation of a construction permit or operating license, "if it finds that such action will provide substantial, additional protection which is required for the public health and safety or the common defense and security."³⁵ At present the basis for imposing backfits is essentially staff and Commission judgment in response to new information.

3.0 SAFETY GOALS AND THEIR ANTICIPATED USE

Safety goals would fit within the current regulatory framework, and to some extent modify it. In particular, they would give NRC an explicit safety philosophy, provide operational measures for its achievement, and provide a partial basis for regulation, licensing, and backfitting. As described in this chapter, the anticipated use of safety goals in regulation, licensing, and backfitting is based on the NRC staff's Action Plan to Implement the Commission's Draft Safety Goal Policy Statement.

3.1 SAFETY PHILOSOPHY

NRC's safety goals would provide an explicit statement of the Commission's safety philosophy--that is, a statement of the acceptable level of risks to public health and safety, the role of safety cost tradeoffs in regulatory decisionmaking, and the relative risk that might be imposed on the public as a result of nuclear power plant accidents. This safety philosophy takes the form of two qualitative safety goals. First, no individual should bear a significant additional risk to life and health as a result of a possible nuclear power plant accident. Second, societal risks to life and health from nuclear power plant accidents should be as low as reasonably achievable and comparable to or less than the risks of generating electricity by viable competing technologies.

3.2 OPERATIONAL MEASURE

The achievement of the qualitative goals is to be measured in terms of provisional numerical guidelines. In its policy statement, the Commission has emphasized the provisional aspect of the guidelines. They are to serve as aiming points or numerical benchmarks, subject to revision. They are not intended as substitutes for existing regulations.

Four guidelines are proposed. The first two concern individual and societal mortality risks. According to the first guideline, the risk of prompt fatality to an individual of the local population resulting from reactor accidents should not exceed 0.1% of the sum of prompt fatality risks resulting from all other accidents. According to the second guideline, the risk of cancer fatalities to an individual or local population resulting from nuclear accidents should not exceed 0.1% of the sum of cancer fatality risks resulting from all other causes. The third guideline concerns benefit-cost comparisons. It provides that the benefit of incremental risk reduction below the guidelines for societal mortality risks should be valued at \$1,000 per person-rem averted. The fourth plant performance guideline provides that the probability of an accident resulting in a large scale core melt should be less than 10^{-4} per year of reactor operation.

3.3 USE OF SAFETY GOALS AND NUMERICAL GUIDELINES IN REGULATION

According to the NRC Staff's Action Plan, the qualitative safety goals and provisional numerical guidelines would be used to assess the adequacy of existing rules, standards, guides, and the need for their revision.³⁶ The exact application of safety goals to regulation would vary depending on the particular issue, the quality of the data, and the limits of PRAs.³⁷

The guidelines would not themselves become surrogates for design and siting criteria otherwise established by regulation. Rather, the guidelines would be "considered as an envelope within which further implementing engineering guidance will be developed."³⁸ Two levels of implementing engineering guidance would be developed. First level guidance would include guidelines for core melt frequency, to be formulated immediately, and perhaps guidelines for containment performance, siting, and emergency preparedness, to be formulated later. Second level guidance would entail design features important to the achievement of first level guidance.³⁹

3.4 USE OF SAFETY GOALS AND NUMERICAL GUIDELINES IN LICENSING

As explained in the proposed policy statement, individual licensing decisions would continue to be based on Commission regulations.⁴⁰ The issuance of construction permits and operating licenses would not be conditioned on demonstrated compliance with numerical guidelines.⁴¹

However, the Staff Action Plan contemplates that numerical guidelines and PRAs may be used in the licensing process to a limited degree. For example, they may be used to provide a "perspective" for possible improvements in case work reviews, where a PRA clearly demonstrates a potential need for additional safety measures. In this application, PRAs would normally be limited to quantifying core melt frequencies from internally initiated accidents.⁴² Once a standardized PRA methodology becomes available, license applicants might be required to perform PRAs to provide such perspective, but not to demonstrate compliance with numerical guidelines.⁴³ The guidelines and PRAs might also be used in deciding whether to exempt plants from existing regulatory requirements, based on plant-specific PRAs.⁴⁴

3.5. USE OF SAFETY GOALS AND NUMERICAL GOALS IN BACKFITTING

According to one Commissioner, how to handle backfitting is NRC's most pressing practical question.⁴⁵ Under current plans, the numerical benefit-cost guideline applied in conjunction with plant-specific PRAs may be used as at least a consideration in assessing the need to backfit new safety requirements.⁴⁶ Again, however, PRAs would probably be limited to the quantification of core melt frequencies from internally initiated accidents.⁴⁷ At present, the staff has stated that it believes that the calculation of the offsite radiological consequences is not a cost-effective way to implement ALARA. Therefore, the staff would assign a dollar value for incremental reductions in core melt probability that it has determined is roughly comparable to \$1,000 per person-rem. The staff's proposed figure is \$20,000 per 10^{-5} reduction in mean or best-estimate core melt frequency per reactor year for a site with average demographic characteristics.⁴⁸

4.0 LEGAL ISSUES IN SAFETY GOAL IMPLEMENTATION

Major changes in regulatory practices are almost always subject to legal challenge. Some individuals or groups may believe they are disadvantaged by the change in the regulatory process. Feeling worse off under the new regime, they may try to force a return to the status quo. Others may feel positively advantaged by the prospect of change. Anticipating better treatment under the new regime, they may try to hasten its establishment or expand its coverage. Regulatory change also provides an opportunity or vehicle for challenges motivated by considerations other than reaction to the changes themselves. Further, regulatory change almost always creates uncertainty on the part of regulators, regulated entities, and others who participate in the regulatory process. Often they look to the courts for resolution of such uncertainty. The adoption and use of safety goals and numerical guidelines in nuclear reactor regulation seems likely to stimulate all four sources of challenge.

This chapter discusses legal issues in the implementation of safety goals. The issues discussed fall into three broad categories. First are those issues that could arise from NRC's adoption of any general scheme of safety goals and numerical guidelines, to be verified by some analytic methodology such as probabilistic risk assessment. Short of major surgery, these are the sorts of issues that NRC must be prepared to confront however it modifies the proposed goals and guidelines and however it chooses to implement them. Second are those issues that could arise from the particular formulation of goals and guidelines set forth in the proposed policy statement. Some of these issues could perhaps be resolved by revisions to be reflected in a final policy statement. Third are those issues that could arise from the particular plan for implementation that NRC has tentatively developed. Some of these issues could perhaps be resolved by modification of present implementation plans. In short, the discussion of legal issues is organized according to the types of actions NRC could take to resolve them.

This chapter is organized as follows. Section 4.1 identifies the general forms legal challenge of safety goals could take. Section 4.2 states several caveats applicable to predicting legal issues in this area. Both sections apply to all three categories of legal issues. Section 4.3 then discusses legal issues arising from the general concept of regulation based on safety goals and PRAs. Section 4.4 discusses issues arising from the particular formulation set forth in the proposed policy statement. Section 4.5 discusses issues arising from current implementation plans.

4.1 FORMS OF LEGAL CHALLENGE

Essentially, qualitative goals and numerical guidelines could lead to four main types of challenges. First, challengers could attack the policy statement itself. Second, challengers could attack the use or non-use of safety goals in NRC rulemaking (i.e., in the establishment of regulations). Third, challengers could attack the use or non-use of safety goals in NRC licensing. Fourth, challengers could attack the use or non-use of safety goals in backfitting (a special case of rulemaking or licensing).

In attacking the policy statement, challengers would essentially have to argue that the safety goals or guidelines are in some sense defective. In attacking the use or non-use of safety goals in rulemaking, licensing, or backfitting, challengers could choose among several approaches. They could challenge the safety goals or guidelines as defective. They could challenge the safety goals or numerical guidelines as wrongly applied in establishing a regulation, granting (or failing to grant) a license, or requiring (or failing to require) a backfit. Or they could challenge rulemaking, licensing, or backfitting proceedings for failing to make use of safety goals or numerical guidelines at all. Further, challengers could seek to compel the initiation of a proceeding such as a rulemaking or a license modification, suspension, or revocation, on the grounds that appropriate application of safety goals requires such a proceeding. Finally, the goals and guidelines could be used as a defense. A licensee facing license modification, revocation, or suspension could attempt to show compliance with the goals or guidelines. These possible forms of legal challenge are summarized in Table 1, on page 18.

TABLE 1. Possible Forms of Legal Challenge

1. Challenge the policy statement
 - (a) Goals or guidelines are defective
2. Challenge a rulemaking
 - (b) Goals or guidelines are defective
 - (c) Goals or guidelines were wrongly applied
 - (d) Goals or guidelines were not used at all
 - (e) Rulemaking based on goals should be initiated
3. Challenge a license proceeding
 - (a) Goals or guidelines are defective
 - (b) Goals or guidelines were wrongly applied
 - (c) Goals or guidelines were not applied at all
 - (d) License modification proceeding based on goals should be initiated
 - (e) Based on goals or guidelines, license should not be modified

4.2 CAVEATS

Making confident predictions about the response of the courts to implementation of the safety goals and numerical guidelines is extremely difficult, for several reasons.

First, courts are notoriously unpredictable in their review of regulatory action. In part, this unpredictability stems from the existence of two, somewhat contradictory bodies of case law.⁴⁹ One line of cases supports exacting judicial scrutiny of regulatory action, including the substance of agency decisions.⁵⁰ The other is highly deferential, looking primarily to see whether the agency has followed proper procedures.⁵¹ Somewhat ironically, the leading deferential decision in Vermont Yankee may actually lead to a more intense substantive review. In that case, the Supreme Court held that the federal courts may not ordinarily impose procedures on an agency such as NRC that are more stringent than those procedures required by the Administrative Procedure Act. As a result, the courts are deprived of a favorite means of reversing agency decisions with which they disagree: imposition of extra procedural requirements. Robbed of this tool, courts may be expected to look more deeply into substantive decisions. And in fact, in the very Vermont Yankee case on remand, the D.C. Circuit Court of Appeals faulted NRC for the substance of its decision.⁵²

A second source of unpredictability in judicial review of NRC action is the very broad sweep of the Atomic Energy Act. This statute requires NRC to regulate in the interest of public health and safety and common defense and security. Neither the Act itself nor its legislative history provides much guidance as to the meaning of these terms. Congress enacted "a regulatory scheme which is virtually unique in the degree to which broad responsibility is reposed in the administrative agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives."⁵³

A third difficulty in predicting the response of the courts concerns the peculiar nature of policy statements. As discussed below, a policy statement such as NRC's is probably not itself ripe for judicial review. It is likely to be challenged in the context of application in a particular rulemaking or licensing proceeding. Therefore, some of the issues raised in this chapter may not be reached, or may be presented in a somewhat different fashion than anticipated here. To the extent the validity of the policy statement is addressed by judicial review, predictions about judicial response are further complicated by the somewhat uncertain standard of review that applies to policy statements.

4.3 GENERAL LEGAL ISSUES

One set of legal issues is quite general. These issues stem from NRC's basic decision to establish an explicit safety philosophy, set numerical guidelines, and embrace probabilistic analysis. These issues arise because present rules governing access to the regulatory process, burden of proof, and similar matters are well-suited for exploitation of such a new regime.

Of course, simply because such rules could be exploited does not necessarily mean that they will be exploited. Whether intervenor groups, utilities, or others will seize the opportunity depends on their inclination and resources, matters beyond the scope of this report. However, as stated in Chapter 5's Conclusions and Recommendations, there are steps that NRC may wish to consider taking that may somewhat reduce the opportunity for such groups to use safety goals as a vehicle for legal challenges.

4.3.1 Access to the Legal System

To mount a legal challenge, a party must first gain access to the legal system--that is, either to administrative proceedings or to judicial review. As with the other legal concepts discussed in this chapter, access to nuclear regulatory decisionmaking is governed primarily by two federal statutes: the Administrative Procedure Act (APA)⁵⁴ and the Atomic Energy Act.⁵⁵ The APA is a broad statute governing federal agency procedures generally. The Atomic Energy Act is NRC's basic statute. It expressly provides that the APA applies to all NRC actions.⁵⁶ In turn, particular provisions of the APA refer to the possible applicability of agency-specific statutes. Thus the two acts must be read together, along with applicable NRC regulations, NRC decisions, and judicial decisions.

In general, both the APA and the Atomic Energy Act grant interested parties broad rights of participation in nuclear regulatory decisionmaking. Means of access include the right to intervene in administrative proceedings, the right to compel administrative proceedings, and the right to obtain judicial review of agency action. Although in principle NRC's Rules of Practice in 10 CFR Part 2 require interested parties to meet certain preconditions in order to exercise these rights, in practice reviewing courts, the Commission, the Atomic Safety and Licensing Appeal Board, and individual licensing boards have made such requirements easy to meet. As a result, parties desiring to place safety goals at issue should have little trouble at least receiving a hearing.

Right to Intervene

The right to intervene refers to a person's right to participate in administrative proceedings initiated by others, including both rulemaking proceedings and adjudicatory (licensing) proceedings.⁵⁷

Because an agency need not initiate any sort of administrative proceeding to issue a policy statement,⁵⁸ the concept of intervention does not strictly speaking apply to the issuance of policy statements (because there may be no proceeding in which to intervene). However, the APA contains a general provision providing that so far as orderly conduct of public business permits, an interested person may appear before an agency for the "presentation, adjustment, or determination of an issue, request, or controversy in . . . connection with an agency function."⁵⁹ This provision can be read as granting interested persons a limited right to participate in the issuance of policy statements, for example by commenting on proposed policy statements before they are issued. And in fact NRC has solicited just such comments in connection with the proposed policy statement on safety goals.

For rulemaking and adjudication, broad rights of intervention are provided by both the APA and the Atomic Energy Act. The APA provides that in rulemaking proceedings, the agency must give notice and an opportunity to participate through submission of written data, views, or arguments, with or without the opportunity for oral presentation.⁶⁰ In adjudicatory (licensing) proceedings, the APA requires the agency to give all interested parties an opportunity to participate when the time, the nature of the decision, and the public interest permit, and in the event an agreement cannot be reached, a hearing and decision.⁶¹ The Atomic Energy Act grants similar rights of intervention. In any rulemaking or licensing proceeding, NRC must grant a hearing to any person whose interest may be affected by the proceeding, and admit such person as a party to the proceeding.⁶²

In its regulations under the Atomic Energy Act, NRC distinguishes between "intervention" and "participation by a person not a party." Intervention is afforded "any person whose interest may be affected by a proceeding," and who properly files a written petition for leave to intervene. A person whose petition is accepted then becomes a party to the proceeding.⁶³ Participation by a person not a party to a proceeding, which confers a somewhat different status, may be permitted in the discretion of the presiding officer. Such a party makes an appearance only for the limited purpose of stating his or her views.⁶⁴

In practice, licensing boards are relatively liberal in granting petitioners the right to intervene.⁶⁵ Once intervenors have been admitted to a licensing proceeding, the boards generally try to facilitate their participation. For example, licensing panels frequently recast faulty contentions by intervenors in order to make them acceptable for litigation.⁶⁶ Licensing boards may also use their "sua sponte" powers (powers to initiate their own investigations) to develop contentions dropped by intervenors.⁶⁷ Safety goals, numerical guidelines, and PRAs may afford intervenors an opportunity to exploit these tendencies. Merely raising questions about the adequacy of a PRA or the compliance of a specific plant with goals or guidelines could trigger elaborate and time-consuming investigations aimed at addressing contentions that are easy to make, but hard to confirm or refute. As noted below, some guidance to licensing boards may therefore be desirable.

Right to Petition for Rulemaking

The APA clearly gives interested persons a right to ask an agency to issue, change, or repeal regulations through the right of petitions for rulemaking. Each agency must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule."⁶⁸ If the agency denies the petition, the denial must be accompanied by a brief explanation.⁶⁹ In keeping with these requirements, NRC regulations provide that "any interested person may petition the Commission to issue, amend, or rescind any regulation."⁷⁰ If NRC denies the petition, it will "notify the petitioner with a simple statement of the grounds of denial."⁷¹

Other Rights to Compel Administrative Proceedings

Interested parties have a similar right to ask NRC to revoke, suspend, or modify a license. Specifically, NRC regulations give any person the right to file a request for NRC to institute a proceeding to modify, suspend, or revoke a license. Review of the NRC staff decision with respect to such a request is discretionary with the Commission.⁷²

In short, anyone may attempt to compel the initiation of a rulemaking or the revocation, suspension, or modification of a license. If the request is denied, NRC must explain why. The adoption of safety goals and numerical guidelines could facilitate use of this vehicle by utilities and by intervenor groups. For example, utilities could attempt to force NRC to justify or relax existing regulations on the ground that they are more stringent than required by the goals and guidelines. Similarly, others could petition NRC to establish new and more stringent regulations on the ground that existing regulations do not meet the goals or guidelines. NRC may have the formal legal authority to deny such petitions, without conducting new PRAs or reviewing existing PRA results. However, such a denial could test NRC's credibility. By declining to make an express determination as to whether its own regulations meet the goals and guidelines, NRC could be portrayed as lacking faith in the regulations, the safety goals, or both.

Right to Obtain Judicial Review of Agency Action

The right to intervene and the right to compel administrative proceedings determine a person's access to NRC's regulatory process. If such a person is dissatisfied with the outcome of that process, however, he or she may seek redress in the courts.

The right to obtain judicial review of agency action is governed by both statute and judicial decisions. The Atomic Energy Act provides for judicial review of any final order issued in a licensing or rulemaking proceeding.⁷³ Such review is as prescribed by the APA⁷⁴ and by Title 28 of the United States Code.⁷⁵ The United States Courts of Appeals have exclusive jurisdiction over all final NRC orders made reviewable by these laws.⁷⁶ Reviewable final orders also include denial of a petition for rulemaking and the written refusal by NRC staff or the Commission to institute a proceeding to modify, suspend, or revoke a license pursuant to 10 CFR Sec. 2.206.⁷⁷

Whether a particular party may obtain judicial review at a particular time depends on several somewhat overlapping doctrines known as primary jurisdiction, exhaustion of administrative remedies, ripeness for judicial review, and standing. In the context of safety goals, the most important of these doctrines are ripeness and standing.

Primary jurisdiction. Primary jurisdiction is a judge-made doctrine governing whether the reviewing court or the agency will initially decide an issue. For example, NRC may have primary jurisdiction over the issue of

whether it must suspend a license. Therefore, an interested party must first ask NRC to suspend the license. Only when NRC has refused to do so may such a party seek judicial review.

Exhaustion of administrative remedies. Exhaustion is a judge-made doctrine governing whether judicial review is appropriate, given the completion or lack of completion of administrative action. Exhaustion of administrative remedies is required when the question presented is within the agency's expertise and when the administrative remedy is as likely as the judicial remedy to provide the desired release.⁷⁸ More specifically, the Administrative Procedure Act provides that "agency action made reviewable by statute and final agency action of which there is no other adequate remedy in a court are subject to judicial review."⁷⁹

Ripeness for judicial review. Ripeness is a judge-made doctrine precluding judicial review of agency action that does not yet substantially affect or threaten the interests of the parties seeking review.⁸⁰ However, the propriety of actions not yet ripe for review may be addressed later, when subsequent actions are reviewed. In the words of the APA, "a preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."⁸¹

Ordinarily, valid policy statements and interpretive rules are not ripe for review until they are applied in a rulemaking or adjudicatory proceeding. Only the "strongest showing" of "immediate and inescapable effect" is sufficient to trigger review at the point of mere announcement.⁸² Thus assuming NRC's safety goals and guidelines meet judicial criteria for issuance as a policy statement, they will not be ripe for review on adoption. Instead judicial review must await their application in a licensing or rulemaking proceeding, when NRC must be prepared to support them "just as if the policy statement had never been issued."⁸³

The consequences would be different were NRC's policy statement challenged and held by the courts to be a de facto regulation. In that case, the statement itself would be subject to APA notice and comment rulemaking procedures and would also be entitled to more deference in subsequent NRC actions and upon judicial review.⁸⁴ Unfortunately, there is no bright line test for determining whether a policy statement is actually a regulation. The key question appears to be how much scope for reconsideration or refinement the statement purports to allow in later rulemaking or adjudication. "When the agency states that in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order as a general policy statement."⁸⁵ In contrast, when an agency pronouncement restricts the freedom of agency decisionmakers to exercise discretion, it must be treated as a regulation.⁸⁶ On these grounds, NRC's goals and guidelines probably qualify as a valid policy statement because their application is expressly made subject to the discretion of NRC staff.⁸⁷

Standing. Standing refers to the right of a particular person or category of persons to obtain judicial review. The APA gives the right of review to a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within a meaning of a relevant statute."⁸⁸ The Supreme Court has established a two-pronged standard for standing under the APA. First, a person must suffer "injury in fact" as a result of the agency action being challenged. Injury in fact includes harm to aesthetic, conservation, recreational, and economic interests, and possibly to "ideological" interests as well.⁸⁹ Second, the person must be "arguably within the zone of interest to be protected or regulated" by the relevant statute--i.e., the interest the statute requires the agency to consider in taking action.⁹⁰ The interests to be protected by NRC are public health and safety, common defense and security (all by virtue of the Atomic Energy Act), and environmental interests, broadly defined (by virtue of NEPA). Essentially, the right to obtain standing is congruent with the right to intervene in administrative proceedings, although a person need not necessarily participate in administrative proceedings in order to obtain judicial review of the outcome.⁹¹ While relatively expansive, neither right is unlimited. NRC decisions seem to require residence within 50 miles of a nuclear power plant to show an interest in its safety.⁹²

Some uncertainty surrounds standing to obtain judicial review of NRC proceedings that apply the policy statement. For example, does one utility have standing to challenge the policy statement as applied in a proceeding affecting another utility's license? Or does a local intervenor group have standing to challenge a license proceeding in another geographic area? Even current liberal standing requirements might be difficult to satisfy in such instances. For example, the Licensing Appeal Board has expressly denied standing to such an intervenor seeking to obtain protection from creation of an adverse precedent.⁹³ But there is some residual uncertainty.

Autonomy of Licensing Boards

NRC's procedural rules give licensing boards and licensing appeals boards broad powers to limit proceedings so that they do not become unduly protracted. For example, it is the responsibility of the licensing boards to determine that would-be intervenors have demonstrated an interest affected by the proceeding, have filed their petition to intervene in timely fashion, and have set forth "contentions" to be litigated with reasonable specificity.⁹⁴ To prevent needless hearing delays or an unwieldy record, the presiding officer may limit the appearance of witnesses giving similar testimony; "strike argumentative, repetitious, cumulative, or irrelevant evidence;" control cross-examination; and impose time limits on oral argument.⁹⁵ In addition, the presiding officer need examine and decide matters not put into controversy by the parties "only where he or she determines that a serious safety, environmental, or common defense and security matter exists."⁹⁶ Thus in principle, licensing boards can prevent intervenors from abusing the policy statement to raise false issues that create licensing delay. However, simply because licensing boards have the power to limit proceedings does not mean that they will do so. Indeed, the recent record shows the opposite tendency. Licensing boards often make every effort to give intervenors the benefit of the doubt.⁹⁷ Therefore, NRC's procedural

rules do not completely guarantee that the safety goals and guidelines will not complicate licensing proceedings.

Conclusion

NRC's procedural rules as applied in practice provide significant opportunity for parties desiring to place safety goals and PRAs at issue in NRC proceedings. To keep the introduction of PRA-related issues within reasonable bounds, NRC may wish to develop guidance on these matters.

4.3.2 Burden of Proof

Burden of proof encompasses two concepts under a single label. Burden of proof partly refers to the "burden of production," the responsibility for producing evidence. But burden of proof also refers to the "burden of persuasion," the burden of convincing the finder of fact as to the truth of key issues.⁹⁸ In establishing the burden of proof, it is important to distinguish between these two concepts because the party having the burden of production does not necessarily also have the burden of persuasion. Two other caveats are also important. First, burden of proof applies to adjudication (licensing and judicial review), not to rulemaking.⁹⁹ Second, burden of proof refers to the locus of responsibility (who must produce evidence or persuade the factfinder), not the level of responsibility (how much evidence or what level of certainty), although the two questions are related.

The burden of proof in NRC licensing is governed by both the APA and the Atomic Energy Act. The APA states that except as statutes otherwise provide, the proponent of an order has the burden of proof.¹⁰⁰ To the same effect, NRC's corresponding regulations provide that "unless otherwise ordered by the presiding officer, the applicant or the proponent of an order has the burden of proof."¹⁰¹ However, these provisions allocate the burden of production, not the ultimate burden of persuasion, which is instead controlled by the agency's substantive statute,¹⁰² in NRC's case the Atomic Energy Act.

In a construction permit or operating license proceeding, the Atomic Safety and Licensing Appeal Board has applied these principles as follows. As to the burden of production, (1) the license applicant must produce evidence showing that it is entitled to the license, and (2) anyone opposing the license (that is, the proponent of an order to deny it, such as NRC staff or an intervenor) must produce evidence at least "sufficient to require reasonable minds to inquire further."¹⁰³ As to the burden of persuasion, (3) the license applicant must also bear the ultimate responsibility.¹⁰⁴ In other words, the applicant must prove its entitlement to a license by showing that the facility complies with all applicable NRC requirements and by rebutting staff or intervenor evidence to the contrary.

These principles are applied in a slightly different manner to proceedings involving modification, suspension, or revocation of a license. Under the APA, it would be NRC staff or an interested party that would be the "proponent of an order" to suspend, modify, or revoke the license. Such a party would first have to make out a prima facie case for doing so.¹⁰⁵ Then, however, the Atomic

Energy Act takes over, again placing the ultimate burden of persuasion on the licensee. Thus the licensee would still have to persuade NRC that license suspension, modification, or revocation were inappropriate.¹⁰⁶

Establishment of safety goals and numerical guidelines could afford intervenors an opportunity to exploit rules governing burden of proof. For example, in a construction permit or operating license proceeding intervenors could produce rather minimal evidence purporting to show that the plant would not comply with goals or guidelines. If such evidence cast sufficient doubt on the plant's safety to require reasonable minds to inquire further, the license applicant might then have to conduct a PRA to rebut the evidence and thereby the plant's safety. Similarly, in a license suspension, revocation, or modification proceeding an interested party could produce a cursory PRA on the plant in question or a PRA on a similar plant. Assuming the evidence were sufficient to establish a prima facie case, the licensee might again have to perform its own PRA in rebuttal. To avoid unnecessary and protracted exercises along these lines, NRC may wish to consider setting more explicit standards for the evidence that would establish a prima facie case in this context.

4.3.3 Standard of Proof

While burden of proof refers to who is responsible for producing relevant facts, standard of proof refers to what level of certainty is required. The APA requires that an agency order be supported by "reliable, probative, and substantial evidence."¹⁰⁷ Both the courts and the Nuclear Regulatory Commission have interpreted this standard of proof as requiring an agency decisionmaker such as an NRC licensing board to decide according to the "preponderance of the evidence."¹⁰⁸ In other words, the agency must decide according to which version of the facts is more probable than not.¹⁰⁹

Because the applicant (in a construction permit or operating license proceeding) or the licensee (in a license modification, suspension, or revocation proceeding) has the burden of persuasion, it is the applicant or licensee that must meet this standard of proof by showing that its version of the facts is more probable than not. If the applicant or licensee is in the posture of using probabilistic risk assessment to demonstrate compliance with the numerical guidelines, this standard could be difficult to meet. PRA results may simply be too uncertain. To mitigate this problem, NRC may wish to establish rules of interpretation to guide licensing boards and other Commission decisionmakers in using PRA results consistently.

4.3.4 An Analogy to NEPA

In some respects, issuance of the policy statement on safety goals may be analogous to the enactment of the National Environmental Policy Act in 1969.¹¹⁰ Just as NEPA introduced a new analytic procedure to government decisionmaking (the environmental impact statement), adoption of safety goals and numerical guidelines could elevate the legal visibility of probabilistic risk assessment. Just as NEPA specified new decision criteria (environmental considerations), so does the policy statement (safety goals and guidelines). One may therefore expect a similar response from those objecting to government policy: legal

challenges based on the new framework. Intervenor groups and disgruntled utilities will probably seek to compel NRC and/or the utilities to do PRAs (just as they seek to compel EISs). They may also challenge the adequacy of PRAs that have been done (just as they challenge the adequacy of EISs). And they may argue that particular PRAs have been wrongly interpreted in the light of the safety goals and numerical guidelines (just as they challenge NEPA decisions for failure to give enough weight to environmental values).

Of course, there are limits to the analogy between NEPA and the policy statement. In particular, the policy statement is a non-statutory interpretation of an existing mandate, rather than the imposition of a new mandate by Congress. NRC will be entitled to considerable deference in the interpretation of its own policies. Nonetheless, the limited role and gradual phase-in of safety goals, numerical guidelines, and probabilistic risk assessments apparently envisioned by NRC may be somewhat unrealistic. While NRC can expect to exert substantial control over the process of implementation, that control will probably not be complete. Intervenor groups, utilities, the Advisory Committee on Reactor Safeguards, and the licensing and licensing appeals boards, may all have different ideas about appropriate implementation. In particular, these various groups may desire faster or slower implementation of safety goals, guidelines, and PRAs than NRC, or they may desire implementation that is broader or narrower. These differing ideas are apt to be resolved in part through litigation. It has taken the courts at least a decade to determine what NEPA requires. NRC's position on safety goals issues may ultimately be upheld in the courts. But a shake-down process involving litigation seems at least possible. NRC may be able to make this process go more smoothly by developing its own guidance as to when PRAs must be done and what constitutes an adequate PRA.

4.4 ISSUES ARISING FROM THE PROPOSED POLICY STATEMENT

A second set of issues arises from the particular formulation of goals and guidelines contained in the proposed policy statement. As in the case of the general issues discussed in Section 4.3, the possibility that the specific issues described in this chapter could be raised should not imply that they necessarily will be raised. Moreover, much of the discussion in this chapter assumes that NRC will make some use of the goals and guidelines in regulation and licensing. Thus the issues identified could perhaps be largely avoided if NRC simply avoided endorsement of the goals and guidelines in its regulatory decisions. However, such a course could leave unfulfilled much of the promise of the safety goals enterprise, which after all purports to introduce a regulatory philosophy. Therefore it seems reasonable to consider the legal issues that could arise from use of the goals and guidelines in regulatory decision-making. Again, the Conclusions and Recommendations in Chapter 5 suggest steps NRC could take to reduce the opportunities for litigation.

Thus the issues emerge from the application of standard principles of judicial review to the policy statement itself or to rulemaking or licensing actions based on them. This chapter first sets out the general principles and then applies them to several potential weaknesses in the policy statement.

4.4.1 Background: Standards of Judicial Review

Standards of judicial review refer to the principles a reviewing court will apply in judging the adequacy of agency action. Standards of review differ, depending on whether the agency action being reviewed is a statement of policy, a rulemaking proceeding, or an adjudicatory decision, such as the issuance, denial, modification, suspension, or revocation of a license.

Policy Statements

Policy statements are agency pronouncements that do not purport to establish a binding norm, but rather purport only to announce an agency's tentative intentions for the future.¹¹¹ Unless otherwise provided by statute, notice and comment rulemaking requirements do not apply. An agency need follow no particular procedures in issuing a general policy statement.¹¹²

The reviewability of general policy statements is ordinarily doubtful because ripeness and standing requirements are difficult to meet.¹¹³ However, policy statements may be reviewable under certain circumstances.¹¹⁴ If reviewable, courts may apply less deference to policy statements than to other agency actions. In other words, courts may assess the underlying wisdom of a policy, not just its reasonableness.¹¹⁵

Rulemaking

Under the APA, reviewing courts must set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."¹¹⁶ In the leading case of Citizens to Preserve Overton Park v. Volpe,¹¹⁷ the Supreme Court has interpreted the APA standard to require the reviewing court to make three determinations.

First, the court must determine whether the agency acted within the scope of its authority. In making this determination, the court looks to the basic statute under which the agency is operating to ensure that the agency action is within its delegated authority. As previously indicated, NRC has fairly sweeping powers under the Atomic Energy Act to regulate nuclear materials, facilities, and activities to protect the public health and safety and the common defense and security. Thus NRC's scope of authority is very broad.¹¹⁸

Second, the court must determine whether the agency followed proper procedures in taking the action. In particular, a reviewing court must ensure that the agency has followed the APA's procedural requirements for informal notice comment and rulemaking. In the past, reviewing courts sometimes required agencies to employ additional, "hybrid" rulemaking procedures to address especially complex issues. However, the Supreme Court has recently held that except in unusual circumstances, a reviewing court may not require procedures beyond those imposed by the APA.¹¹⁹

Third, the court must determine whether the agency based its decision on a sustainable rationale.¹²⁰ In conducting this "substantive review," a reviewing court considers "whether the decision was based on a consideration of relevant factors and whether there has been a clear error in judgment."¹²¹ Sometimes known as the "hard look" doctrine, this standard of review requires that the agency state its assumptions, reveal the process it used, explain its rejection of any alternative theories or courses of action, and set forth a rationale for its decision with reasonable clarity and conciseness.¹²²

In applying this standard of substantive review, courts keep several considerations in mind. First, the "relevant factors" that an agency must consider are derived from the statutes under which the agency is taking action.¹²³ For NRC, the principal statute is the Atomic Energy Act and the relevant factors are public health and safety and common defense and security. Of course, some NRC rulemaking proceedings may involve other statutes: for example, proceedings to resolve NEPA issues on a generic basis, such as those involved in the Vermont Yankee litigation. In such cases, these statutes provide additional relevant factors to be considered. Second, it is the agency and not the reviewing court that must supply the rational connection between the facts found and the conclusions reached.¹²⁴ Third, the agency decision need not have ideal clarity, but its path must be reasonably discernible.¹²⁵ Fourth, the ultimate standard of review is narrow. "The court is not empowered to substitute its judgment for that of the agency."¹²⁶

Licensing

For purposes of the APA, licensing (including the issuance, denial, modification, suspension, or revocation of a license) is accomplished through adjudication.¹²⁷ Therefore, licensing decisions are reviewed according to standards appropriate to adjudication. The APA standard for reviewing agency adjudication provides that such decisions be set aside if "arbitrary, capricious, or an abuse of discretion,"¹²⁸ as in the case of informal rulemaking decisions. Thus the same general principles are applied as in the case of informal rulemaking. The agency must have interpreted its statute correctly, complied with procedural requirements, and provided a sustainable rationale for its decision.¹²⁹ As discussed in Section 4.3.3, adjudicatory decisions may also be set aside if "unsupported by substantial evidence."¹³⁰

4.4.2 Specific Issues

Against this backdrop of judicial scrutiny, a number of issues could arise, whether in a proceeding challenging the policy statement itself or (more likely) in the context of a rulemaking or licensing proceeding. Most involve NRC's failure to explain or justify certain aspects of the goals and guidelines. While many of these issues are at least partially addressed by OPE's Discussion Paper,¹³¹ this analysis lacks endorsement by the Commission itself. Accordingly, it would seem preferable to address these issues expressly in any final policy statement or in any subsequent regulatory proceeding that makes use of the goals and guidelines.

In particular, legal issues could arise from failure to supply rationales, failure to supply definitions, avoidance of key issues, failure to specify responses to time and place variations, excess conservatism, and insufficient conservatism.

Rationale Needed

As stated above, the prevailing standard of judicial review requires that regulatory decisions be based on a sustainable rationale. In other words, the agency must have "demonstrated a logical connection between the evidence it adduced and the conclusion it reached."¹³² Future regulations or licensing decisions based on the qualitative goals or numerical guidelines may be found defective if the pertinent goals and guidelines themselves lack an identifiable rationale.

Several particular guidelines could benefit from justification more careful than that found in the policy statement. For example, the 0.1% incremental risk levels in the first numerical guideline are explained as "reflecting" the first qualitative goal (no significant additional individual risk) and "consistent" with the second qualitative goal (risk as low as reasonably achievable, comparable to alternative power generation risks). But only minimal evidence for this "reflection" is cited. Perhaps more problematic is the absence of virtually any rationale for the \$1,000 per person-rem averted value in the second numerical guideline or the 10^{-4} per reactor year probability of large-scale core melt in the third numerical guideline. That both are expressly subject to revision will not insulate them from attack in the meantime.

A somewhat different aspect of the goals and guidelines not justified in the policy statement is their limitation to nuclear power plant accident risks. If this approach makes so much sense, intervenors may ask, why is it not applied to risks from routine emissions, fuel cycle activities, sabotage, and the diversion of nuclear material?

Sustainable rationales for these choices should not be difficult to supply. For example, application to risks other than those of nuclear power plant accidents could be shown to be impractical in light of the limited data base for probabilistic risk assessment. When its regulations "turn on choices of policy, an assessment of risks, or on predictions dealing with matters on the frontiers of scientific knowledge," NRC must supply adequate reasons and explanations.¹³³ It must also "provide sufficient data to demonstrate a systematic approach to problems." But NRC need not "adduce vast quantities of factual data."¹³⁴ Nor is a "rigorous, step-by-step proof of cause and effect" required. Rather, NRC may apply its "expertise to draw conclusions from suspected, but not completely substantiated, relationships between facts, from trends among facts, from theoretical projections from imperfect data, from probative preliminary data not yet certifiable as 'fact,' and the like."¹³⁵

Definition Needed

Another weakness in the policy statement arises from its failure to define key terms. Subsequent disagreement over their meaning could complicate the application of safety goals and numerical guidelines, possibly forcing remand to NRC for clarification, or leading the courts to supply their own definitions possibly at odds with NRC's intent.

Definitional problems include the following. First, how is the \$1000 to be measured? In a period of high inflation, the difference between constant dollars and nominal dollars may differ significantly over a period of several years. Similarly, if the expenditure occurs over a period of time, the manner in which it is discounted could be a significant factor.

A second definitional problem concerns the distinction between individual and societal (sometimes "population") risk. The failure to distinguish between the probability that a particular individual (even if an "average" individual) will be harmed and the probability that at least one individual of a population will be harmed poses a similar problem. To use anything other than the individual definition would allow the arrival of new neighbors to move a plant out of compliance. This may be appropriate policy, but since such backfits may be onerous and caused by actions far outside the operator control, more definite direction to impose such burdens may be wise. The law does have some experience with "societal" risk, as separate from the risks facing a set of individuals. Certain events, either because of their magnitude or other characteristics, pose risks to the social fabric beyond the harm to individuals. The suggestion already made in comments to the policy statement is that at least a magnitude-based definition be considered (e.g., the probability of 10 or more prompt fatalities at a single site). These societal risks face the same possibility of confusion between the chance of such an event posed by a single plant and the chance of one or more such events posed by a set of plants.

A third definitional problem concerns what is meant by "large scale core melt." Presumably, the core melt of most concern would be one that resulted in fuel melting and large releases of radiation to the population. But this limitation is nowhere made explicit in the policy statement. It could be critical because an individual power plant's ability to meet the large scale core melt guideline obviously depends on the type of core melt envisioned.

A fourth definitional ambiguity concerns the distinction between maximum total risk and maximum incremental risk. Even when speaking only of the risk to one individual posed by one plant, there can be important differences between adding x to the chance of a prompt fatality and adding $x\%$ to that chance. The second measure is highly sensitive not only to other risks faced by that individual, but also to change in those risks over time. The relative measure also has the somewhat perverse characteristic (also found in certain environmental laws), that the safer an individual already is, the more protection NRC would offer.

Issues Avoided

The policy statement also avoids discussing several difficult issues. Under prevailing standards of judicial review for both rulemaking and licensing, NRC must state its assumptions and explain why it has rejected alternative theories or abandoned alternative courses of action.¹³⁶ Therefore, if the goals and guidelines are used as a basis for rulemaking or licensing decisions, these issues will need to be addressed. Failure to "generate a record in which the factual issues are fully developed"¹³⁷ could lead to a remand of the policy statement or regulatory actions based on it. Issues not treated in full include the following.

First, NRC does not explain the current risks from nuclear power plant accidents and from non-nuclear sources. The data on both are sparse and highly uncertain. Although the policy statement never specifically describes these risks, it seems to imply that they are well understood.

Second, the policy statement does not establish a clear relationship between the qualitative goals and the second numerical guideline (ALARA and benefit-cost value). The guideline is supposed to allocate resources to reduction of risk below the first numerical guideline. But does this standard also imply possible risk reduction beyond the qualitative goals?

Third, the policy statement does not discuss the advantages and disadvantages of the proposed approach compared with alternative regulatory strategies. For example, while the introductory remarks cite advantages of goals and guidelines relative to the status quo, it acknowledges no disadvantages. Nor does it discuss the advantages and disadvantages of still other approaches (such as establishing goals and guidelines for accident probabilities only).

Fourth, the policy statement does not specify the "utility function" imbedded in NRC's safety philosophy. For example, if low-probability high-consequence events are of particular concern, why is this the case, and how do the goals and guidelines take them into account?

Fifth, the policy statement does not acknowledge the primitive state of probabilistic risk assessment and the high degree of uncertainty attached to the results.

As in the case of supplying a rationale, it is not necessary that NRC treat each issue exhaustively. Rather, NRC needs to demonstrate that it has not ducked such issues. A frank admission of uncertainties and imponderables, with a reasonable explanation of how NRC has chosen to resolve them is likely to meet with judicial favor.¹³⁸

Response to Variations in Time and Place Unspecified

The goals and guidelines themselves, as well as their application, depend on a variety of facts external to the policy statement. These include background risk, the risks of other electricity generating technologies, demographic conditions (including numbers of people and their susceptibility to

risk), the number of power reactors operating in the United States, and the geographic distribution of all the above. Establishing these facts for the purpose of rulemaking and licensing will be difficult enough. A further complication is that these factual conditions are apt to vary from place to place and over time. Unless principles are established for addressing these variations, application is apt to be extremely difficult. NRC may find any regulations based on the goals and guidelines remanded for vagueness, or it may discover that courts or other bodies themselves supply such principles or if the Commission has not itself done so.

Excess Conservatism

Some of the goals and guidelines could be challenged by utility or other groups on the grounds that they go beyond NRC's statutory authority under the Atomic Energy Act to protect the public health and safety. For example, the second qualitative goal requires risks from nuclear power plant accidents to be comparable to or less than the risks from the operation of competing electricity generating technologies. Although the explanatory paragraph purports to qualify this goal, on its face it seems to require that nuclear power plant accident risks be comparable to or less than the total fuel cycle risks of alternative power generation technologies. Another instance of apparent conservatism is the \$1000 per person-rem averted guideline. This value translates to \$5,000,000 per life saved, using the linear dose hypothesis, which is likely to be conservative. If \$1,000 per person-rem is taken to be an expected value, the 99% confidence interval implies as much as \$50,000,000 could be spent to avert a single death. Yet another extremely stringent standard is the first numerical guideline's requirement that reactor accident risks be no greater than 0.1% of the risks from all other accidents. A relative contribution of 1% or even 10% might still be considered small relative to other accident risks.

NRC could defend such conservatism by expressly stating in any final policy statement or subsequent regulatory decision that it is intended to balance the high uncertainty surrounding low-probability high-consequence catastrophic accidents. In a somewhat analogous situation (regulation of workplace carcinogens under OSHA, where health effects are similarly uncertain) the Supreme Court has authorized the use of "conservative assumptions," "risking error on the side of overprotection rather than underprotection."¹³⁹ In general, the courts will defer to the agency in determining the appropriate level of conservatism, provided the agency explains its choice and the choice is not irrational.¹⁴⁰

Insufficient Conservatism

Others may challenge the policy statement or regulatory actions based on it as insufficiently conservative, asserting that they fail to protect the public health and safety as required by the Atomic Energy Act. For example, one could argue that the 0.1% risk guideline for latent cancer fatalities is too lax in light of Commissioner Bradford's calculation that it implies the acceptability of 13,000 statistically expected deaths over the life of the

nuclear power plants now in operation or under licensing review. Similarly, the large-scale core melt guideline could be considered too lenient if read to refer only to fatality-causing core melts involving large-scale fuel melting and large uncontrolled releases of radioactivity.

The need for NRC to anticipate and address charges of insufficient conservatism by express justification is even more urgent than the need to justify extreme conservatism. While the federal courts have granted regulatory agencies substantial leeway to assess risks,¹⁴¹ they have also stressed the need to act with extreme caution in the face of high uncertainty and potentially disastrous consequences.¹⁴² Nonetheless, courts will not upset a regulation as too lax if reasonably justified by the agency.¹⁴³

4.5 ISSUES OF IMPLEMENTATION

A third set of issues arises from implementation. In the proposed policy statement, NRC is appropriately cautious about the ease of verifying compliance with the goals and guidelines through probabilistic risk assessment. However, implementation depends as much on how staff, licensing boards utilities, and others respond as it does on NRC's initiative. To the extent there is disagreement or confusion, the courts could play at least some role in their resolution.

Interpretation and Application

Two sources of legal issues complicate the implementation of almost any regulatory policy: interpretation and application. No matter how explicit and detailed the policy statement, these issues will arise. In this case, some of them have already arisen. For instance, as background for preparing an action plan for the policy statement NRR staff have developed what they call "assumptions" about the statement. These assumptions may well be the most reasonable extrapolations from the text of the statement, but nonetheless may be brought into question. To be more specific, one suggestion is that the numerical guidelines be considered design objectives, but that looser or higher numbers be allowed in practice. One can expect controversy to arise, in legal forums and elsewhere, about such suggestions. Debate will not only cover how the guidelines should be treated, but also who should decide.

Problems of interpretation are almost always accompanied by problems of application. The Commission itself, and the staff discussions, have suggested a number of limitations on the application of the proposed statement, e.g., to radiological releases stemming from accidents, to planning about regulations, and the like. However, these decisions are similarly subject to debate.

Linkage to Probabilistic Risk Assessment

No matter how careful the Commission, NRC staff, and others are on the point, it will be difficult to keep the policy statement and PRA separate. With such a direct and obvious tie in subject matter, the development and effectiveness of the policy statement will inevitably be tied, to the development and acceptance of PRA.

Such intense focus on PRA is probably at best a mixed blessing. Many experts believe that PRA is most useful for such purposes as the identification of fault sequences and areas for concern, which can appear to be an indirect use of the techniques. They consider PRA much less useful, at least at present, for developing bottom line estimates of risk. However, the process of implementation itself will create very powerful pressures to concentrate on the bottom line. As discussed previously, the uncertainties inherent in PRA results so complicate the use of a bottom line to show compliance that the party with the burden of proof may frequently lose.

Events versus Consequences

The policy statement more often speaks in terms of consequences than in terms of events. Such ultimate judgments may be the most appropriate policy, but they certainly increase the difficulty of implementation, primarily by broadening the environment NRC and parties involved with it must scan. Contrast the "harm to individuals" section of the policy statement with the "core melt" section. Although both have problems, the second section clearly involves a subject matter in which NRC is presumed to be expert. Harm to individuals, particularly when expressed in relative terms, shifts the debate more widely.

For instance, will licensing boards eventually have to hear evidence on the background risk of cancer? Will the data be national or site-specific? Will it be limited to the cancers similar to those caused by radiation, or expanded to all dread diseases? What does the hearing tribunal do with the data? The point is not that these specific questions must be answered, but that the policy statement's treatment of consequences almost inevitably raises such questions and the problem of who answers them.

Use of PRA Results

In the meantime, the policy statement creates the possibility that PRAs done for purposes other than licensing or regulation may give rise to a variety of legal challenges. For example, if PRAs seem to demonstrate that existing regulations are more stringent than the goals and guidelines require, utilities or others in the nuclear industry may challenge regulations on that basis. Similarly, if PRAs seem to show that existing regulations are less stringent than the goals and guidelines require, they may be subject to challenge by environmental interest groups. Analogous problems could arise at the level of an individual plant. For example, an intervenor could attempt to demonstrate that an individual plant fails to meet a goal or guideline, and on that basis petition for the modification, suspension, or revocation of its license. A weaker version of the same challenge could be made if the uncertainties in an individual plant PRA results overlap the goals or guidelines.

A probabilistic approach, particularly one posed in relative probabilities, poses a sharp version of a commons problem. That is, societal well-being is particularly sensitive to the sums and products of individual actions, as well as to the actions themselves. The problem is not unique. In the field

of environmental protection, improvements in air quality are sometimes achieved through sacrifice in water quality. But it does create special problems of equity.

In the definitional case, the actor in the best position to make a major contribution to societal well-being may be the best-behaved or least damaging in its own actions. In a very real legal sense, such actors should be most protected from extensive and expensive regulation. Yet a probabilistic, consequence-based system operates on a different standard. Those potentially subject to more onerous requirements due to factors far beyond their control, while admittedly "less deserving" actors may be called on to do less, are understandably likely to protest.

Such commons problems are neither unique to the scheme proposed in the policy statement nor are they insolvable. Nonetheless, they create difficulties in implementation if they are not recognized and addressed.

5.0 AN ALTERNATIVE APPROACH: THE FAA EXPERIENCE

In addressing some of the issues identified in Chapter 4, NRC may wish to consider the experience of other agencies in formulating and implementing similar regulatory regimes. By far the closest analogy is the approach taken by the Federal Aviation Administration to the certification of new transport aircraft.

Like NRC, FAA is responsible for regulating the safety of complex technological systems with the potential for catastrophic accidents. Just as NRC must license new power plants, FAA must certify new transport aircraft. Of course, the two agencies differ in some respects. FAA has a single administrator who is generally someone with a professional history in aviation. This arrangement contrasts sharply with NRC's collegial leadership where a professional history in nuclear energy is not a requirement for all commissioners. NRC seems to go to considerable lengths not to be a proponent of nuclear power, while FAA is a strong and consistent voice supporting civilian aviation. Indeed, the criticism most often voiced is that FAA is "in bed" with the industry. FAA is also more insulated from the general public and special interest groups than NRC. It employs less formal procedures, does not generally hold public hearings, and is far less subject to public interest group political pressure.

Despite the differences, the FAA experience should be instructive to NRC. The overall regulatory missions are similar, involving as both do the licensing of complex new technologies based on limited information. Most important, FAA has actually adopted and applied a system of qualitative safety goals and numerical guidelines for use in transport aircraft certification. Thus bearing in mind the differences, the analogy should be useful.

As a basis for comparison, this chapter provides some general background on FAA, describes its experience with safety goals, contrasts FAA practice with NRC's proposed approach, and draws implications for resolution of some of the legal issues identified in Chapter 4.

5.1 BACKGROUND ON FAA

FAA was established as an independent regulatory authority by the Federal Aviation Act of 1958. The legislation that split off FAA from the Civil Aeronautics Board invested in FAA the dual role of fostering aviation and protecting safety of the public. This dual role is important because while the relationship between FAA and the civilian airline industry is an adversarial one it is less so than the relationship between NRC and the civilian nuclear power industry.

Some general characteristics of the FAA and its regulatory philosophy are:

- Regulatory emphasis is on performance. The rules do not generally contain specific design requirements.

- Technology leads regulation, not the other way around. The view is that the expertise is in the industry and FAA serves as an overview or check. The opinion has been expressed that FAA personnel have not stayed current with the rapidly changing aircraft technology and have fallen dangerously behind their counterparts in industry.¹⁴⁴
- Most rules that comprise the body of regulations have derived from bad experiences.
- Aircraft need only meet the rules and the level of safety that applied when they were certified. New rules are not made retroactive. Retrofits to resolve safety problems uncovered through experience with previously certified aircraft or accepted maintenance procedures are handled through Airworthiness Directives (AD's) issued by the office that did the certification in the name of FAA.
- AD's may require changes in maintenance procedures, aircraft equipment, or the like. But these changes are only those judged necessary to comply with the airworthiness standards in effect when the aircraft was originally certified.

The airworthiness of an aircraft is defined as: the safety and physical integrity of the aircraft, including its component parts and subsystems, its performance capabilities, and its flight handling characteristics, when operated within its intended environment and within its quantified and declared limitations. The airworthiness certificate, granted by the FAA, states that the aircraft meets all specifications required by the Type Certificate, and has been flown and found to be in compliance with applicable airworthiness standards. Between 1980 and the introduction of jet-powered commercial aircraft in 1958, U.S. air carriers have been involved in 216 accidents resulting in fatalities. Sixteen of these were attributed primarily to failures of a jet aircraft or its equipment with the balance attributed to human error in flight and/or the air traffic control system.¹⁴⁵ The accidents where the primary cause was equipment failure can be roughly categorized into two groups: (i) equipment failure due to environmental conditions outside the design environment (extreme turbulence, lightning strikes, etc.); and (ii) equipment failure due to a cascade of failures (multiple faults) that were not identified using analyses required by the "single fault" criteria that was part of the certification procedure at the time. A good example of aircraft failure as a result of multiple faults in the American Airlines DC-10 crash on May 25, 1979 in Chicago. The National Transportation Safety Board determined that the probable cause of the accident was the asymmetrical state and ensuing roll of the aircraft because of the uncommanded retraction of the left-wing outboard leading edge slats and the loss of stall warning and slat disagreement indication system resulting from the separation of the No. 1 engine and pylon assembly at a critical point during takeoff. The initiating event was the separation of the engine and pylon assembly but the subsequent failures are what resulted in the loss of the aircraft. The "single fault" criterion in certification has been supplanted by a "multiple fault" analysis requirement that is, in fact, the FAA safety goal.

The FAA, through recent organizational changes, has assigned the certification responsibility for all new major transport aircraft to the Northwest Regional Office in Seattle. Two new Boeing aircraft (B757 and B767) are currently involved in certification testing. These aircraft are the first to be certified under the amended regulations that contain the safety goal statements. Other aircraft have been reviewed with respect to the amended regulations but these other reviews were strictly on a volunteer basis by the manufacturers.

5.2 FAA SAFETY GOALS

Prior to 1970, aircraft systems were evaluated by the FAA in accordance with the "single fault" criteria contained in Section 4b.606 of the Civil Air Regulations (restructured as Section 25.1309 of the Federal Aviation Regulations--14 CFR). With the development of more complex systems and the increasing importance of those systems, the FAA revised the rules in 1970 to require consideration of single and multiple faults in the system under study. The safety goal statements first appeared in the 1970 revisions as amendment 23. The portion of Section 25.1309, Amendment 23 of interest to us reads as follows:

The airplane systems and associated components, considered separately and in relation to other systems, must be designed so that

- (1) The occurrence of any failure condition which would prevent the continued safe flight and landing of the airplane is extremely improbable, and
- (2) The occurrence of any other failure conditions which would result in injury to the occupants, or reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions is improbable.

Warning information must be provided to alert the crew to unsafe system operating conditions, and to enable them to take appropriate corrective action. Systems, controls, and associated monitoring and warning means must be designed so that crew errors that would create additional hazards are improbable.

At the time that Amendment 23 was formally incorporated the FAA began working on an Advisory Circular that was, in effect, the implementation plan for the safety goals.¹⁴⁶ The analogous situation at NRC would be to incorporate the qualitative safety goals from NUREG-0880 in 10 CFR and to publish the implementation plan as a Regulatory Guide. The intent of the Advisory Circular was to operationalize the words "extremely improbable" and "improbable" in probability terms and to describe a means by which compliance with the regulations could be demonstrated.

Amendment 23 as reflected in Section 25.1309 was never applied in the certification of a major transport aircraft simply because none were being built that required certification between 1970 and 1977, when Section 25.1309 of 14 CFR was again modified through Amendment 41. The pertinent part of Section 25.1309, then (and now), is:

The airplane system and associated components, considered separately and in relation to other systems, must be designed so that

- (1) The occurrence of any failure condition which would prevent the continued safe flight and landing of the airplane is extremely improbable, and
- (2) The occurrence of any other failure conditions which would reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions is improbable.

Warning information must be provided to alert the crew to unsafe system operating conditions, and to enable them to take appropriate corrective action. Systems, controls, and associated monitoring means must be designed to minimize crew errors which could create additional hazards.

There were two changes in the language of FAR 25.1309 as originally put forward in Amendment 23 and its current form per Amendment 41:

- The reference to failure conditions that would result in injury to the occupants as being improbable was removed.
- The last sentence that read "Systems, controls, and associated monitoring and warning means must be designed so that crew errors that would create additional hazards are improbable." was changed to read "Systems, controls, and associated monitoring and warning means must be designed to minimize crew errors that could create additional hazards."

These changes were prompted by implementation concerns. The rationales for the changes are relevant and will be addressed following a more detailed description of the Advisory Circular.

Work on the Advisory Circular (AC) began around 1970 when FAR 25.1309 was modified through Amendment 23. There were many iterations across approximately 12 years and clearly the process has not been easy. Part of the difficulty in getting out the AC was that Amendment 23 had implementation problems that eventually led to Amendment 41 some seven years later. Throughout the time that the AC was under development, FAA and industry personnel were working with the analyses presumed to be required under the amended regulation even though no new aircraft were being certified.

The purpose of the AC is to provide guidance material for acceptable means of demonstrating compliance with the requirements of Part 25 of the Federal Aviation Regulations. The reference regulation, as was stated earlier, is Section 25.1309 (FAR) as amended through Amendment 41. The AC gives some background material on the consideration that lead to amendments and then proceeds to the following discussion:

- a. Section 25.1309 of Part 25 of the Federal Aviation Regulations, subsequent to Amendment 25-23, requires substantiation by analysis, and where necessary, by appropriate ground, flight, or simulator tests, that the probability of a failure condition is expected to remain within limits which are related to the consequence of the failure. The requirements in the referenced regulation are intended to assure an orderly and thorough evaluation of single and multiple failures involving one or more systems.
- b. Systems should be considered separately and in relation to other systems, and be designed so that the probability of the occurrence of a hazardous failure condition is low. These failure conditions, including combinations of failures which would prevent the continued safe flight and landing of the airplane, must be shown to be extremely improbable. The occurrence of any failure condition of combination of failure conditions which would reduce the capability of the crew to cope with adverse operating conditions must be shown to be improbable.
- c. The probability of the occurrence of a failure condition may be considered within three subdivisions; probable, improbable, and extremely improbable. These subdivisions are considered to overlap due to the inexact nature of probabilities. These three subdivisions may be related to the loss of airplane functions which have increasingly more severe impact on the continued safe flight and landing of the airplane.

The AC then goes on to describe analysis requirements (note that in identifying failure modes, damage from external sources is specifically mentioned) and provides a definition of terms. The probability terms are defined as follows:

1. Probable--A frequency of occurrence in an order of 1.0×10^{-5} or greater per hour of flight time. Probable events may be expected during the operational life of each airplane.
2. Improbable--A frequency of occurrence in the range from approximately 1.0×10^{-5} to 1.0×10^{-9} per hour of flight time. Improbable events are not expected to occur during the total operational life of a single airplane of a particular type, but are expected to occur during the total operational life of all airplanes of a particular type.

3. Extremely Improbable--A frequently of occurrence on the order of 1.0×10^{-9} or less per hour of flight. Extremely improbable events are so unlikely that for purposes of analysis they need not be considered, unless engineering judgment would require their consideration.

The remainder of the AC is devoted to some caveats regarding the use of the probability terms and a description of analytical techniques. Fault tree methods play an important role and NUREG-0492, "Fault Tree Handbook" is given as a basic reference. The AC carefully points out that these analytical tools are intended to supplement, but not replace, the judgment of FAA certification personnel.

The AC has stirred considerable controversy. The manufacturers of aircraft generally support the interpretation of the regulations contained in the AC while the operators (airlines) do not. The reason has to do with maintenance requirements. A newly certified aircraft has an associated maintenance plan developed by the manufacturer. The intent of the plan is to maintain the aircraft in an as-certified condition. The operators have the flexibility to modify (conditioned on FAA approval) the maintenance plan so that it fits better with other aspects of their business. They see the implementation of FAR 25.1309, Amendment 41 per the AC as sharply curtailing this flexibility because of the fixed maintenance schedules necessary to assure that probabilities of system failures remain at the certified levels.

The current form of FAR 25.1309 through the interpretation provided in the Advisory Circular clearly places an emphasis on quantitative analysis as a means of showing compliance. The changes in 25.1309, Amendment 23 per Amendment 41 described earlier were made because:

- Injury to an occupant as a result of some failure condition can depend upon the mental and physical condition of particular passengers. The FAA approach is to protect the welfare of passengers by assuring that the airplane performs as designed. For example, given that a failure condition exists that results in a rapid depressurization or loss of altitude, then the incremental risk of injury will likely not be the same for all passengers. This further consideration is beyond FAA's regulatory authority and is certainly not amenable to quantitative treatment. Had the requirement that injury to an occupant be improbable remained as part of the regulation then, presumably, some sort of consequence analysis that addressed the characteristics of individual passengers would be needed to demonstrate compliance.
- A regulation that crew errors which would create additional hazards be improbable requires a quantification of human error rates judged by the FAA and the industry to be beyond their capabilities. The NRC is struggling with similar problems regarding the performance of reactor operators and management personnel.

5.3 COMPARISON WITH NRC SAFETY GOALS

There is no question that the regulation of the civilian nuclear power industry has many complications that the FAA does not face. The need to communicate the intent of NRC regulatory decisionmaking to Congress, special interest groups, and the public is of great importance because the general perception of the risk of nuclear power, and the NRC's role in managing the risk, is greatly removed from what the actual experience has been. Hence, the NRC safety goals seem to have been derived first as a means of communicating the risks of nuclear power and second as a regulatory or policy tool. The FAA has no such problem. Their safety goal has been derived and directly utilized as a regulatory tool.

Of course, FAA has had difficult moments as well. The DC-10 accident in Chicago and TMI have remarkable similarities. In both cases the agencies are accused of having been forewarned and failing to act. The aviation industry's view of FAA's response to the DC-10 accident closely parallels the nuclear industry's view of NRC's performance during the first few hours of TMI.

The most striking difference between the two goals is that the FAA goal focuses on the performance of the system (i.e., the airplane) while the NRC goal focuses on the incremental risk to an individual and society as a result of living near a nuclear power plant. It is interesting to note that the FAA safety goal as originally stated (FAR 25.1309, Amendment 23) referenced injury to occupants of the airplane. This reference was later abandoned when the FAA ran into implementation problems. Clearly, a safety goal that addresses the performance of the system directly will be easier to implement than a safety goal that addresses system performance indirectly through the potential consequences of a system failure.

Nonetheless, there are many similarities. The major implementation tool for the FAA safety goal is probabilistic risk assessment--a methodology partly developed by NRC. The FAA safety goal has been under development for 12 years. Perhaps the NRC can benefit from this experience.

5.4 IMPLICATIONS FOR RESOLUTION OF LEGAL ISSUES

Although this review of the FAA experience is more provocative than prescriptive at this point, it does have implications for the resolution of some of NRC's legal issues.

(Of course, adoption of the FAA approach would not address all legal issues arising from the establishment of NRC safety goals.) The key implications are as follows:

1. In the second version of its policy statement, FAA moved from consequence-based statements to event-based ones. At the moment, the NRC policy statement contains both. Given that NRC has already heard from advocates of both approaches, study of FAA experience may be valuable in identifying and evaluating advantages and disadvantages of both forms of statement.

2. The tradeoff between initial design approaches versus operation and maintenance approaches is more clear-cut in the FAA, where manufacturers are separate entities from operators. The fact that manufacturers seem to like the goal statement approach more than operators suggests that here is another place where the FAA experience could help NRC identify and evaluate tradeoffs it will have to make, given its proposed approach.
3. The FAA experience suggests that a long gestation period, with difficulties along the way, is to be expected. Even with, for this context, the "luxury" of no new planes to certify, FAA had difficulty. Clearly, NRC, in its situation, must plan for an extended effort if it hopes to be successful.
4. Nonetheless, FAA has established qualitative goals, with quantitative guidelines, backed at least in part by quantitative analysis. The FAA provides evidence that progress in this direction can be made.

6.0 CONCLUSIONS AND RECOMMENDATIONS

The overall conclusion of this report is that implementation of safety goals will probably give rise to some legal problems. These problems should not be insurmountable, and NRC can take some steps to reduce their severity. Here we present some tentative recommendations for doing so, based on the three issue types discussed in Chapter 4, and the FAA experience discussed in Chapter 5.

6.1 SPECIFIC ISSUES

Specific issues are those likely to arise from the implementation of any regime of safety goals, numerical guidelines, and probabilistic risk assessment. Legal rules concerning access to the legal system, burden of proof, standard of proof, and licensing board autonomy all guarantee that intervenors will have many opportunities to exploit safety goals for their own purposes. To keep these opportunities within reasonable bounds NRC should consider providing clear direction on the conduct and use of PRAs within the safety goal regime so that courts, licensing boards, and others will not make these decisions for themselves on an ad hoc basis, creating precedents that sow confusion in an already complex arena. Useful guidance could be supplied as to when PRAs must be done, when they may not be done, and when their use is discretionary. Guidance could also be provided as to how PRAs should be done and how the results should be interpreted. Such guidance could go a long way to limiting the exploitation of safety goals and PRA for purposes inconsistent with sound regulatory practice.

6.2 GENERAL ISSUES

General issues are those arising from the particular formulation of qualitative safety goals and numerical guidelines contained in the proposed policy statement. In general, the policy statement is too elliptical. The likelihood of legal controversy could be reduced by drafting the policy statement so that necessary rationales are supplied, definitions provided, and issues discussed. In addition, discussion could be added that explicitly justified the level of safety provided by the goals and guidelines. Again such discussion could help insulate the policy statement and regulatory actions based on it from legal challenge.

6.3 IMPLEMENTATION ISSUES AND THE FAA EXPERIENCE

Implementation issues, and problems, inevitably arise when an agency moves to put the principles of a policy statement into practice, when they impact directly on interested parties and are applied to fact situations that could not have been foreseen in advance. In general, the safety goals' emphasis on risks to populations rather than systems, seems likely to make implementation particularly difficult. Therefore, NRC should give early consideration to the implementation benefits that could result from reformulation of the goals and

guidelines to correspond to the FAA approach, which emphasizes limiting the probability of system performance failures. Such an approach should help to minimize implementation and associated legal challenges.

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