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Development of Safety Goals and Implementation of the Safety Goal Policy: A Historical Perspective and the Role of the Advisory Committee on Reactor Safeguards

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Development of Safety Goals and Implementation of the Safety Goal Policy: A Historical Perspective and the Role of the Advisory Committee on Reactor Safeguards

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ABSTRACT

As part of its commitment to the U.S. Nuclear Regulatory Commission's knowledge management efforts, the Advisory Committee on Reactor Safeguards (ACRS) has begun an initiative to capture the Committee's institutional knowledge and memory. An important motivation for this initiative is to increase the effectiveness and efficiency of the Committee's review process by providing ready access to background information, insights, and understanding related to technical and regulatory issues. This report provides a historical background on the development of safety goals. It also discusses the implementation of the safety goal policy and presents an overview of past ACRS observations and recommendations for the development of the safety goals and the implementation of the safety goal policy.

The views expressed in this report are solely those of the author and do not necessarily represent the views of the ACRS.

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ABBREVIATIONS

ABWR	advanced boiling-water reactor
ACRS	Advisory Committee on Reactor Safeguards
AEC	Atomic Energy Commission
AIF	Atomic Industrial Forum
ALARA	as low as reasonably achievable
ALWR	advanced light-water reactor
CCFP	conditional containment failure probability
CDF	core damage frequency
CFR	*Code of Federal Regulations*
DG	draft regulatory guide
EAB	exclusion area boundary
EDO	Executive Director for Operations
EOP	Executive Office of the President
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
F-C	frequency-consequence
GA	General Atomics
GE	General Electric
HTGR	high-temperature, gas-cooled reactor
kWh	kilowatt hour(s)
LBE	licensing basis event
LERF	large early release frequency
LMR	liquid-metal-cooled reactor
LRF	large release frequency
LWR	light-water reactor
MWe	megawatt(s) electric
NCRP	National Council on Radiation Protection
NEI	Nuclear Energy Institute
NEIMA	Nuclear Energy Innovation and Modernization Act
NRC	U.S. Nuclear Regulatory Commission
PAG	protective action guide
PRA	probabilistic risk assessment

PSA	probabilistic safety assessment
QHO	quantitative health objective
RG	regulatory guide
SRM	staff requirements memorandum
SSC	structure, system, and component
TMI-2	Three Mile Island, Unit 2
yr	year

1 INTRODUCTION

The Atomic Energy Act of 1954 gave the Atomic Energy Commission (AEC) broad authority to establish regulations "necessary in order to enable it to find that the utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public" (Atomic Energy Act, 1954). The Atomic Energy Act did not formally define "adequate protection." Rather, Congress left it up to the AEC to give practical meaning to this term based on its technical expertise and all relevant information. Today, the U.S. Nuclear Regulatory Commission (NRC), created in 1974, operates under the same congressional authority.

The AEC safety philosophy, as summarized in a March 14, 1956, AEC letter to the Congress of the United States (AEC, 1956) (in response to a letter from Congress to the Advisory Committee on Reactor Safeguards (ACRS) on the question of public safety of nuclear reactors) was based on the proposition that the ultimate safety of the public depends on three factors:

1. Recognizing all possible accidents that could release unsafe amounts of radioactive materials.

2. Designing and operating the reactor in such a way that the probability of such accidents is reduced to an acceptable minimum.

3. By the appropriate combination of containment and isolation, protecting the public from the consequences of such an accident, should it occur. (AEC, 1956)

At the time, the operating experience with power reactors and the state of knowledge of safety analysis had not progressed to the point where it was possible to use quantitative techniques to estimate the probabilities and consequences of accidents. Instead, conservative assumptions were used to bound "real" accidents and to provide upper bounds of the potential public consequences resulting from certain hypothetical accidents (the so-called "deterministic" approach) (Nourbakhsh, et al., 2018). The fundamental concept of defense in depth was invoked to provide reasonable assurance that the facility can be operated without undue risk to public health and safety. The standard of "no undue risk" is equivalent to the "adequate protection" standard derived from the Atomic Energy Act.

In judging that there was reasonable assurance that a plant could be operated without undue risk to the public, the question of "how safe is safe enough?" was not addressed directly, nor was the residual risk that was implicitly being accepted quantified. In fact, until the publication of the landmark "Reactor Safety Study—An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants" (WASH-1400) in October 1975 (NRC, 1975), a methodology did not exist for quantitative assessment of light-water reactor (LWR) safety (Okrent, 1987).

As early as 1967, F.R. Farmer of the United Kingdom Atomic Energy Authority suggested a quantitative safety criterion for nuclear reactors based on acceptable frequency and the associated consequence of accidents (Farmer, 1967). Accident consequences were measured by the release in curies of iodine-131.

During the 1970s, more suggestions for a quantitative safety criterion were made (Okrent, 1981). In a 1973 technical report on anticipated transients without scram (WASH-1270) (AEC, 1973), the AEC regulatory staff suggested that the frequency of a serious reactor accident should be less than 10^{-6} per reactor-year. A serious accident was defined as one that led to doses exceeding those in the siting regulations (Title 10 of the *Code of Federal Regulations* (10 CFR) Part 100, "Reactor Site Criteria"), specifically 25 rem whole-body or 300 rem to the thyroid.

In 1976, the ACRS, in responding to questions from the U.S. Congress, proposed, as an interim safety criterion, the use of 10^{-6} per reactor-year for a serious accident, which the Committee defined as one having consequences similar to that of the crash of a mid-sized jet airliner. It was generally agreed that simply exceeding the limits of 10 CFR Part 100 did not necessarily constitute "serious consequences" (Okrent, 1979).

In 1979, shortly after the accident at Three Mile Island, Unit 2 (TMI-2), the ACRS recommended that the NRC consider establishing quantitative safety goals for nuclear power reactors. In its May 16, 1979, letter on quantitative safety goals, the ACRS recognized the difficulties and uncertainties in quantifying risk and acknowledged that, in many situations, engineering judgment would be the only or the primary basis for a decision. Nevertheless, the Committee believed that the existence of quantitative safety goals and criteria could provide important yardsticks for such judgment (ACRS, 1979).

The President's Commission on the Accident at Three Mile Island (Kemeny, et al., 1979) and the NRC's Special Inquiry Group (Rogovin and Frampton, 1980) both recommended that the NRC better articulate its objectives and philosophy on the adequacy of reactor safety. In response to the recommendations of the President's Commission, the NRC stated that it was "prepared to move forward with an explicit policy statement on safety philosophy and the role of safety-cost tradeoffs in the NRC safety decisions" (NRC, 1979). Thus, the task of developing quantitative safety goals for nuclear power plants was just beginning.

The ACRS was at the forefront of the development of quantitative safety goals as it developed the first set of trial goals in 1980 (ACRS, 1980a). These safety goals were the basis for the later NRC work on developing the agency's safety goal policy (NRC, 1986a).

This paper begins with the historical background of the development of safety goals. It then discusses the implementation of the safety goal policy. The paper also presents an overview of past ACRS observations and recommendations for the development of the safety goals and the implementation of the safety goal policy.

2 DEVELOPMENT OF SAFETY GOALS

2.1 The ACRS Proposed Approach to Quantitative Safety Goals

The ACRS was at the forefront of the development of quantitative safety goals. As noted before, in a letter dated May 16, 1979, the ACRS recommended that the NRC consider establishing quantitative safety goals for nuclear power reactors (ACRS, 1979). In a letter dated June 1979 to the ACRS, the Commission noted that it would appreciate any further development of the concept of quantitative safety goals that the ACRS could provide.

In a letter dated October 31, 1980 (ACRS, 1980a), the ACRS forwarded its preliminary proposal for a possible approach to quantitative safety goals. The ACRS proposed a trial approach, documented in NUREG-0739, "An Approach to Quantitative Safety Goals for Nuclear Power Plants" (ACRS, 1980b), which was intended to serve as a focus of discussion and, thus, was expected to be only a first step in an iterative process (ACRS, 1980a).

The ACRS trial approach to quantitative safety goals included the predominantly social and political task of setting the safety criteria (termed "decision rules"). The safety criteria or decision rules were as follows (ACRS, 1980a):

- Limits should be placed on the frequency of occurrence of certain hazardous conditions ("hazard states") within the reactor.
- Limits should be placed on the risk to an individual of early death or delayed death from cancer as a result of an accident.
- Limits should be placed on overall societal risk of early and delayed death.
- An "as low as reasonably achievable" (ALARA) approach should be applied with a cost-effectiveness criterion that includes both the economic costs and monetary value of preventing premature death.
- A small element of risk aversion should be applied to infrequent accidents involving large numbers of early deaths compared to a similar number of deaths caused by many accidents involving one or two deaths (that is, infrequent high-fatality accidents were given more weight).

Although the ACRS report (ACRS, 1980b) discussed the loss of societal or regional resources (e.g., an important aquifer, rich farmland) as a potentially important measure, no goals were proposed in this regard. The report acknowledged that the development of these risk measures was incomplete, and sound rationales for specific limits, if any, on such risks remained to be proposed (ACRS, 1980b).

Each decision rule on hazard states and on individual and societal risk consisted of a pair of numbers: an upper, nonacceptance limit on risk and a lower, safety goal level of risk.

The ACRS defined a tentative set of hazard states of progressive severity and proposed a preliminary set of limits on their rate of occurrence, as shown in table 1. The limit on the frequency of a large offsite release, assuming that a fuel melt has occurred, emphasized mitigation as well as prevention of serious accidents. Such a division between accident prevention and accident mitigation was believed to be necessary because of the difficulty in demonstrating with a very high degree of confidence that a frequency of large-scale fuel melt much less than the proposed goal of 10^{-4} per reactor-year can be achieved in view of the complexities introduced by factors such as sabotage, earthquakes, and other potential multiple failure scenarios (ACRS, 1980a).

Table 1 ACRS Proposed Limits on Occurrence of Hazard States (ACRS, 1980a)

Hazard State	Probability Goal	Decision Rules on Mean Frequency	
		Goal Level	Upper Limit
Significant Core Damage (> 10% of noble gas inventory leaking into primary coolant)	Less than 1/100 per reactor lifetime	$f_{cd} < 3x10^{-4}$ per reactor year	$f_{cd} < 1x10^{-3}$ per reactor year
Large Scale Fuel Melt - LSFM (> 30% of oxide fuel becoming molten)	Less than 1/300 per reactor lifetime	$f_m < 1x10^{-4}$ per reactor year	$f_m < 5x10^{-4}$ per reactor year
Large Scale Uncontrolled Release from Containment given LSFM (> 10% of Iodine inventory and 90% of noble gas)	Small, given a Large Scale Fuel Melt	$f_{R/m} < 0.01$ per LSFM	$f_{R/m} < 0.1$ per LSFM

f_{cd} is the frequency of Significant Core Damage per reactor year.

f_m is the frequency of Large Scale Fuel Melt per reactor year.

$f_{R/m}$ is the frequency of Large Scale Uncontrolled Release per Large Scale Fuel Melt.

The upper non-acceptance limits must be satisfied for extended operation of a new plant or for issuance of a construction permit. Between the upper limits and the goal levels is a discretionary range for case-by-case consideration of uncertainties and competing risk. Once the risk level decision rules have been applied, risk must still be reduced if such reduction is reasonably achievable within the cost-effectiveness criterion of Table 4.

Table 2 summarizes the ACRS proposed decision rules for risks of delayed death from cancer and of early death. The limits on risk to individuals living closest to the reactor site were set well below the sum of all other risks for any age group and below those from the principal competing source of generated electricity. Lower levels were chosen (by a factor of 5) for the risk of early death than for delayed death from cancer many years after an accident. Note that relatively few people would have risks as high as the most exposed individuals who presumably resided close to the plant site boundaries. Most people would be exposed to risks lower than the goal levels (ACRS, 1980a).

Table 2 ACRS Proposed Limits on Risks to Most Exposed Individuals (ACRS, 1980a)

Probability Goal	Mean Frequency per Site-year		Decision Rules on Mean Frequecy per Large Scale Fuel Melt-LSFM	
	Goal Level	Upper Limit	Goal Level	Upper Limit
Probability of delayed death from cancer due to all reactors at a site over lifetime of individual <0.0005	$f_d < 5\times10^{-6}$ per site-year	$f_d < 2.5\times10^{-5}$ per site-year	$f_{d/m} < 0.01$ per LSFM	$f_{d/m} < 0.05$ per LSFM
Probability of early death due to a reactor accident over lifetime of individual < 0.0001	$f_{ed} < 1\times10^{-6}$ per site-year	$f_{ed} < 5\times10^{-6}$ per site-year	$f_{ed/m} < 0.002$ per LSFM	$f_{ed/m} < 0.01$ per LSFM

f_d is the individual risk of delayed cancer death per site year.

$f_{d/m}$ is the individual risk of delayed cancer death per large scale fuel melt.

f_{ed} is the individual risk of early death per site year.

$f_{ed/m}$ is the individual risk of early death per large scale fuel melt.

The upper non-acceptance limits must be satisfied for extended operation of a new plant or for issuance of a construction permit. Between the upper limits and the goal levels is a discretionary range for case by case consideration of uncertainties and competing risks. Once the risk level decision rules have been applied, risk must still be reduced if such reduction is reasonably achievable within the cost-effectiveness criteria of Table 4.

Table 3 summarizes the ACRS proposed decision rules for the societal risks to most exposed individuals. In its proposed approach, the ACRS suggested that the social cost of delayed cancer deaths should be assessed as equal to the calculated number of fatalities. An estimated 10 to 200 people would die from the pollution arising from a coal-fired plant that generates 10^{10} kilowatt hours (kWh). The ACRS proposed 10 as the upper, nonacceptance limit on the delayed cancer deaths due to a nuclear power plant. The goal level was proposed to be less than two cancer fatalities per 10^{10} kWh. To provide incentives to reduce the catastrophic potential of accidents, the ACRS proposed to assess the equivalent social cost of early deaths with a value of slightly larger than unity (risk aversion coefficient of 1.2 for early deaths in table 3). The limits on equivalent early deaths were reduced by the same factor of 5 from the delayed death limits as was chosen for the limits on individual risk (ACRS, 1980a).

Table 3 ACRS Proposed Limits on Societal Health Risks (ACRS, 1980a)

Measure of Risk	Decision Rules on Societal Health Risks	
	Goal Level	Upper Non-Acceptance Limit
E_d = the expected value of: $\sum$ (Frequency) (Delayed Cancer Deaths) accidents and normal operation	$E_d < 2$ per 10^{10} kWh	$E_d < 10$ per 10^{10} kWh
E_{ed} = the expected value of: $\sum$ (Frequency) $(\text{Early Deaths})^{1.2}$ accidents	$E_{ed} < 0.4$ per 10^{10} kWh	$E_{ed} < 2$ per 10^{10} kWh

E_d is the average number of delayed cancer deaths per 10^{10} kWh of electricity generated.

E_{ed} is the average number of equivalent early deaths per 10^{10} kWh of electricity generated.

10^{10} kWh is the amount of electricity generated by a large (1200 MWe) power plant operating at full capacity for one year.

The upper non-acceptance limits must be met for extended operation of a new plant or for issuance of a construction permit. Between the upper limits and the goal levels is a discretionary range for case by case consideration of uncertainties and competing risk. Once the risk level decision rules have been applied, risk must still be reduced if such reduction is reasonably achievable within the cost-effectiveness criteria of Table 4.

The ACRS proposed to use an ALARA cost-effectiveness criterion to judge whether additional risk reduction is required beyond that level of safety needed to meet the other decision rules. The cost of an improvement would be balanced against the combined change in economic losses and in the risk of delayed cancer deaths and equivalent early deaths. The ACRS acknowledged that while there is some limit on how much the United States can afford to spend to reduce risk from all of its technological activities, lest economic instability lead to greater risk directly or indirectly, the current perspective on nuclear may be such that society is willing to spend more for LWR safety than for many other things. It was tentatively proposed that the marginal cost limit on expenditures be set at $1 million per delayed cancer death averted and $5 million per equivalent early death averted, when “equivalent” early deaths are calculated using the coefficient of 1.2 for risk aversion. It was anticipated that careful study would be required to quantify the economic losses due to property and resource damage. Because of uncertainties and because some impacts cannot be quantified, the ACRS proposed that the marginal cost limit on expenditures to reduce adverse economic impacts be twice the expected reduction in impact when applying the ALARA criterion. This also stresses prevention rather than repair of possible damage. Table 4 summarizes the quantified ALARA criteria (ACRS, 1980a).

Table 4 ACRS Proposed Quantified ALARA Cost-Effectiveness Criteria (ACRS, 1980a)

Expenditure Limits for Impact Reduction	
\$1 million per delayed cancer death averted	$\$1 \times 10^6/(\Delta E_d\ L)$
\$5 million per early equivalent death averted	$\$5 \times 10^6/(\Delta E_{ed}\ L)$
2 times the economic loss (due to resource damage) averted	$2/(\Delta E_r\ L)$
A particular improvement is "cost-effective" and required if $\text{Cost} \leq [\,2\Delta E_r + (\$5\times10^6)(\Delta E_{ed}) + (\$1\times10^6)(\Delta E_d)]\ L$	

ΔE_d is the change (due to the proposed improvements) in the expected value of:

$$\sum_{\substack{\text{accidents}\\ \text{and}\\ \text{normal}\\ \text{operation}}} (\text{Frequency})(\text{Delayed Cancer Deaths})$$

ΔE_{ed} is the change (due to the proposed improvements) in the expected value of:

$$\sum_{\text{accidents}} (\text{Frequency})\ (\text{Early Deaths})^{1.2}$$

ΔE_r is the change (due to the proposed improvements) in the expected value of:

$$\sum_{\text{accidents}} (\text{Frequency})\ (\text{Economic Losses})$$

L is the remaining lifetime of the plant in units of 10^{10} kWh to be generated and the frequencies are calculated per 10^{10} kWh. This is the amount of electricity generated by a large (1200 MWe) plant operating at full capacity for one year.

The ACRS report on approaches to quantitative safety goals also dealt with the technical tasks of risk quantification. The Committee acknowledged that there would be both large uncertainties in such risk estimates and significant differences between independent estimates of the same risk. The ACRS noted that the form of the decision rules was intended to compensate in part for some of this uncertainty. Limits were placed on the expected values of the various risks. These expected values are the weighted average of the probabilities and therefore reflect some of the uncertainties. Also, limits were placed on both the risk of a damaging accident to the fuel and on the risk of a large release of radioactive material assuming the occurrence of fuel damage, thereby requiring both prevention and mitigation (ACRS, 1980a).

2.2 Other Early Safety Goal Proposals

The ACRS proposed trial approach was the only safety goal proposal that was formally presented to the Commission for consideration or for discussion. However, other proposals were elaborated in varying degrees or widely communicated at the time (NRC, 1981a). Some of those proposals are briefly discussed below.

2.2.1 Atomic Industrial Forum

In May 1981, the Atomic Industrial Forum (AIF) proposed an approach to the establishment and use of quantitative safety goals in the nuclear regulatory process (AIF, 1981). The AIF proposal had been presented earlier to the ACRS Subcommittee on Reliability and Risk Assessment on July 1, 1980. The AIF proposal contained primary goals that placed limits on individual and aggregated population health effects. Its secondary goals focused on the probability of large-scale fuel melt and on the cost-effectiveness of reducing population radiation exposures due to accidents.

Table 5 summarizes the AIF-proposed quantitative safety goals. The proposed limit on individual health effects was intended to make the incremental risk of adverse health effects to the maximally exposed individual in the vicinity of a nuclear plant site not to result in a significant increase in annual mortality risk or in significant shortening of expected statistical life span. This was interpreted in terms of a surrogate goal of 10^{-5}/year individual mortality risk (mean value).

Table 5 AIF Proposed Quantitative Safety Goals

Primary Goals	
Individual Risk	**Population Risk**
< 10^{-5}/year individual mortality risk (mean value)	< 0.1 fatality/year per 1,000 MW(e) (mean value)
Secondary Goals	
Cost-Benefit Criteria	**Serious Core Degradation**
$100/man-rem	< 10^{-4} per reactor-year

The proposed limit on population health effects was intended to make the incremental cumulative risk of adverse health effects to the exposed population per 1,000 megawatts electric (MW(e)) of nuclear power capacity, considering the probability and consequences of events integrated over the spectrum of potential accidents, not to be more than a small fraction of the averaged background incidence of health effects. This was reflected in a suggested goal of 0.1 fatality/year per 1,000 MW(e) (mean value).

The AIF suggested that decisions for improvements beyond the safety goal and for possible exemption from it should be guided by cost-benefit analyses. A numerical criterion of $100/man-rem was suggested. The criterion was based on the principle that the benefit in terms of population risk reduction afforded by a change in plant design or operating procedure should be comparable to that which is generally achievable through alternative investments of the cost of the change in other areas of public risk reduction. The numerical criterion of $100/man-rem (which was lower than the $1,000/man-rem for ALARA criterion in radiation protection) was said to be equivalent to $1 million per life saved and was considered comparable to median cost-benefit ratios for other health and safety protective measures. The AIF proposed that the ALARA criterion be used only in the evaluation of backfitting (that is, the requirement for additional safety measures in a plant that had already received a construction permit or operating license).

The AIF also proposed a limit on the probability of accidents involving serious core degradation so that, for an expected population of reactors, the recurrence interval for accidents as serious as TMI-2 be on the order of one per several decades. This was reflected in terms of a core degradation frequency limit of 10^{-4} per reactor-year. It was argued that such a limit establishes minimum requirements for accident prevention, prevents undue emphasis on mitigation, reduces the frequency of stress-provoking events for populations near plants, and limits the economic risks of accidents.

The AIF called for use of probabilistic risk assessment (PRA) to support deterministic requirements. The AIF also recommended that PRA be used in interpreting the goals in terms of generic requirements, but not as a licensing condition for individual plants. The AIF proposal would depend primarily on generic or surrogate risk analyses.

The AIF proposed the following cautions in setting quantitative safety goals:

- The suggested numerical values should be used with mean values of risk. Higher values would be appropriate for more conservative estimates of risk.
- The initial set of values should be interim, for trial use for a period of 3 years.
- Qualitative judgment must supplement quantitative goals. This is particularly important in borderline cases.

2.2.2 Electric Power Research Institute

Chauncy Starr of the Electric Power Research Institute (EPRI) advocated a safety goal approach that would build heavily on nuclear industry's economic self-interest in safety (Starr, 1981). He argued that the economic requirements for the protection of investment in the plant may often be a more demanding safety constraint than social acceptability based on hazard to the public.

Criteria were proposed for both an acceptable upper bound of nuclear power plant risk and a lower bound as a design target. The lower design target and the upper bound were considered to provide a margin for uncertainty in the probabilistic estimate. It was argued that the combination of a low probabilistic design target with this margin provides a reasonable expectation that the overall performance would be in the domain of an acceptable risk level (Starr, 1981). It was suggested that the upper bound be set at a risk level equivalent to those risks of routine living that are normally accepted (i.e., about 10^{-4} deaths per year (yr) per person (100 deaths/yr/million). The proposed lower design target is 10^{-8} (0.1 deaths/yr/million), about one-hundredth of the minimal risk from the natural hazards to which all people are exposed (Starr, 1981).

Starr's proposal included recognition that the licensees' self-motivated safety goals needed to be supplemented by NRC requirements, in two respects. First, the NRC should establish design criteria for systems that protect the public but not the plant (remote siting and reactor containment). Second, the NRC should check that the industry acts in accordance with its own financial interest by requiring good engineering and management practices in siting, design, construction, and operation.

2.2.3 General Atomic Company

Voin Joksimovic and L.F. O'Donnell of General Atomics (GA) proposed an approach that was centered around definition of quantitative safety regions (Joksimovic and O'Donnell, 1981). The regions were termed design basis, safety margin or design capability, and safety research. The GA proposal had been presented earlier to the ACRS Subcommittee on Reliability and Risk Assessment in July 1980.

The design-basis (prevention) region was proposed to be bounded by the frequency of 10^{-4}/reactor-year and the consequences of no identifiable public injury. Events that have a 50 percent chance of happening were included in the design-basis region. The frequency of 10^{-4}/reactor-year was associated with the total projected lifetime of a commercial U.S. nuclear power program.

In the safety margin or design capability (mitigation) region, which extends below the design-basis region, protection was provided against some events whose probability of not happening during the expected course of the U.S. nuclear power program was within the range of 50 to 90 percent. Setting the lower mean frequency to this region of 10^{-5}/reactor-year. Rare events with a mean frequency below 10^{-5} could be predicted to occur. However, accidents predicted to have a probability of less than 10^{-6} were 99 percent certain not to happen at all and were thus not expected to affect public health and safety. The area between 10^{-5} and 10^{-6} defined the frequency portion of the safety research region. Accidents predicted to carry that degree of risk and that could result in injury to the public were considered to be candidate subjects for safety research studies (Joksimovic and Houghton, 1981). It was acknowledged that the results of such studies had to be examined with great care to determine more exactly in which region certain frequencies and degrees of consequences belonged, and it might take several years to perform such studies. In the meantime, this approach advocated that the designers build into their plants the capacity to mitigate such events until their insignificance could be confirmed (Joksimovic and Houghton, 1981).

For the acceptable individual and societal risks, a "limit line" approach was proposed. The limit lines were the plots of consequences as a function of the annual probability with which such consequences may acceptably occur. Figure 1 depicts the individual risk limit line proposed by GA. The protective action guides (PAGs) of the U.S. Environmental Protection Agency (EPA) (EPA, 1975) limit the acceptable dose of radiation to an individual in the event of a nuclear incident to a whole-body exposure of less than 5 rem. GA proposed 5 rem as the consequence limit for an event whose risk is determined to be in the range of 10^{-4}/ reactor-year (refer to figure 1), based on its conclusion that both the EPA rules and information reported by the National Council on Radiation Protection (NCRP) (NCRP, 1971) implied that a single such exposure would result in no identifiable injury to any member of the public (Joksimovic and Houghton, 1981). The individual risk limit line drawn in figure 1 is also consistent with the dose limit of

5 millirem per reactor-year from normal nuclear plant operations and radioactive emissions given in Appendix I, “Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion ‘As Low as is Reasonably Achievable’ for Radioactive Material in Light- Water-Cooled Nuclear Power Reactor Effluents,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities.”

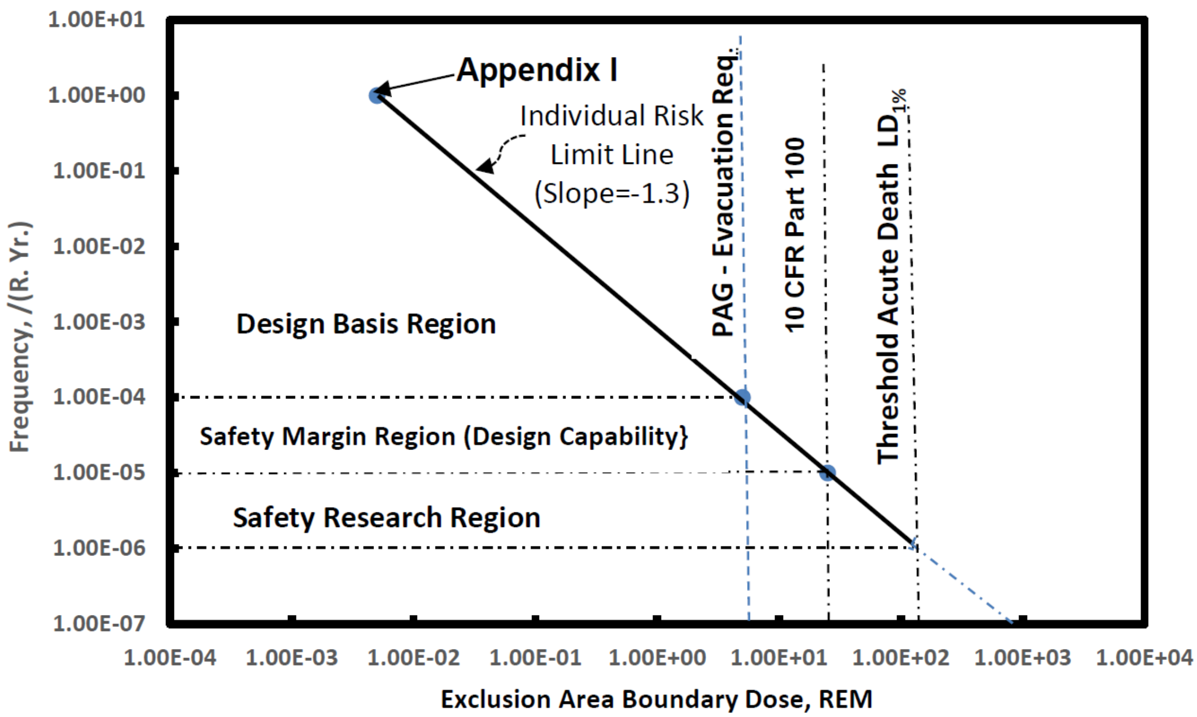

Figure 1 GA-Proposed Quantitative Safety Goal—Individual Risk to Maximum Exposed Member of the Public (Adapted from Joksimovic and Houghton, 1981)

Two alternative limit lines were proposed for the societal risk as shown in figure 2. One, reflecting “a balanced risk policy,” established a 10^{-4}/reactor-year probability limit on accidents causing 100 latent cancer fatalities. The other, based on an “emphasized risk policy,” would limit fatalities at that probability level to 0.1.

A limit line was also constructed in terms of frequency of and dollar value of property damage of accidents. This limit was developed quite independently of the Price-Anderson regime and did not address the issues of indemnification or liability limitations. It was, however, consistent with insurance underwriting practice to the extent that accidents with a frequency in the neighborhood of 10^{-5} having a damage potential of $300 million represented the upper limit of insurability at the time. The slope of the limit line was set at -1.0 to reflect an equi-risk approach, which was considered appropriate for commercial practice (Joksimovic and Houghton, 1981).

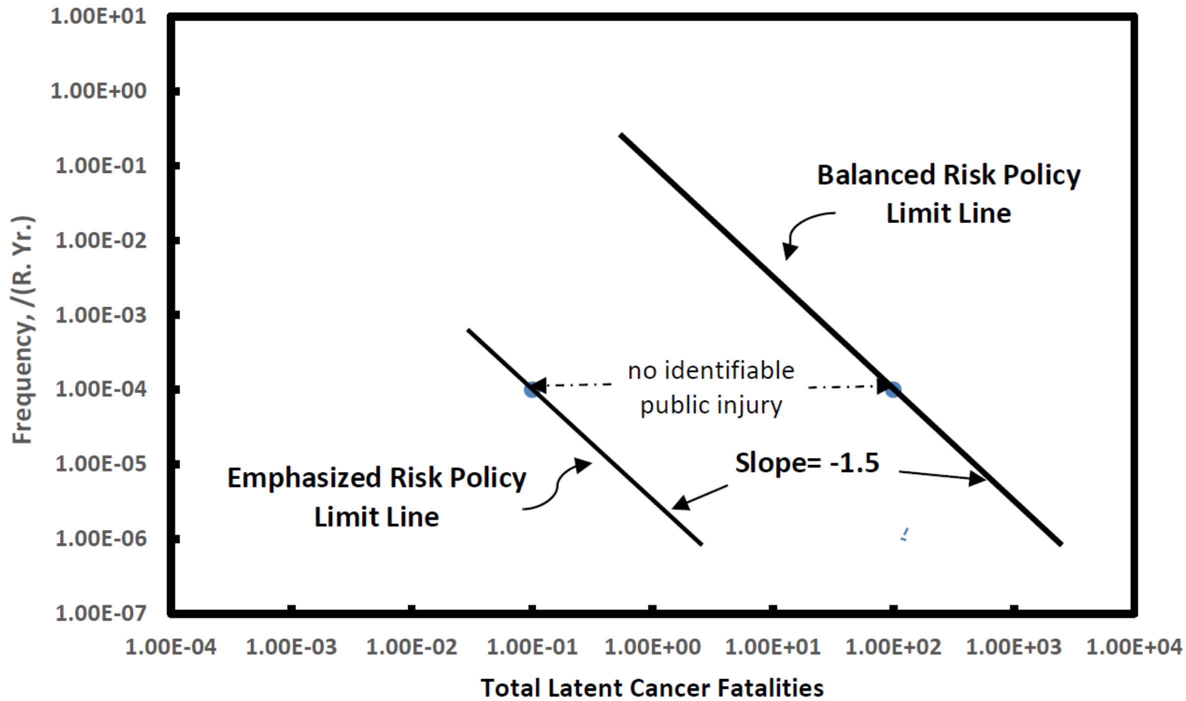

Figure 2 GA-Proposed Quantitative Safety Goal—Societal Risk (Adapted from Joksimovic and Houghton,1981)

2.3 NRC Proposal on Safety Goals

In the fall of 1980, the Commission instituted a project to state explicitly the level of protection that it believed adequate to ensure public safety with regard to nuclear reactor accidents and, to that end, issued a plan for developing a safety goal (NRC, 1980). The Commission subsequently issued a preliminary statement of policy considerations that may enter into an articulation of the NRC's statement of its safety goal. The Commission's statement, along with a more detailed discussion, was published as NUREG-0764, "Toward a Safety Goal Discussion of Preliminary Policy Considerations," issued March 1981 (NRC, 1981a).

Recognizing the need for a broad range of perspectives for narrowing safety goal options for further consideration, the NRC sponsored a workshop in Palo Alto, California, on April 1–3, 1981 (NRC, 1981b). The ACRS proposed approach to quantitative safety goals (ACRS, 1980b), "to serve as one focus for discussion," was used as one example of a concrete application of the concepts discussed. This workshop illuminated many important issues of safety goal formulation, including both qualitative and quantitative elements and economic, ethical, social, and political issues, as well as technical considerations

A second NRC-sponsored workshop held in Harpers Ferry, West Virginia, on July 23–24, 1981 (NRC, 1981c), addressed a reference safety goal statement (NRC, 1981d) and explored significant alternatives. Like the first workshop, it featured discussions among representatives from industry, public interest groups, universities, and elsewhere, with a broad range of perspectives and disciplines.

In February 1982, the Commission issued for public comment a proposed policy statement on safety goals for nuclear power plants (NRC, 1982a) and a report discussing the development of the proposed policy statement (NRC, 1982b). The Commission proposed to adopt two qualitative safety goals supported by provisional numerical guidelines.

Qualitative Safety Goals

The proposed qualitative goals (NRC, 1982a) were as follows:

- Individual members of the public should be provided a level of protection from the consequences of 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 should be as low as reasonably achievable and should be comparable to or less than the risks of generating electricity by viable competing technologies.

Provisional Numerical Guidelines for Individual and Societal Risk

The Commission (NRC, 1982a) proposed the following two provisional numerical guidelines for the individual and societal mortality risks:

- The risk to an individual or to the population in the vicinity of a nuclear power plant site of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.

- The risk to an individual or to the population in the area near a nuclear power plant site of cancer fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes.

In applying the numerical guideline for prompt fatalities as a population guideline, the Commission proposed to define the vicinity as the area within 1 mile of the nuclear power plant site boundary.

In applying the numerical guideline for cancer fatalities as a population guideline, the Commission proposed that the population considered subject to significant risk be the people within 50 miles of the plant site.

Cost-Benefit Guideline

The Commission proposed (NRC, 1982a) the following cost-benefit guideline for use in decisions on safety improvements that would reduce individual and societal risks below the levels specified in the first and second numerical guidelines in accordance with the ALARA principle:

- The benefit of an incremental reduction of risk below the numerical guidelines for societal mortality risks should be compared with the associated costs on the basis of $1,000 per man-rem averted.

Plant Performance Guideline for Large-Scale Core Melt

Because of the substantial uncertainties inherent in PRAs of potential reactor accidents, especially in evaluation of accident consequences, the Commission proposed a limitation on the probability of a core melt as a provisional guideline for the NRC staff to use in reviewing and evaluating PRAs of nuclear power plants (NRC, 1982a):

- The likelihood of a nuclear reactor accident that results in a large-scale core melt should normally be less than one in 10,000 per year of reactor operation.

The Commission also recognized the importance of mitigating the consequences of a core-melt accident and emphasized containment, remote siting, and emergency planning as integral parts of the defense-in-depth concept (NRC, 1982a).

Implementation

The Commission's intention was that the NRC staff would use the goals and guidelines in conjunction with PRAs and would not substitute them for the agency's reactor regulations (NRC, 1982a).

The Commission stated that in all applications of the goals and guidelines, the PRAs, if performed, should be documented, along with the associated assumptions and uncertainties, and considered as just one factor among others in the regulatory decision-making process. The nature and extent of the consideration given to the numerical guidelines in individual regulatory decisions would depend on the issue itself, the quality of the data base, and the reach and limits of analyses involved in the pertinent probabilistic calculations. The proposed numerical guidelines should aid professional judgment, not replace judgment with mathematical formulas (NRC, 1982a).

The Commission also asked the staff to develop a specific action plan for implementing the proposed qualitative safety goals and numerical guidelines. The plan should indicate for Commission review and approval how the NRC staff plans to use the goals and guidelines in conjunction with the PRAs (NRC, 1982a). The Commission would consider this plan, along with the public comments on the proposed policy statement and the discussion paper (NRC, 1982b), in reaching a final decision on the adoption of a reactor safety policy statement and its associated goals and guidelines (NRC, 1982a).

2.4 Policy Statement on Safety Goals for the Operation of Nuclear Power Plants—1983

In response to the comments from the ACRS, the industry, and the public on the proposed policy statement, in 1983, the Commission issued a revised policy statement on safety goals for a 2-year evaluation period (NRC, 1983a). The Commission also issued an evaluation plan describing the activities to be performed during the evaluation of the safety goals and solicited comments on that plan (NRC, 1983b).

The objective of the Commission's policy statement was "to establish goals which limit to an acceptable level the radiological risk which might be imposed on the public as a result of nuclear power plant operation" (NRC, 1983a). While this policy statement included the risks of normal operation, as well as accidents, the Commission believed that risks from routine emissions are small and therefore do not need to be routinely analyzed on a case-by-case basis in order to demonstrate conformance with the safety goals (NRC, 1983a).

The risks from the nuclear fuel cycle were not included in the safety goal. These had been considered in their own right and determined to be quite small. The possible effects of sabotage or diversion of nuclear material were also not included in the safety goal because there is no basis for measuring risk in these cases. It was the Commission's intention that everything necessary would be done to keep such risks very low (NRC, 1983a).

Qualitative Safety Goals

The two qualitative safety goals were changed in only one significant way. The second goal now omitted the statement that risks "should be as-low-as-reasonably-achievable." Thus, the Commission's qualitative safety goals were as follows (NRC, 1983a):

- Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.

- Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

Quantitative Design Objectives

The previous "provisional numerical guidelines" were now termed "quantitative design objectives." The Commission adopted the following two design objectives (NRC, 1983a):

- The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1%) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.

- The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1%) of the sum of cancer fatality risks resulting from all other causes.

In applying the design objective for individual risk of prompt fatality, the vicinity was defined as the area within 1 mile of the nuclear power plant site boundary. If no individuals reside within a mile of the plant boundary, then the vicinity should be taken as a 1-mile annulus measured outward from the location of the first individual (NRC, 1983a).

In applying the design objective for cancer fatalities as a population guideline, the Commission proposed that the population within 50 miles of the plant site generally be considered subject to significant risk.

Cost-Benefit Guideline

The Commission (NRC, 1983a) adopted the following cost-benefit guideline for use as one consideration in decisions on safety improvements:

- The benefit of an incremental reduction of societal mortality risks should be compared with the associated costs on the basis of $1,000 per person-rem averted.

The guideline of $1,000 per person-rem averted was adopted for trial use. The value was in 1983 dollars which should be modified to reflect general inflation in the future (NRC, 1983a).

The 1983 policy statement on safety goals stated that the "application of the cost-benefit guideline should be focused principally on situations where one of the quantified safety goals is not met. No further cost-benefit analysis should be made when it is judged that all of the design objectives have been met." The policy statement continues, "this guideline does not replace the Commission's backfitting regulation (10 CFR 50.109)" (NRC, 1983a). The main change from the 1982 proposed cost-benefit guideline was that now its application was restricted to decisions about whether to backfit plants that did not meet the safety goals, but not to measure possible safety improvements if the safety goals were met.

Plant Performance Design Objective

To ensure emphasis on accident prevention, the Commission (NRC, 1983a) adopted the following limitation on the probability of a large-scale core melt as a design objective:

- The likelihood of a nuclear reactor accident that results in a large-scale core melt should normally be less than one in 10,000 per year of reactor operation. [NRC, 1983a]

The design objective for large-scale core melt is subordinate to the principal design objectives limiting individual and societal risks. The policy statement also stated that "this design objective may need to be revised as new knowledge and understanding of core performance under degraded cooling conditions are acquired" (NRC, 1983a).

The Commission also recognized the importance of mitigating the consequences of a core-melt accident and continued to "emphasize features such as containment, siting in less populated areas, and emergency planning as integral parts of the defense-in-depth concept" (NRC, 1983a).

Implementation

The qualitative safety goals supported by the quantitative design objectives were being adopted for use during a 2-year evaluation period. The Commission believed that an evaluation period was necessary to judge the effectiveness of the goals and design objectives (NRC, 1983a). The policy statement noted that, at the end of the evaluation period, the Commission would consider changes in the regulations and regulatory practices that appear necessary in light of experience during the 2 years (NRC, 1983a).

The policy statement also said that the qualitative safety goals and quantitative design objectives in the Commission's policy statement would not be used in the licensing process or be interpreted as requiring the performance of PRAs by applicants or licensees during the evaluation period. The goals and objectives were also not to be litigated in the Commission's hearings. The Commission directed the staff to continue using conformance to regulatory requirements as the exclusive licensing basis for plants (NRC, 1983a).

2.5 Evaluation of the 1983 Safety Goals

As part of the 2-year evaluation of the 1983 safety goal policy statement, retrospective comparisons of a few generic regulatory actions with the safety goals were made (NRC, 1985a). The results of these comparisons were not intended to alter or support previous regulatory decisions, but to determine whether and how the decision processes might have been changed by use of the safety goals as guidelines. The decisions made were generally consistent with the decisions suggested by the safety goals. However, this judgment was contingent on how the safety goals were applied, how the quantitative uncertainties were viewed, and how relevant factors outside the safety goals were taken into account (NRC, 1985a).

The NRC also established a steering group of senior NRC staff members to review the safety goals. Some of the steering group recommendations suggested significant changes in the proposed 1983 safety goal policy statement. The ACRS reviewed the Safety Goal Evaluation Steering Group report (NRC, 1985b). In its July 17, 1985, letter (ACRS, 1985), the ACRS agreed with many of the findings and conclusions of the NRC Staff Safety Goal Steering Group, including the following:

- PRA methods and resulting insights have proven to be very valuable in establishing priorities for regulatory activities, the development of regulatory positions on generic safety issues, and the assessment of plant-specific safety issues.

- PRA has limitations that must be understood when the results are used. The results of a PRA should normally be used in conjunction with traditional safety review methods in making regulatory decisions.

- The statement of the Qualitative Safety Goals in the 1983 Safety Goal Policy Statement is satisfactory.

- For sites where no people reside within a mile of the site boundary, for purposes of calculation of early fatalities, an individual should ordinarily be assumed to reside one mile from the site boundary.

- In applying the latent cancer fatality numerical guideline, we agree with the Steering Group that it is better to consider the population within 10 miles of the site, rather than 50 miles as proposed in the 1983 Policy Statement. This goal is not a societal risk goal but an individual risk goal because it is not related to the number of persons affected. Consideration should be given to the use of a one-mile distance, as suggested by Mr. Denton.

- We support the general principle that no more than about 10 percent of any quantitative design objective should be accounted for by a single major issue or accident.

The July 17, 1985, ACRS letter also stated that the Committee believed that "greater attention should be placed on working toward an objective of a mean-core-melt frequency of 10^{-4} per reactor year and use of a containment performance objective." The Committee was concerned that "the Safety Goal Policy Statement may not give sufficient emphasis to defense-in-depth and may place too much emphasis on benefit-cost analyses" (ACRS, 1985).

The ACRS also reviewed a February 14, 1986, memorandum from V. Stello, Acting Executive Director for Operations (EDO), to the Commission on Safety Goal Policy (NRC, 1986b). In its March 19, 1986, letter (ACRS, 1986a), the Committee made several comments on the EDO's memorandum including the following:

- The safety goal policy should include the two qualitative goals of the general form recommended by the EDO.

  However, we are divided on whether the second qualitative safety goal should be modified to say that the societal risks to life and health from nuclear power plant operation should be less than the risks of generating electricity by viable competing technologies (rather than "comparable to or less than," as stated in the 1983 Safety Goal Policy).

- The safety goal policy statement should include explicitly the two quantitative health effect objectives. We disagree with the NRC Staff that these quantitative objectives should not appear as discrete statements of expectation in the policy statement.

- We have considerable concern that quantitative cost-benefit analysis will become a major factor, if not the major factor, in decision making on safety issues, rather than being treated as only one attribute of the judgmental process.

- We fail to see appropriate guidance for including uncertainties in decision making. The calculation of best estimate rather than conservative values, together with a full display of uncertainties, assumptions, and omissions, will be in the right direction. How to factor this highly uncertain information into specific decisions remains to be determined.

In its April 15, 1986, letter (ACRS, 1986b), the ACRS recommended some additional changes, including a new guideline related to containment performance: "the chance of a very large release of radioactive materials to the environment should be less than 10^{-6} per reactor-year."

2.6 Final Policy Statement on Safety Goals for the Operation of Nuclear Power Plants—1986

In August 1986, the Commission issued a final policy statement on safety goals (NRC, 1986a). Agreement on the statement was reached under the aegis of retiring NRC Chairman Nunzio J. Palladino (also a former ACRS member) in late June, but the statement was signed by Lando W. Zech, Jr., the new NRC chairman. Commissioners James Asselstine, Fredrick Bernthal, and Thomas Roberts concurred, but the first two voiced additional views.

In developing the final policy statement, the Commission used the staff report and the recommendations that resulted from the 2-year evaluation of safety goals. Additionally, the Commission had the benefit of further comments from the ACRS and senior NRC management.

The Commission decided to adopt qualitative safety goals that are supported by quantitative health effects objectives for use in regulatory decision-making.

Qualitative Safety Goals

The Commission determined that the qualitative safety goals would remain unchanged from its March 1983 revised policy statement. Thus, the Commission's two safety goals are as follows (NRC, 1986a):

- Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.

- Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

The policy statement omitted the quantitative objective on core-melt frequency and the quantitative cost-benefit criterion. The final safety goal policy statement (NRC, 1986a) also stated the following, which represented a major change from the 1983 draft policy statement:

> Severe core damage accidents can lead to more serious accidents with the potential for life-threatening offsite release of radiation, for evacuation of members of the public, and for contamination of public property. Apart from their health and safety consequences, severe core damage accidents can erode public confidence in the safety of nuclear power and can lead to further instability and unpredictability for the industry. In order to avoid these adverse consequences, the Commission intends to continue to pursue a regulatory program that has as its objective providing reasonable assurance, while giving appropriate consideration to the uncertainties involved, that a severe core damage accident will not occur at a U.S. nuclear power plant.

Quantitative Objectives Used to Gauge Achievement of the Safety Goals

Of the quantitative design objectives in the 1983 revised policy statement, the Commission decided to adopt only the following two health effects as quantitative objectives for mortality risks to be used in determining achievement of the qualitative safety goals (NRC, 1986a):

- The risk to an average individual in the vicinity of a nuclear power plant of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.

- The risk to the population in the area near a nuclear power plant of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

The Commission believed that this ratio of 0.1 percent appropriately reflects both of the qualitative goals to provide that individuals and society bear no significant additional risk. However, this does not necessarily mean that additional risk that exceeds 0.1 percent would by itself constitute a significant additional risk. The 0.1 percent ratio to other risks is low enough to support an expectation that people living or working near nuclear power plants would have no special concern due to the plant's proximity (NRC, 1986a).

In applying the objective for individual risk of prompt fatality, the Commission defined the vicinity as the area within 1 mile of the nuclear power plant site boundary, since calculations of the consequences of major reactor accidents suggest that individuals within a mile of the plant site boundary would generally be subject to the greatest risk of prompt death attributable to radiological causes. If no individuals reside within a mile of the plant boundary, an individual should, for evaluation purposes, be assumed to reside 1 mile from the site boundary (NRC, 1986a).

In applying the objective for cancer fatalities as a population guideline for individuals in the area near the plant, the Commission defined the population generally considered subject to significant risk as those living within 10 miles of the plant site. Because the bulk of significant exposures of the population to radiation would be concentrated within this distance, this is the appropriate population to use in comparing with cancer fatality risks from all other causes (NRC, 1986a).

Treatment of Uncertainties

The policy statement asserted that "to the extent practicable, the Commission intends to ensure that the quantitative techniques used for regulatory decision-making take into account the potential uncertainties that exist so that an estimate can be made on the confidence level to be ascribed to the quantitative results" (NRC, 1986a).

The Commission adopted the use of mean estimates for purposes of implementing the quantitative objectives of the safety goal policy. The policy statement (NRC, 1986a) noted the following:

> Use of mean estimates does not however resolve the need to quantify (to the extent reasonable) and understand those important uncertainties involved in the reactor accident risk predictions. A number of uncertainties (e.g., thermal-hydraulic assumptions and the phenomenology of core-melt progression, fission product release and transport, and containment loads and performance) arise because of a direct lack of severe accident experience or knowledge of accident phenomenology along with data related to probability distributions.

The policy statement specified that "in such a situation, it is necessary that proper attention be given not only to the range of uncertainty surrounding probabilistic estimates, but also to the phenomenology that most influences the uncertainties" (NRC, 1986a).

The policy statement (NRC, 1986a) also noted the following:

> Depending on the decision needs, the probabilistic results should also be reasonably balanced and supported through use of deterministic arguments. In this way, judgements can be made by the decisionmaker about the degree of confidence to be given to these estimates and assumptions. This is a key part of the process of determining the degree of regulatory conservatism that may be warranted for decisions. This defense-in-depth approach is expected to continue to ensure the protection of public health and safety.

Guidelines for Regulatory Implementation

The Commission approved use of the qualitative safety goals, including the quantitative health effects objectives, in the regulatory decision-making process. The Commission recognized that "the safety goal can provide a useful tool by which the adequacy of regulations or regulatory decisions regarding changes to the regulations can be judged" (NRC, 1986a). However, to do this, the policy statement asserted that the staff would require specific guidelines to use as a basis for determining whether a level of safety ascribed to a plant is consistent with the safety goal policy. As a separate matter, the Commission intended to review and approve guidance to the staff regarding such determinations. The policy statement (NRC, 1986a) further noted that the guidance would be based on the following general performance guideline, which was proposed by the Commission for further staff examination:

> Consistent with the traditional defense-in-depth approach and the accident mitigation philosophy requiring reliable performance of containment system, the overall mean frequency of a large release of radioactive materials to the environment from a reactor accident should be less than 1 in 1,000,000 per year of reactor operation.

The policy statement (NRC, 1986a) also specified the following:

> …to provide adequate protection of the public health and safety, current NRC regulation, require conservatism in design, construction, testing, operation and maintenance of nuclear power plants. A defense-in-depth approach has been mandated in order to prevent accidents from happening and to mitigate their consequences. Siting in less populated areas is emphasized. Furthermore, emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding population.

The policy statement (NRC, 1986a) also noted the following:

> These safety goals and these implementation guidelines are not meant as a substitute for NRC's regulations and do not relieve nuclear power plant permittees and licensees from complying with regulations. Nor are the safety goals and these implementation guidelines in and of themselves meant to serve as a sole basis for licensing decisions. However, if pursuant to these guidelines, information is developed that is applicable to a particular licensing decision, it may be considered as one factor in the licensing decision.

3 IMPLEMENTATION OF THE SAFETY GOAL POLICY

3.1 Plans for Safety Goal Policy Implementation

In January 1987, the staff proposed an implementation plan for the 1986 Policy Statement on Safety Goals for the Operations of Nuclear Power Plants (NRC, 1987a). This topic was discussed during several ACRS meetings in 1987. In its May 13, 1987, report (ACRS, 1987), the ACRS did not consider the staff proposal suitable as a plan for implementing the safety goal policy. Instead, the Committee proposed a plan with three elements:

(1) Use of safety goal criteria by the NRC Staff to judge the adequacy of regulation rather than to make regulatory judgments about specific plants.

(2) Recognition and formulation of an explicit hierarchical structure among the interrelated criteria in the overall goal.

(3) Continuation of a program to make risk estimates for specific plants, as a sampling process to assist in the evaluation of regulation.

In its May 13, 1987, report (ACRS, 1987), the ACRS also recommended a hierarchical arrangement of the multiple goals in the policy statement as presented below.

~ Level One: This would be the pair of qualitative goals as stated in the Commission Policy Statement of August 4, 1986.

~ Level Two: This would be the pair of quantitative health objectives as stated in the same Policy Statement.

~ Level Three: This would be the previously proposed general performance guideline that the likelihood of a large accidental release should be less than 10E-6 per reactor year.

~ Level four: This level of the hierarchy would consist of three performance objectives to be relied on in ensuring that the safety of operating plants is consistent with the Level One, Two, and Three criteria. These objectives should be explicit enough that they could be used by the NRC Staff in making decisions about specific regulations and regulatory practices. Such objectives are described below.

(1) The first performance objective would be an expression of the effectiveness of plant accident prevention systems. We have previously recommended a goal of “less than 10E-4 per reactor-year” for the mean core melt frequency “for all but a few existing plants.” By core melt, we mean loss of assured core cooling which can result in severe core damage….

(2) The second performance objective would be an expression of the effectiveness of the design of plant accident mitigation systems. Between core melt, as defined above, and challenge to containment, as normally understood, there are several stages at which the accident sequence may be arrested. A containment performance objective cannot be stated simply in terms of the Level Three probability of a large release and the probability of a core melt as discussed above.

> We recommend that as a minimum the containment performance objective should be such that there is less than one chance in ten for a large release for the entire family of core melt scenarios.
>
> (3) The third performance objective would be an expression of how well the plant is operated. This remains to be developed. A separate objective of this sort would not be necessary if operating performance were appropriately considered in the first two performance objectives. However, present methods of analysis for performance objectives are based primarily on system design only. For this reason, it seems necessary at this time to consider operations in a separate objective, if the Safety Goal Policy is to be applied to plant operation and not just to plant design. We recognize this to be a major undertaking, but regard it as essential to a meaningful implementation of the Safety Goal Policy.

In its May 13, 1987, report (ACRS, 1987), the ACRS also noted the need to recognize important limitations in the implementation of the Safety Goal Policy, including the following statements:

> We note that there must be recognition of important limitations in the implementation of the Safety Goal Policy. These limitations are essentially those of the PRA methodology used, and are caused by a fundamental inability to accurately predict and calculate precise values of risk. Variability in data, uncertainty about applicability of data, imperfect understanding of important physical phenomena, and inevitable incompleteness in analysis all contribute to this limitation.
>
> The NRC Staff must recognize the limitations of risk analysis and limitations in the definition of the Safety Goals themselves and must apply sufficient margins within its regulations and regulatory practices to accommodate these limitations. They have always had to make such judgments and allowances. The key point is that the NRC Staff and the industry will be better able to make balanced and consistent decisions about regulation, design, and plant operation with guidance provided by the Safety Goals and PRA than without.

In a staff requirements memorandum (SRM), "Commission Guidance on Implementation of the NRC's Safety Goal Policy," dated November 6, 1987 (NRC, 1987b), the Commission indicated its support for the ACRS recommendations and directed the staff to develop a revised implementation plan. In late 1987 and early 1988, the staff met with the ACRS to discuss how to carry out the ACRS recommendations.

In a letter dated April 12, 1988 (ACRS, 1988), the ACRS commented further on its prior recommendations for the definition of "large release," "core melt," and the "plant performance objective," as well as "use of cost-benefit analysis."

In SECY-89-102, "Implementation of Safety Goal Policy," dated March 30, 1989 (NRC, 1989), the staff outlined its recommended general approach to the implementation of safety goals and quantitative objectives and compared its approach to that suggested by the ACRS.

In SRM-SECY-89-102, dated June 15, 1990 (NRC, 1990a), the Commission approved several actions relating to the Safety Goal Policy, including the following:

- The result of the several PRA level calculations (i.e., core damage probability, source terms, consequence estimates), as well as the results of the various internal steps within each level, can be compared with certain specific regulatory requirements. This has resulted in the suggestion that the Safety Goals and health objectives be partitioned into further subsidiary objectives. While the Commission believes that such "partitioned" objectives can be useful in making regulatory decisions and improving regulatory practices, it does not believe it is necessary to specifically incorporate the partitioned objectives into the Safety Goal Policy Statement.

- The Commission believes that the basic concept of a plant performance objective that focuses on accidental releases from the plant and eliminates site characteristics, as suggested by the ACRS, is appropriate. The staff should evaluate and advise the Commission whether such an objective can be developed and how it would be useful. In conducting this evaluation, the staff should formulate a new definition for large release and supporting rationale consistent with this approach.

- The staff, in developing and reviewing regulations and regulatory practices, should routinely consider the safety goals. To achieve this objective, the staff should establish a formal mechanism including documentation for ensuring that future regulatory initiatives are evaluated for conformity with the safety goal. (Recognizing that the state of knowledge is such that the degree to which regulatory issues can be related to the safety goals will vary considerably, the staff's consideration of the safety goals could range anywhere from quantitative risk comparisons involving the safety goals themselves to a deterministic judgment that, in light of the safety goals and available knowledge (or lack thereof), a given issue does or does not warrant a change to the regulations or regulatory practices.)

- Based upon the NRC's review of a sample of plant PRAs, it appears that these plants not only meet the quantitative health effects objectives but exceed them. This may or may not reflect excessive conservatism in regulations. While there have been improvements in PRA techniques, uncertainties in the summary results are still such that quantitative PRA objectives should not be used as licensing standards or requirements.

- …for the purpose of implementation, the staff may establish subsidiary quantitative core damage frequency and containment performance objectives through partitioning of the Large Release Guideline. These subsidiary objectives should anchor or provide guidance on "minimum" acceptance criteria for prevention (e.g., core damage frequency) and mitigation (e.g. containment or confinement performance) and thus assure an appropriate multi-barrier defense-in-depth balance in design. Such subsidiary objectives should be consistent with the large release guideline, and not introduce additional conservatism so as to create a de facto new Large Release Guideline.

  A core damage probability of less than 1 in 10,000 per year of reactor operation appears to be a very useful subsidiary benchmark in making judgements about that portion of our regulations which are directed toward accident prevention. Containment performance objectives for evolutionary and advanced designs should be submitted to the Commission for approval, together with a justification for the recommended approach. In developing recommendations, the staff should assure that:

(a) The CCFP [conditional containment failure probability] objective is not so conservative as to constitute a de facto new "Large Release Guideline."

(b) Establishment of a CCFP should be approached in such a manner that additional emphasis on prevention is not discouraged. In this regard, staff should develop appropriate guidance for establishing CCFPs to address this concern and provide a uniform methodology for implementing such an approach.

(c) Recognizing that it is entirely possible that a deterministically established containment performance objective could achieve the same overall objective as a CCFP, staff should be prepared to review the merits of such an approach (if proposed) and, if workable, accept such an approach as an alternative to a CCFP.

The Commission has no objection to the use of a $I0^{-1}$ CCFP objective for the evolutionary design, as applied in the manner described above.

Within a particular design class (e.g., LWRs, LMRs [liquid-metal-cooled reactors], HTGRs [high-temperature, gas-cooled reactors]) the same subsidiary objectives should apply to both current as well as future designs. A specific subsidiary objective might differ from one design class to another design class to account for different mitigating concepts (e.g., confinement instead of containment). However, the Large Release Guideline relates to all current as well as future designs.

<u>These partitioned objectives are not to be imposed as requirements themselves but may be useful as a basis for regulatory guidance.</u>

- The term "credible" is used in Part 100 and has in some instances been given a probabilistic interpretation or definition by the staff which is more stringent than the Large Release Guideline. This lack of uniformity should be addressed by the staff in conjunction with the staff's efforts on siting.

- All Commissioners agree that how well a plant is operated is a vital component of plant safety. In order to improve communication to the public, ACRS has recommended that this fact be given more prominence in the Safety Goal Policy Statement as a major element of uncertainty, recognizing that it is not quantifiable in a fashion similar to the other objectives. The current wording of the policy statement contains such a message implicitly; therefore, the Commission does not believe a change is necessary. The staff should, however, recognize this as a major element of uncertainty when referring to the safety goals in making regulatory decisions.

3.2 The Safety Goal Policy and Its Relationship to the Concept of Adequate Protection

The term "adequate protection" has an important legal implication in safety regulation. Although it is used with apparent precision in legal instruments, its technical definition is not precise. In general, it is accepted as equivalent to the term "with no undue risk to public health and safety" often used in other contexts. The term “in full compliance with the regulations” is also used as a surrogate, on occasion, for either of these (ACRS, 1989a).

In its February 16, 1989, letter (ACRS, 1989a), the ACRS stated the following:

> The safety goal should play an important, but indirect, role in defining adequate protection. Ideally, compliance with the Commission’s regulations is a suitable surrogate for defining adequate protection of the public. However, we believe that the adequacy of the regulations should be judged from the viewpoint of whether nuclear power plants, as a class, licensed under those regulations, meet the safety goals. It is our understanding, following discussions with the staff, that the staff proposes the safety goal to be a sort of aspirational objective which would be sought but not necessarily reached.

In a letter dated October 11, 1989 (ACRS, 1989b), the ACRS stated that, in general, its position remains as stated in previous reports. That is—

> On the one hand, compliance with the regulations is generally regarded as presumptive evidence that the public is adequately protected from risk associated with operation of a nuclear power plant. On the other hand, as we have proposed, adequacy of the body of regulations should be judged by whether the population of nuclear power plants built and operated under these regulations is causing risk no greater than the objectives given in the Safety Goal Policy.

In SRM-SECY-89-102 (NRC, 1990a), the Commission stated its belief that—

> “Adequate protection” is a case by case finding based on evaluating a plant and site combination and considering the body of our regulations. Safety goals are to be used in a more generic sense and not to make specific licensing decisions. It is not necessary to create a generic definition of adequate protection, nor is it necessary to amend the Safety Goal Policy Statement in order to provide a direct relationship between the safety goals and the concept of adequate protection.”

In an August 25, 1997, Commission Action Memorandum (NRC, 1997a), the Commission approved a discussion of safety and compliance. This memorandum (NRC, 1997a) discussed the nexus between compliance and safety, including the following statement:

> Adequate protection is presumptively assured by compliance with NRC requirements. Circumstances may arise, however, where new information reveals, for example, that an unforeseen hazard exists or that there is a substantially greater potential for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.

3.3 Definition of a Large Release for Use with the Safety Goal Policy

The safety goal policy includes a general performance guideline that there should be a probability no greater than 10^{-6} per reactor-year of a large release from any operating nuclear power plant. The policy did not define a “large release” exactly but as part of a program to implement the safety goal policy, the Commission directed the staff to develop a definition for “large release.” This would be a major release of fission products to the environment from a severe accident coupled with containment failure. Such a large, but exceedingly rare, event was intended to be a surrogate definition for the major accident that would create a public health threat equivalent to quantitative health objectives (QHOs) in the Commission’s safety goal policy.

The ACRS recommended, and the Commission endorsed, a position that surrogates for the QHOs should be simple and not be so conservative as to create a de facto new policy. In a revised plan for safety goal policy implementation (NRC, 1989), consistent with ACRS recommendations (ACRS, 1987) and Commission direction (NRC, 1987b), the staff recommended the following hierarchy of objectives:

- Level 1: qualitative safety goals
- Level 2: QHOs
- Level 3: large release
- Level 4: core damage frequency (CDF)

The staff recommended the following qualitative definition of a large release: “A large release is a release that has a potential for causing an offsite early fatality*”* (NRC, 1989).

The staff noted that there was no need to recommend a surrogate for the latent cancer QHO since the prompt fatality QHO was recognized as more controlling.

The Commission, in response, directed the staff to evaluate whether a plant performance objective (i.e., large release frequency (LRF)) that focuses on the release and eliminates site characteristics could be developed and implemented (NRC, 1990a). The Commission acknowledged that while a large release guideline of 10^{-6} per reactor-year is inherently more conservative than either of the QHOs, this more conservative result is within an order of magnitude of the Commission’s health objectives and provides a simple goal that has generally been accepted. The Commission further directed the staff to formulate a new definition for large release that focused on the release rather than site characteristics (NRC, 1990a).

In 1990, the staff (NRC, 1990b) recommended the following definition of “large release” for Commission approval:

> A release of radioactivity from the containment to the environment of a magnitude equal to or greater than: (An amount, to be determined by the staff, inventory, which has the potential, based on representative site characteristics, for causing one or more prompt fatalities).

The Commission approved the staff’s recommendation (NRC, 1991a) and stated that the staff should keep in mind the following ACRS guidelines for subordinate levels of the safety goals hierarchy:

- should be consistent with the level above
- should not be so conservative as to create a de facto new policy
- should represent a simplification of the previous level
- should provide a basis for ensuring that the Safety Goal Policy objectives are being met
- should be defined to have broad generic applicability
- should be stated in terms that are understandable to the public
- should generally comport with current PRA usage and practice

Development of a practical definition for a "large release" proved difficult. The staff completed a comprehensive analysis that illuminated the many facets of the issue.

In accordance with Commission direction, the staff performed analyses using a representative site to evaluate candidate large releases to identify those releases that would lead to a prompt fatality. The staff found that the proposed LRF goal was more conservative than previously understood. Specifically, in SECY-93-138, "Recommendation on Large Release Frequency," dated May 19, 1993 (NRC, 1993a), the staff concluded that, given a large release at 10^{-6} per reactor-year, any large release definition would result in a degree of conservatism several orders of magnitude more conservative than the QHOs.

The staff further concluded that development of a large release definition and magnitude, beyond a simple qualitative statement related to the 10^{-6} per year release frequency (such as that in the safety goal policy statement), was not practical or required for regulatory or design purposes. The staff asked for Commission approval to terminate efforts in this area. Instead, the staff proposed using guidance for implementing the safety goal policy statement developed in parallel with the work evaluating a large release. For operating reactors, the staff proposed a framework for regulatory decision-making using CDF and CCFP as the subsidiary safety goal objectives (NRC, 1991b). For new reactor design certification reviews, the staff proposed a CDF goal and a CCFP goal complemented by a deterministic containment performance goal (NRC, 1990b).

The ACRS also reviewed the draft Commission paper on large release definition. In its April 22, 1993, letter (ACRS, 1993), the Committee supported the recommendation that the Commission approve the staff's proposal to terminate its effort to develop a definition of a large release. The Committee (ACRS, 1993) also stated its views as follows:

1. A large release definition would either represent a replacement for the existing safety goals or, if made consistent with the quantitative health objectives (QHOs), would be redundant and unnecessary.

2. New guidelines being developed for implementing the Safety Goal Policy within regulatory analysis and issue prioritization processes adequately meet the originally perceived need for a large release component of the safety goals. These utilize a core damage frequency (CDF) and a conditional containment failure probability (CCFP).

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3. Plant performance objectives, viz CDF $\leq 10^{-4}$ and CCFP ≤ 0.1, provide an easily understandable and adequate surrogate for the QHOs and provide quantitative prioritization for two basic aspects of defense in depth (prevention and mitigation). These could help ensure that a plant does not end up with great core protection but marginal containment performance.

In June 1993, the Commission approved ending the staff effort to define large release (NRC, 1993b).

3.4 Implementation of the Safety Goal Policy within Regulatory Analysis

Cost-benefit considerations are used as input to NRC decisions on whether to implement proposed regulatory actions. A regulatory analysis is performed to estimate benefits and costs and reach a conclusion as to whether the proposed regulatory action is "cost-beneficial" (i.e., the benefits of the proposed action are equal to, or exceed, the costs of the proposed action). Such analyses are conducted to support proposed and final rules and to evaluate requirements, guidance, or staff positions that would result in a change in licensee resources. It should be noted that no legislation or regulation requires a regulatory analysis for NRC-initiated actions. However, multiple Executive orders have been issued on this topic over the past several years, and the NRC has been voluntarily performing such analyses since 1976.

The regulatory analyses prepared by the NRC before 1983 were termed "value-impact" analyses and followed the guidance in SECY-77-388A, "Value Impact Analysis Guidance," dated December 19, 1977 (NRC, 1977). In February 1981, President Reagan issued Executive Order 12291, "Federal Regulation" (EOP, 1981), which directed executive agencies to prepare a regulatory impact analysis for all major rules and stated that regulatory actions should be based on adequate information concerning the need for and consequences of proposed actions. As an independent agency, the NRC was not required to comply with Executive Order 12291. However, the Commission determined that clarifying and formalizing the existing NRC value-impact procedures for the analysis of regulatory actions would enhance the effectiveness of NRC regulatory actions and further meet the spirit of Executive Order 12291. In January 1983, the NRC issued the original version of these guidelines as NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (NRC, 1983c). The NRC issued revisions to NUREG/BR-0058 in 1984, 1995, 2000, 2004, and 2017 (draft for Comment).

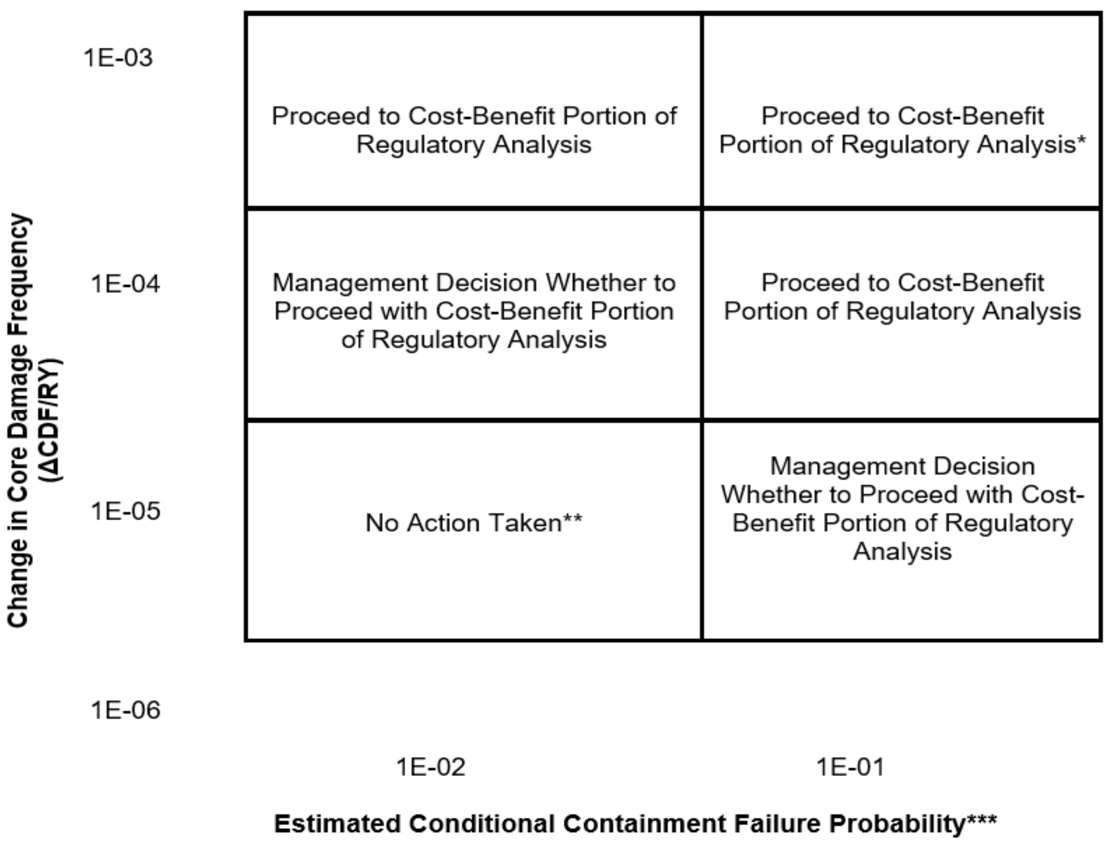
Revision 2 to NUREG/BR-0058, issued November 1995 (NRC, 1995b), is noteworthy as it reflected changes in NRC regulations and procedures since 1984, particularly the promulgation of the backfit rule (10 CFR 50.109, "Backfitting") and the publication of the Commission's Policy Statement on Safety Goals for the Operations of Nuclear Power Plants. This revision also significantly benefited from the ACRS review of its draft versions (ACRS, 1992; ACRS, 1994).

Cost-benefit analysis is also used to support any backfit that represents an enhancement to safety beyond what may be required for adequate protection. According to 10 CFR 50.109, such backfits may be imposed only if the NRC determines that "there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection."

A complete regulatory analysis will provide all the information necessary for backfit analysis. However, the backfitting decision criterion differs from the regulatory analysis decision criterion in that a "substantial increase" is needed to justify backfitting. The Commission has indicated that "substantial" means "important or significant in a large amount, extent, or degree," but the Commission has not set thresholds for a substantial increase. The Commission believed "these words embody a sound approach to the 'substantial increase' criterion and that this approach is flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety" (NRC, 1993c).

Several factors are considered in determining whether the backfit would substantially increase protection to public health and safety or the common defense. For backfits associated with nuclear reactors, typically a safety goal screening evaluation is used as a surrogate for such determination. According to the NRC's regulatory analysis guidelines (NRC, 1995b), "if the proposed safety goal screening criteria are satisfied, the NRC considers that the substantial additional protection standard is met for the proposed new requirement." Once it is decided that the potential backfit would result in a substantial increase in protection, it is then determined whether it is cost justified in light of this increased protection.

Figure 3 depicts the safety goal screening criteria and provides guidance as to when the staff should proceed to the estimation and evaluation of the costs and benefits portion of the regulatory analysis and when a management decision is needed.



* A determination is needed regarding adequate protection or compliance (NUREG-1409, Revision 1, "Backfitting Guidelines," issued March 2020 (NRC, 2020a), discusses the extent to which costs are considered).

** Unless an office director decides that the screening criteria do not apply (refer to NUREG/BR-0058 for additional consideration of containment performance).

*** Conditional upon core damage accident that releases radionuclides into the containment (refer to NUREG/BR-0058 for additional consideration of containment performance).

Figure 3 Safety Goal Screening Criteria of the Regulatory Analysis (Adapted from NUREG/BR-0058 (NRC, 1995b))

The change in the mean value of CDF is considered in determining whether the substantial additional protection criterion of the backfit rule is met. The mean CDF of 10^{-4} per reactor-year was used as the subsidiary safety goal. A reduction in CDF is clearly substantial if the reduction is equal to or greater than 10^{-4} per reactor-year.

To achieve a balance between prevention and mitigation, the safety goal screening includes a mechanism for considering containment performance. As figure 3 shows, greater staff emphasis is required for the higher values (i.e., greater than 0.1) of the conditional probability of early containment failure or bypass.

The regulatory analysis guidelines require that in estimating the change in CDF, to the extent that information is available and pertinent to the issue, contributions from both internal and external events are considered. However, in view of the large uncertainties associated with certain external event risk contributions, qualitative insights should also be used to supplement any available quantitative information (NRC, 1995b).

3.5 Consideration of Economic Consequences

The NRC uses the safety goal policy to support decision-making on actions beyond adequate protection where cost may be considered (refer to section 3.4). During the development of the safety goals, the Commission debated extensively debated on whether and how offsite property damage and other economic consequences caused by a significant radiological release should be taken into account.

The 1983 preliminary policy statement for a 2-year evaluation period expressed the Commission's views on the acceptable level of risks to public health and safety and on the safety-cost tradeoffs in regulatory decision-making. However, the Commission did not address non-health-related economic consequences but did adopt for trial use a health benefit-cost guideline of $1,000 per person-rem averted as one consideration in decisions on safety improvements. As noted in section 2.4, the value was in 1983 dollars. The Commission also stated that this value should be modified to reflect general inflation in the future (NRC, 1983a).

In its report (NRC, 1985b), the Safety Goal Evaluation Steering Group concluded that the economic costs of onsite consequences, as well as offsite costs borne by the public, should be considered as a benefit in the cost-benefit guideline. The report also concluded that the $1,000 per person-rem conversion factor adequately bounded the offsite non-health-related economic costs. As such, the $1,000 per person-rem factor was determined to include both health and non-health-related offsite impacts. However, the Steering Group recommended that the safety goals exclude the loss of societal resources (e.g., water bodies, arable land, endangered species, burial grounds, national monuments, and parks), beyond their economic value, because of the difficulty in quantifying the loss of such resources.

The final policy statement issued in 1986 describes the goals and QHOs in terms of health risks only. No goal or objective was established to directly address potential land contamination, offsite property damage, and interdiction. Although the safety goal policy statement did not address economic consequences, the Commission noted that the specific guidance required to implement the safety goal policy statement would address matters such as the conduct of cost-benefit analyses.

The NRC has occasionally considered modifying the safety goal policy to include economic consequences. In SECY-97-208, "Elevation of the Core Damage Frequency Objective to a Fundamental Commission Safety Goal," dated September 12, 1997 (NRC, 1997e), the staff stated that "the goals and QHOs are described in terms of health risks; no goal has been established with respect to potential land contamination and interdiction. As evidenced by the Chernobyl accident, this can be a major societal impact of accidents involving core damage and containment failure." Also, in SECY-00-0077, "Modifications to the Reactor Safety Goal Policy Statement," dated March 30, 2000 (NRC, 2000), the staff noted that adding a safety goal or subsidiary objective for land contamination and overall societal impacts would provide a clear message of the importance of considering contamination of the environment following a severe accident. However, the staff recommended that no additional safety goal be developed in this area because of the uncertainties in predicting severe accident consequences and weaknesses in the analytical tools for evaluating land contamination and collective dose at significant distances from the plant. The staff instead recommended that the policy statement add a qualitative statement that there be no adverse impact on the environment. Ultimately, the Commission disapproved issuance of any revised reactor safety goal policy statement, citing the need for the staff to focus on the agency's new risk-informed regulatory initiatives (NRC, 2001).

The 2011 accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion of how the NRC's regulatory framework considers the economic consequences of a significant radiological release from an NRC-licensed facility and licensed material. In SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," dated August 14, 2012 (NRC, 2012a), the staff provided the Commission with information and options to address to what extent, if any, the NRC's regulatory framework should be modified regarding its consideration of the economic consequences of an unintended release of licensed nuclear materials to the environment. The staff identified three primary options for the Commission to consider: (1) status quo, (2) updates to regulatory analysis guidance to enhance consistency, and (3) exploration of the merits of potential changes to the regulatory framework, including developing a policy statement for offsite property damage that parallels the design and structure of the Policy Statement on Safety Goals for the Operation of Nuclear Power Plants.

In its November 13, 2012, report (ACRS, 2012), the Committee supported option 3 in SECY-12-0110 to explore whether changes to the regulatory framework are needed to further consider adverse economic consequences from severe accidents. The Committee stated that "the possible changes to the treatment of economic consequences should not be considered in isolation from other on-going initiatives that may affect Commission policy" (ACRS, 2012). It should be noted that the ACRS report also contained comments by three Committee members who supported option 2, reasoning, in part, that option 2 would correct deficiencies and inconsistencies in current NRC approaches and would provide regulatory stability.

In SRM-SECY-12-0110, dated March 20, 2013 (NRC, 2013a), the Commission approved the staff's recommended option 2, to enhance the currency and consistency of the existing framework through updates to guidance documents integral to performing cost-benefit analyses in support of regulatory, backfit, and environmental analysis, subject to certain comments and additional direction. The Commission also stated that "economic consequences should not be treated as equivalent in regulatory character to matters of adequate protection of public health and safety" (NRC, 2013a).

3.6 Emergence of Large Early Release Frequency

As a key part of the implementation of the severe accident policy statement (NRC, 1985c), the NRC issued Generic Letter 88-20, "Individual Plant Examination for Severe Accident Vulnerabilities—10 CFR 50.54(f)," in November 1988 (NRC, 1988). This generic letter requested that each licensee conduct an individual plant examination, which was intended to identify any plant-specific vulnerabilities to severe accidents. The general purpose of this examination was to evaluate severe accident behavior and sequences, develop probabilities of core damage and fission product release, and, if necessary, reduce these probabilities through hardware and procedural modifications.

The NRC did not require the licensees to use PRAs. However, by the time the Commission issued its policy statement on PRA in 1995 (NRC, 1995a), most operating reactor licensees had completed their individual plant examinations by performing PRAs of varying quality. Operating reactor licensees expected subsequent PRA applications to involve the assessment of changes to the plant operation, maintenance, or design, or to involve a prioritization evaluation to help optimize the expenditure of resources (NRC, 2013b). With these applications in mind, EPRI issued its "PSA [Probabilistic Safety Assessment] Applications Guide," in August 1995 (EPRI, 1995), to provide utilities with guidance on the preparation, application, interpretation, and maintenance of plant-specific PRAs.

The "PSA Applications Guide" (EPRI, 1995) introduced the term "large early release frequency" (LERF) and included the following definition of large early release:

- unscrubbed containment failure pathway of sufficient size to release the contents of the containment (i.e., one volume change) within 1 hour, which occurs before or within 4 hours of vessel breach; or

- unscrubbed containment bypass pathway occurring with core damage.

In its August 15, 1996, letter (ACRS, 1996), the ACRS stated the following:

> The safety goals and subsidiary objectives can and should be used to derive guidelines for plant-specific applications. It is, however, impractical to rely exclusively on the Quantitative Health Objectives (QHOs) for routine use on an individual plant basis. Criteria based on core damage frequency (CDF) and LERF focus more sharply on safety issues and can provide assurance that the QHOs are met. They should be used in developing detailed guidelines.

As part of agency efforts to support implementation of the Commission's 1995 policy on the use of risk information in the regulatory process, the NRC staff proposed using LERF and CDF in Draft Regulatory Guide (DG)-1061 (later issued as Regulatory Guide (RG) 1.174), "An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," issued June 1997 (NRC, 1997), as risk measures against which licensing-basis changes would be assessed instead of the QHOs themselves. The staff defined large early release as "a significant unmitigated release from containment before effective evacuation of the close-in population such that there is a potential for prompt health effects" (NRC, 1997c).

As discussed in SECY-97-077, the staff proposed an LERF guideline of 10^{-5} per reactor-year for use in evaluating proposed risk-informed licensing-basis changes (i.e., plants with an LERF greater than 10^{-5} per reactor-year would be expected to propose changes that decrease the LERF or are neutral). The staff noted that the LERF guideline of 10^{-5} per reactor-year corresponds to that value, estimated from existing PRA results, necessary to ensure that the prompt fatality QHO would be met without undue conservatism. Although work on defining a large release at a frequency of 10^{-6} per reactor-year was stopped (as discussed in section 3.3 of this report), the staff believed that the management attention region defined in draft RG 1.174 (LERF of 10^{-6} to 10^{-5} per reactor-year) ensured that the intent of the Commission's general performance guideline was considered in the review of risk-informed changes to the current licensing basis. The staff also proposed a CDF guideline of 10^{-4} per reactor-year for use in evaluating proposed risk-informed licensing-basis changes (i.e., plants with a CDF greater than 10^{-4} per reactor-year would be expected to propose changes that decrease the CDF or are neutral).

The staff's recommendation and Commission's approval to publish draft RG 1.174 (NRC, 1997d) resulted in the transition from LRF to LERF and CDF as surrogates for the two QHOs for operating reactors.

In 2000, the staff recommended possible modifications to the safety goal policy statement, including incorporating subsidiary goals of a CDF of less than 10^{-4} per reactor-year and an LERF of less than 10^{-5} per reactor-year and deleting reference to the general performance guideline of an LRF of less than 10^{-6} per reactor-year (NRC, 2000a). The Commission approved the staff's recommendation to modify the safety goal policy statement to include the use of LERF and CDF as surrogates for the QHOs (NRC, 2000b).

The staff subsequently recommended to the Commission a modified version of the safety goal policy statement that included the specific changes regarding CDF, LERF, and LRF discussed above (NRC, 2001a). In its response, the Commission disapproved issuance of the revised safety goal policy statement (NRC, 2001b). Instead, the Commission directed the staff to consult with the Commission on a more significant revision to the policy statement in the future, when further progress had been made on the agency's risk-informed initiatives. As a result of that Commission decision, the safety goal policy statement has not changed since it was issued in 1986.

3.7 Implementation of Safety Goal Policy for New Plants

In policy statements on severe accidents (NRC, 1985c) and on advanced reactors (NRC, 1986) (reinforced and updated in 1994 and 2008), the Commission established expectations that new reactor designs achieve a higher standard of severe accident safety performance and provide increased margin before exceeding safety limits. As a result of these and other enhancements, risk estimates for new reactor designs are one or more orders of magnitude lower than for current operating reactor designs.

The utility industry, through EPRI's "Advanced Light Water Reactor Utility Requirements Document," issued March 1999 (EPRI, 1999), proposed to adopt objectives that address severe accidents. Specifically, EPRI proposed the following:

- an objective for CDF of 10^{-5} per reactor-year

- an additional objective stated as follows: "The dose from events whose frequency exceeds 10^{-6} per reactor-year must be less than 25 REM whole body at the assumed site boundary distance of 0.5 miles."

EPRI defined the first of these as a "quantitative investment protection goal" and the second as a public safety goal that the industry should strive for in future advanced light-water reactor (ALWR) designs. General Electric (GE) also adopted the design objective of a CDF of 10^{-5} per reactor-year for its advanced boiling-water reactor (ABWR). GE stated in its ABWR design control document that it did not attempt to define the term "large release," but the dose threshold selected by GE was considered much less than large, so the large release goal was satisfied (NRC, 2013b). The staff believed that these were laudable goals for the industry and were consistent with the Commission's expectations that designers of future plants will strive to make them safer (NRC, 1989).

In SRM-SECY-89-102 (NRC, 1990a), the Commission stated the following:

> It is important to note that the Commission has made it clear in the advanced plant and severe accident policy statements that it expects that advanced designs will reflect the benefits of significant research and development work and experience gained in operating the many power and development reactors, and that vendors will achieve a higher standard of severe accident safety performance than their prior designs. The industry's goal of designing future reactors to a core damage probability of less than 1 in 100,000 per year of reactor operation (EPRI for ALWRs and GE for the ABWR) is evidence of industry's commitment to NRC's severe accident policy. The Commission applauds such a commitment. However, the NRC will not use industry's design objectives as the basis to establish new requirements.

In SRM-SECY-90-016, "SECY-90-16—Evolutionary Light Water Reactor Certification Issues and Their Relationship to Current Regulatory Requirements," dated June 26, 1990 (NRC, 1990d), the Commission disapproved the use of 10^{-5} per year of reactor operation as a CDF for advanced designs. However, the Commission stated, "if the staff in applying the criteria of 10 CFR Part 52 (and in view of the uncertainties associated with PRA's) concludes that additional requirements are needed, based on our experiences with prior designs, in order to provide assurance that future designs will meet the Safety Goal Policy Statement, then the staff should provide those additional requirements to the Commission for consideration as they are identified" (NRC, 1990d).

In that SRM (NRC, 1990d), the Commission also approved the use of a 0.1 CCFP for the evolutionary light-water reactors. This approval reflected the Commission's defense-in-depth regulatory philosophy and its policy on safety goals.

In SRM-SECY-93-087, "SECY-93-087—Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated July 21, 1993 (NRC, 1993d), the Commission approved the staff's proposal to use the following deterministic containment performance goal in the evaluation of the passive ALWRs as a complement to the CCFP approach approved by the Commission in SRM-SECY-90-016 (NRC, 1990d):

> The containment should maintain its role as a reliable, leak-tight barrier (for example, by ensuring that containments stresses do not exceed ASME Service Level C limits for metal containments, or Factored Load Category for concrete containments) for approximately 24 hours following the onset of core damage under the more likely severe

> accident challenges and, following this period, the containment should continue to provide a barrier against the uncontrolled release of fission products.

In SRM-SECY-12-0081, “Staff Requirements—SECY-12-0081—Risk-Informed Regulatory Framework for New Reactors,” dated October 22, 2012 (NRC, 2012b), the Commission approved the staff’s recommendation to transition from LRF to LERF at or before initial fuel load and discontinue regulatory use of LRF and CCFP thereafter.

3.8 Implementation of Safety Goal Policy within the Technology-Inclusive Regulatory Framework for Advanced Non-Light-Water Reactors

In preparing to review and regulate a new generation of non-LWRs, consistent with section 103 of the Nuclear Energy Innovation and Modernization Act of 2019 (NEIMA) (NEIMA, 2019), the NRC has begun establishing a “risk informed, technology-inclusive regulatory framework for advanced reactors,” for optional use by applicants for new commercial advanced nuclear reactor licenses.

In SRM SECY-19-0117, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,” dated May 26, 2020 (NRC, 2020b), the Commission stated the following:

> In its work on the regulatory framework for advanced reactors, the staff should continue to recognize that the Commission’s established policy on the application of the safety goals and safety performance expectations provides an acceptable minimum safety standard for new reactors while taking into account the need to adapt the aspects of our current regulatory framework for reactors that provide operational flexibility based on risk assessment, such as the more than minimal increases in risk test in Section 50.59, the Maintenance Rule of Section 50.65, and the quality assurance criteria of Appendix B to reflect the significantly lower risks inherent in the design of advanced reactors.

The NRC engaged with the Licensing Modernization Project led by Southern Company, coordinated by the Nuclear Energy Institute (NEI), and cost-shared with the U.S. Department of Energy. The interactions between the NRC staff and the Licensing Modernization Project resulted in NEI Technical Report 18-04, Revision 1, “Modernization of Technical Requirements for Licensing of Advanced Non-Light Water Reactors: Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development,” issued August 2019 (NEI, 2019). The guidance focuses on identifying licensing basis events (LBEs); categorizing and establishing performance criteria for structures, systems, and components (SSCs); and evaluating defense in depth for advanced reactor designs.

In June 2020, the NRC issued RG 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors” (NRC, 2020c). The RG endorses, with clarifications, the method documented in NEI 18-04.

NEI 18-04 describes an expanded role for PRA for non-LWRs. The methodology includes plotting event sequence families on the frequency-consequence (F-C) target (shown in figure 4) and assessing margins based on event frequency and estimated 30-day dose at the exclusion area boundary (EAB). In RG 1.233, the staff cautions that the F-C target figure does not depict acceptance criteria or actual regulatory limits. The anchor points used for the F-C target figure are expressed in different units, time scales, and distances than those used in NRC regulations to provide common measures for the evaluations in the methodology. An example is the anchor point at an event sequence frequency of $5x10^{-7}$ per plant year and total effective dose equivalent at the EAB of 750 rem for the 30-day period following the onset of a potential release. This anchor point is used to define a sliding F-C target in the region of potential low-frequency, high-consequence scenarios for use in assessing the importance of SSCs and other measures to provide defense-in-depth. A traditional measure used to assess risk in the low-frequency, high-consequence domain is the NRC's safety goals. However, the anchor point is not intended to directly represent the QHOs for either early or latent health effects (NRC, 2020c).

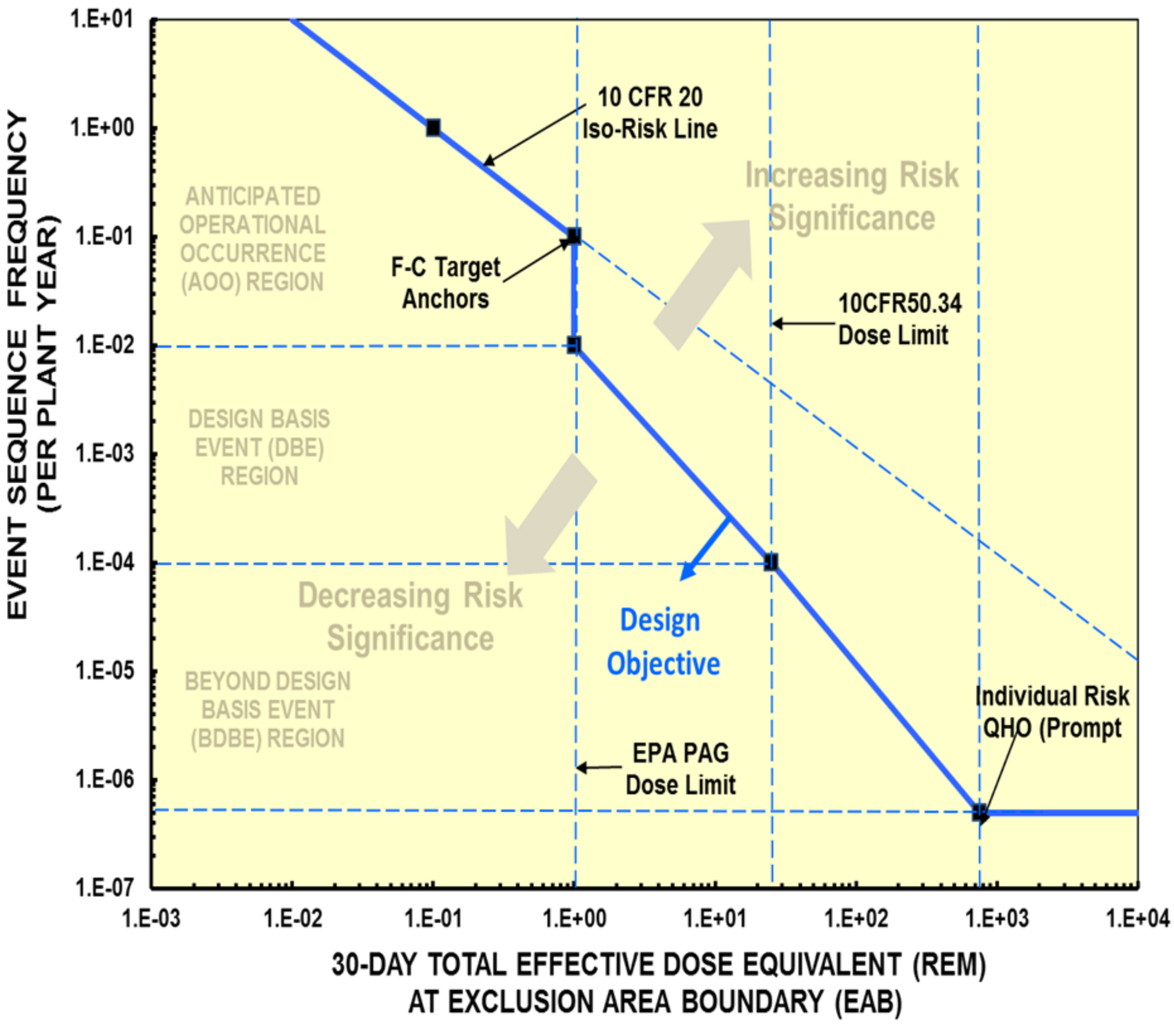


Figure 4 Frequency-Consequence Target from NEI 18-04 (NEI, 2019)

The methodology described in NEI 18-04 includes the following assessment of a design against the QHOs for the integrated risks over all the LBEs:

- The average individual risk of early fatality within 1 mile of the EAB from all LBEs shall not exceed 5×10^{-7}/plant-year to ensure that the plant meets the NRC safety goal QHO for early fatality risk.

- The average individual risk of latent cancer fatalities within 10 miles of the EAB from all LBEs shall not exceed 2×10^{-6}/plant-year to ensure that the plant meets the NRC safety goal QHO for latent cancer fatality risk.

4 SUMMARY AND CONCLUSIONS

The Atomic Energy Act of 1954 gave the AEC broad authority to establish regulations necessary for it to find that the utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. At the time, knowledge of safety analysis had not progressed to the point where it was possible to use quantitative techniques to estimate the probabilities and consequences of accidents. Instead, the fundamental concept of defense in depth was invoked to provide reasonable assurance that the nuclear facility can be operated without undue risk to the health and safety of the public. The standard of “no undue risk” is equivalent to the “adequate protection” standard derived from the Atomic Energy Act.

In judging that there was a reasonable assurance that a plant could be operated without undue risk to the public, the question of “how safe is safe enough?” was not addressed directly, nor was the residual risk that was implicitly being accepted quantified. In fact, until the publication of the landmark reactor safety study (WASH-1400) in 1975, a methodology for quantitatively assessing LWR safety did not exist

In 1979, shortly after the accident at TMI-2, the ACRS recommended that the NRC consider establishing quantitative safety goals for nuclear power reactors. In its May 16, 1979, letter on quantitative safety goals, the ACRS recognized the difficulties and uncertainties in the quantification of risk and acknowledged that, in many situations, engineering judgment would be the only or the primary basis for a decision. Nevertheless, the Committee believed that quantitative safety goals and criteria could provide important yardsticks for such judgment.

The President's Commission on the Accident at Three Mile Island and the NRC’s Special Inquiry Group both recommended that the NRC better articulate its objectives and philosophy on the adequacy of reactor safety. In its 1979 response to the recommendations of the President’s Commission, the NRC stated that it was “prepared to move forward with an explicit policy statement on safety philosophy and the role of safety-cost tradeoffs in the NRC safety decisions.” Thus, the task of developing quantitative safety goals for nuclear power plants was just beginning.

This report was prepared as part of the ACRS commitment to the NRC’s knowledge management program and to capturing the institutional knowledge and memory of the Committee. The report presents historical background on the development of safety goals and the implementation of the safety goal policy. An overview of past ACRS observations and recommendations for the development of the safety goals and the implementation of the safety goal policy are also presented.

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11. ABSTRACT (200 words or less)

As part of its commitment to the U.S. Nuclear Regulatory Commission's knowledge management efforts, the Advisory Committee on Reactor Safeguards (ACRS) has begun an initiative to capture the Committee's institutional knowledge and memory. An important motivation for this initiative is to increase the effectiveness and efficiency of the Committee's review process by providing ready access to background information, insights, and understanding related to technical and regulatory issues. This report provides a historical background on the development of safety goals. It also discusses the implementation of the safety goal policy and presents an overview of past ACRS observations and recommendations for the development of the safety goals and the implementation of the safety goal policy.

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