REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT

APRIL 1, 1990 - MARCH 31, 1991

Supporters of this system argue that it would provide an incentive for better estimates of the costs of legislative proposals and a basis for an explicit discussion of the costs and tradeoffs of such proposals. High cost ceilings would focus attention on the expected benefits of the program, and alternative approaches; cost ceilings that were too low would prevent agencies from issuing implementing regulations. Such an approach would, needless to say, give agencies an incentive to choose regulatory approaches that would produce the greatest benefits at the lowest costs.

ISSUES AND AREAS FOR FURTHER STUDY

While the fiscal budget process provides a continuous record of actual expenditures, there is no comparable record of the cost of meeting regulatory requirements.[20] Members of Congress and the past two Administrations have considered developing an accounting framework to record direct regulatory expenditures, but more work needs to be done to solve the practical accounting problems inherent in measuring the private expenditures that Federal regulations mandate. These include:

- Developing a record of actual expenditures while minimizing the recordkeeping burden on the private sector;
- Identifying an appropriate "baseline," recognizing that some costs would be incurred even in the absence of Federal regulation; and
- Estimating the costs of forgoing certain products where Federal regulation prohibits production or distribution.

Each of these raises difficult issues in designing an effective regulatory budget process. For example, the costs of banning a product are not directly measurable and can only be estimated using complex statistical models. However, measuring only the direct compliance costs for oversight purposes creates a bias toward banning substances and products instead of controlling them.

As a first step in determining the feasibility of the regulatory budget concept, OMB has begun systematically to collect the costs of all significant published regulatory actions. Analysis of these data should aid in the development of ways to overcome the problems of regulatory budgeting, uncover unforeseen problems in developing cost estimates, and more fully refine a workable regulatory budgeting process.

Current Regulatory Issues in Risk Assessment and Risk Management

Many Federal agency regulatory decisions are intended to reduce risks to human life and health. Government regulations control which agricultural chemicals may be used to reduce insect damage, increase farm yields, and improve the quality of food products. Other rules govern hazards in the Nation's workplaces and emissions from its factories. There are regulations directing the way in which automobiles must be manufactured, commercial aircraft maintained, and trains operated. Hardly any widespread human activity that entails risk is free of some degree of social control, often achieved through government regulation.

Regulatory decisions involving risk require agencies to address questions such as, "How safe is 'safe'?" and "How clean is 'clean'?" When government agencies promulgate regulations intended to reduce a risk or mitigate a hazard, they are engaging in what has become known as *risk management*. These policy choices inevitably involve consideration of both the risks entailed by the underlying activity and the social consequences of regulatory intervention. Thus, the first challenge of risk management is to set priorities to determine which risks are worth reducing and which are not.

For government to carry out its risk-management responsibilities, there must be an extensive investment in the careful assessment and quantification of risks. The term *risk assessment* means the application of credible scientific principles and statistical methods to develop estimates of the likely effects of natural phenomena and human activities.

The need to keep risk assessment and risk management separate has long been the objective of responsible public officials. In 1983, the National Academy of Sciences (NAS) studied the process of managing risk

[20] Researchers, using different methods, assumptions, and time periods, have formed incomplete estimates by adding up the cost of individual regulations. These estimates accordingly show considerable variation for current annual costs ranging from $60 billion to $175 billion a year—5 to 15 percent of current Federal outlays.

in the Federal Government and offered the following recommendations, among others:

> *Recommendation 1:* Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessment of risks and the consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[21]

> *Recommendation 2:* Before an agency decides whether a substance should or should not be regulated as a health hazard, a detailed and comprehensive written risk assessment should be prepared and made publicly available. This written assessment should clearly distinguish between the scientific basis and the policy basis for the agency's conclusions.[22]

The belief that risk assessment and risk management should be kept separate enjoys widespread support among professional risk-assessment practitioners and risk-management officials.[23] Others have emphasized the importance of ensuring that policy biases do not distort the analysis of alternative risk-management choices.[24] The NAS principles have also have been endorsed by a number of Federal agencies, including the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS).[25]

Unfortunately, risk-assessment practices continue to rely on conservative models and assumptions that effectively intermingle important policy judgments within the scientific assessment of risk. Policymakers must make decisions based on risk assessments in which scientific findings cannot be readily differentiated from embedded policy judgments. This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.

This section explores some of the continuing difficulties that plague the practice of risk assessment, and describes briefly their policy implications. It can be summarized in three observations:

The continued reliance on conservative (worst-case) assumptions distorts risk assessment, yielding estimates that may overstate likely risks by several orders of magnitude. Many risk assessments are based on animal bioassays utilizing sensitive rodent species dosed at extremely high levels. Conservative statistical models are used to predict low-dose human health risks, based on the assumption that human biological response mimics that observed in laboratory animals. Worst-case assumptions concerning actual human exposure are commonly used instead of empirical data, further exaggerating predicted risk levels.

Conservative biases embedded in risk assessment impart a substantial "margin of safety". The choice of an appropriate margin of safety should remain the province of responsible risk-management officials, and should not be preempted through biased risk assessments. Estimates of risk often fail to acknowledge the presence of considerable uncertainty, nor do they present the extent to which conservative assumptions overstate likely risks. Analyses of risk-management alternatives routinely ignore these uncertainties and treat the resulting upper-bound estimates as reliable guides to the likely consequences of regulatory action. Decisionmakers and the general public often incorrectly infer a level of scientific precision and accuracy in the risk-assessment process that does not exist.

Conservatism in risk assessment distorts the regulatory priorities of the Federal Government, directing societal resources to reduce what are often trivial carcinogenic risks while failing to address more substantial threats to life and health. Distortions are probably most severe in the area of cancer-risk assessment, because many conservative models and assumptions were developed specifically for estimat-

---

[21] National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process*, Washington, DC: National Academy Press, 1983 (hereinafter, *NAS Risk Management Study*), p. 151.

[22] Ibid., p. 153.

[23] For representative views of risk-assessment practitioners see, e.g., Lester B. Lave, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, DC: Brookings, 1981; Lester B. Lave, "Methods of Risk Assessment," Chapter 2 in *Quantitative Risk Assessment in Regulation*, Lester B. Lave, ed., Washington, DC: Brookings, 1982, esp. pp. 52–54. For representative views of risk-management officials see, e.g., William D. Ruckelshaus, "Science, Risk, and Public Policy," *Vital Speeches of the Day*, Volume 49, No. 20, August 1, 1983, pp. 612-615.

[24] See, e.g., Howard Kunreuther and Lisa Bendixen, "Benefits Assessment for Regulatory Problems," and Baruch Fischhoff and Louis Anthony Cox, Jr., "Conceptual Framework for Regulatory Benefits Assessment," Chapters 3 and 4, respectively, in *Benefits Assessment: The State of the Art*, Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower, eds., Dordrecht, Netherlands: D. Reidel, 1986, pp. 44–45, 59–61.

[25] See U.S. Office of Science and Technology Policy, "Chemical Carcinogens: A Review of the Science and Its Associated Principles," Principle 29 (50 FR 10378, March 14, 1985, hereinafter, *OSTP Risk Assessment Guidelines*); U.S. Environmental Protection Agency, "Guidelines for Carcinogen Risk Assessment," 51 FR 34001 (September 24, 1986, hereinafter, *EPA Carcinogen Risk Assessment Guidelines*); U.S. Department of Health and Human Services, *Risk Assessment and Risk Management of Toxic Substances*, April 1985, p. 20.

ing upper bounds for these risks. Risk-assessment methods with similar conservative biases are less common elsewhere, particularly in those areas where real-world data are available, or where the mechanism by which injury or illness occurs is better understood.

A renewed commitment to the NAS recommendations is clearly warranted. As quantitative risk assessment plays an increasingly significant role in risk management, the need to separate science from policy becomes ever more important, if either process is to maintain public confidence. As former EPA Administrator William D. Ruckelshaus has noted:

> Risk assessment...must be based on scientific evidence and scientific consensus *only*. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk.[26]

ALTERNATIVE RISK-ASSESSMENT METHODOLOGIES

Risk assessments of chemical substances in general (and of possible carcinogens in particular) involve a mixture of facts, models, and assumptions. There is considerable debate concerning the scientific merits of the models and assumptions commonly used in risk assessments. In some cases, a scientific consensus has developed to support a particular model or assumption. In other instances, however, certain models and assumptions are relied upon because they reflect past practices rather than the leading edge of science. Furthermore, a scientific basis for several of the most critical models and assumptions simply does not exist.

Most scientists agree that these models and assumptions impart a conservative bias: that is, they lead to risk projections that the actual (but unknown) risk is very unlikely to exceed. These "upper-bound" estimates are often useful as a screening device, to exclude from regulatory concern potential hazards that are insignificant even under worst-case conditions. Unfortunately, upper-bound risk estimates are routinely employed for altogether different purposes, such as estimating the likely benefits of regulatory actions. Policymakers are required to act on the basis of biased representations of both the magnitude of the underlying hazard and the extent to which Government action will ameliorate it.

Contemporary risk assessment relies heavily upon animal bioassay and epidemiology. Each approach has theoretical advantages and disadvantages. In practice, both can be misused to bolster preestablished conclusions. The following discussion emphasizes problems in carcinogenic risk assessment, because the prevention and cure of cancer plays such a major role in policy issues involving risks to life and health.

Animal Bioassay

Animal testing enables scientists to estimate risks ex ante, before human health effects materialize, whereas epidemiological studies can only detect such effects ex post. In addition, animal tests can be conducted under tightly controlled laboratory conditions, which provide more reliable estimates of exposure and avoid many of the confounding factors that often plague epidemiological investigations. The relatively short lifetimes of experimental mammals (such as rats and mice) allow scientists to ascertain the possible effects of long-term exposure in just a few years.

Animal testing suffers serious limitations, however, arising from certain critical assumptions. Despite its routine application, there is no accepted scientifi basis for the assumption that results can be meaningfully extrapolated from test animals to humans.[27] Some scientists believe that animal data should not be used in assessing human health risks.[28]

Another critical limitation is the reliance on very high doses to generate adverse effects in test animals.[29] A mathematical model must be used to bridge the gap between these high-dose exposures and the low-dose exposures more typically faced by people. Many different mathematical models can be constructed to fit the data at high doses. These models often vary enormously, however, in their predictions of risk at low doses.

Beyond these unavoidable methodological constraints, the results of animal bioassays may be subject to conflicting scientific interpretation or strongly influenced by the choice of research method.

---

[26] William D. Ruckelshaus, (*op. cit.*), p. 614.

[27] *OSTP Guidelines*, Guideline 8, p. 10376.

[28] See, e.g., Bruce Ames, Renae Magaw, and Lois Swirsky Gold, "Ranking Possible Carcinogenic Hazards," *Science*, Vol. 236, April 17, 1987; Gio Batta Gori, "The Regulation of Carcinogenic Hazards," *Science*, Vol. 208, April 18, 1980.

[29] *OSTP Guidelines*, Guideline 11, p. 10377.

Tissue preparation and histology present obvious opportunities for error, as experts may disagree as to how slides should be interpreted.[30] This problem generally is not significant at high doses, where malignancies are often obvious. At low doses, however, pathologists often differ in how they distinguish tumors from hyperplasia. Subjectivity cannot be avoided where such interpretations of the data must be made.[31]

Epidemiology

Epidemiology is attractive because it largely avoids these two problems. It focuses on observable human health effects instead of on hypothesized outcomes based on animal experimentation, and it relies upon real-world exposures to generate empirical data. Many of the serious problems associated with animal studies can be avoided, allowing researchers to develop risk estimates that are directly related to human health.

Unfortunately, epidemiological research suffers from its own set of limitations. For example, retrospective studies often have difficulty correlating morbidity and mortality with exposure to specific substances. Exposure data are commonly lacking, incomplete, imprecise, or affected by systematic recall or selection biases. Furthermore, the risks these studies seek to detect are often very small relative to background, thus making statistically significant effects difficult to observe. When health effects are latent, correlating exposures to illness is even harder.

Besides these unavoidable methodological limitations, epidemiological studies often suffer from outright bias. Many studies employ scientifically questionable procedures aimed at demonstrating positive relationships between specific substances and human illness.[32] Some researchers use inappropriate statistical procedures to "mine" existing databases in search of associations. One result of these practices is that epidemiological studies often display contradictory results.[33]

Despite these constraints, properly conducted animal bioassays and epidemiological studies both have useful roles to play in quantitative risk assessment. Indeed, they are complementary. The usual weaknesses of epidemiological investigations—unreliable exposure data, confounding effects—are readily avoided in laboratory experiments on animals. The weaknesses of animal bioassays—high- to low-dose extrapolation, animal-to-man conversion—do not arise in epidemiological studies. Careful risk assessment incorporates both types of analysis to ensure that the emerging picture of human health risk is as complete as possible, and that inferences derived from this picture are themselves internally consistent.

ISSUES IN RISK ASSESSMENTS DERIVED LARGELY FROM ANIMAL BIOASSAYS

Animal bioassays tend to dominate current risk assessments. An important reason for this is that the derivation of dose-response relationships is a critical regulatory motive for performing quantitative risk assessment. Animal studies are ideally suited to serve this purpose by virtue of the controlled conditions under which dose and response can be calibrated. Epidemiological studies often are relegated to providing merely a "reality check" to ensure that the implications of animal bioassays are plausibly consistent with real-world experience. Because of this heavy emphasis on animal testing, the focus here is on several major problems that arise with respect to risk assessments primarily based on the results of animal bioassays.

The Use of Sensitive Test Animals

To enhance the power of animal tests, scientists typically rely on genetically sensitive test animals. It

[30] In the original analysis of the rat bioassay used to derive the dose-response function for dioxin, 9 of 85 controls were said to develop liver tumors. An independent review of this data resulted in 16 of the 85 controls being classified as having such tumors. See U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2, 3, 7, 8-TCDD, Appendix A*, EPA/600/6-88/007Ab, June 1988 (hereinafter, *Dioxin Risk Assessment Appendix A*), pp. 2–3.

[31] Colin N. Park and Ronald D. Snee, "Quantitative Risk Assessment: State-of-the-Art for Carcinogenesis," Chapter 4 in *Risk Management of Existing Chemicals*, Rockville, MD: Government Institutes, 1983, p. 56.

[32] Alvan R. Feinstein, "Scientific Standards in Epidemiological Studies of the Menace of Daily Life," *Science*, Vol. 242, December 2, 1988, pp. 1257–1263.

[33] Linda C. Mayes, Ralph I. Horowitz, and Alvan R. Feinstein, "A Collection of 56 Topics with Contradictory Results in Case-Control Research," *International Journal of Epidemiology*, Vol. 17, No. 3 (1988), pp. 680–685.

is unclear whether these species accurately mimic biological responses in humans.

Some test species are extremely sensitive. For example, approximately one-third of all male B6C3F1 mice, a common test species, spontaneously develop liver tumors.[34] The same phenomenon occurred in an important bioassay concerning dioxin using female Sprague-Dawley (Spartan) rats. Tumors observed in dosed animals were predominantly located in the liver. However, approximately one-fifth of the animals in the control group also developed liver tumors.[35] The relevance of elevated liver tumors in hypersensitive species has been questioned by scientists and is not universally considered probative evidence of carcinogenicity. Nevertheless, cancer risk assessments often proceed on the assumption that these data are sufficient to conclude that a substance is indeed a carcinogen.[36]

The reliance on sensitive test animals also biases risk assessments in a more subtle way. It establishes powerful incentives to search for and develop increasingly sensitive test species. As test animals become more sensitive, repeated testing using identical protocols will tend to result in higher and higher estimates of risk even if all other factors are held constant.

Selective Use of Alternative Studies

In their respective risk-assessment guidelines, both OSTP and EPA recommend that relevant animal studies should be considered irrespective of whether they indicate a positive relationship.[37] In practice, however, studies that demonstrate a statistically significant positive relationship routinely receive more weight than studies that indicate no relationship at all.[38] For example, the plant growth regulator daminozide (Alar) and its metabolite unsymmetrical 1,1-dimethylhydrazine (UDMH) recently received B2 classifications ("probable human carcinogen"). Each of these classifications was based on a single positive animal bioassay.[39] Overcoming such a classification requires, at a minimum, two "essentially identical" studies showing no such relationship.[40] In the case of Alar and UDMH, however, a more stringent test was apparently applied: Three high-quality negative studies showed no significant effects; these studies appear to have received little or no weight in the classification decision.[41]

Selective Interpretation of Results

Risk-assessment guidelines generally give the greatest weight to the most sensitive test animals. Thus, if a substance has been found to cause cancer in one

---

[34] Ames *et al., (op. cit.)*, p. 276.

[35] *Dioxin Risk Assessment Appendix A*, pp. 2–3.

[36] See Ames *et al., (op. cit.)*, p. 276 (arguing that such data are irrevelant); *OSTP Guidelines* Guideline 9, p. 10377 (concluding that such data "must be approached carefully"); and *EPA Carcinogen Risk Assessment Guidelines*, p. 33995 (making the policy judgment that such data are sufficient evidence of carcinogenesis). Liver tumors dominated in EPA's dioxin risk assessment. See *Dioxin Risk Assessment*, appendix A, pp 2–3.

[37] See *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 33995.

[38] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33992–34000. A single animal test that shows a positive result "to an unusual degree" (p. 33999) is sufficient to warrant at least a B2 classification ("probable human carcinogen"), even if this result occurs in a species known to have a high rate of spontaneous tumors. A strong animal bioassay or epidemiological study showing no evidence of carcinogenic effect cannot overcome this presumption (p. 34000).

[39] See "Second Peer Review of Daminozide (Alar) and UDMH (Unsymmetrical 1,1-dimethylhydrazine)," Memorandum from John A. Quest to Mark Boodee, U.S. Environmental Protection Agency, OPTS, May 15, 1989 (hereinafter, *Alar/UDMH Internal Peer Review No. 2*). This internal OPTS panel reviewed several recent studies on Alar and UDMH.

One study of Alar yielded a statistically significant increase in common lung tumors in mice, but only for one of three dosage levels. Results were not statistically significant at one higher and two lower dosages, and controls also displayed unusually high tumor incidence. 90% of the lung tumors in dosed mice were benign, versus 89% in the controls.

One study of UDMH yielded statistically significant increases in common lung and uncommon liver tumors in mice, but only for the higher of two dosages. 97% of the lung tumors in dosed mice were benign, versus 100% in the controls. 29% of the liver tumors in dosed mice were benign; no tumors were observed in the controls.

Prior studies that purported to show a carcinogenic response had been judged inadequate by EPA's Scientific Advisory Panel, an external peer review group. The Office of Pesticides and Toxic Substances (OPTS) panel noted that a different internal EPA risk-assessment panel (the Carcinogen Assessment Group) considered these studies sufficient to justify B2 classifications when it evaluated them for EPA's Office of Solid Waste and Emergency Response. Despite the scientific controversy, the OPTS panel interpreted these prior studies as "supporting evidence" under EPA's risk-assessment guidelines.

[40] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33995 (establishing the need for replicate identical studies showing no effect), and p. 33999 (establishing the minimum requirement of two well-designed studies showing no increased tumor incidence to warrant a "no evidence" determination).

[41] *Alar/UDMH Internal Peer Review No. 2*, pp. 6, 8, 9. EPA's scheme for carcinogen classification is itself an issue among scientists. See, e.g., U.S. Environmental Protection Agency, Risk Assessment Forum, *Workshop Report on EPA Guidelines for Carcinogen Risk Assessment*, EPA/625/3-89/015, Washington, DC, March 1989, pp. 21–26.

species or gender but shown to exhibit no effects elsewhere, the results pertaining to the sensitive species or gender typically will be used to develop estimates of human-health risks. For example, if male mice develop cancer from a substance but female mice and rats of both genders do not, then the results from the male mouse often will be used to derive estimates of cancer risks to humans.[43]

Once a positive result has been obtained in an animal bioassay, a substance often will be provisionally classified as a probable human carcinogen. The statistical burden of proof then shifts to the no-effect hypothesis. Because it is logically impossible to prove a negative, however, this practice establishes a virtually irrebuttable presumption in favor of the carcinogenesis hypothesis.

Severe Testing Conditions

Current risk-assessment protocols require the use of very high doses. Unfortunately, high doses are often toxic for reasons unrelated to their capacity to cause cancer. A common procedure is to use what is called the maximum tolerated dose (MTD), which is the most that can be administered to a test animal without causing acute toxicity. At such exposure levels, substances often cause severe inflammation and chronic cell killing. For example, formaldehyde causes nasal tumors in rats when administered in high doses. However, MTD administration severely inflames nasal passage tissues. It is therefore unclear whether the cancers induced are caused by formaldehyde per se or by the toxic effects of high doses.

Results such as these have caused some scientists to question the validity of rodent tests performed at the MTD for estimating human health risks that arise from exposure at low doses.[43] By combining very high doses with highly sensitive test subjects, some animal bioassays are predisposed to discover apparent carcinogenic effects.

Relevance of Animal Bioassay Results

An important reason why animals vary in their sensitivity is that they have different physiologies, metabolic processes, reproductive cycles, and a host of other species-specific characteristics that largely result from unique evolutionary paths. Each of these factors needs to be carefully considered in evaluating the significance of animal data with respect to human health. This is recognized in both the OSTP and EPA guidelines, but it is often neglected when the guidelines are applied to specific substances.[44]

The most important assumption in this regard is that animal test results can be meaningfully extrapolated to humans. A recent study of chemicals tested under the auspices of the U.S. National Toxicology Program shows that this assumption can lead to the erroneous classification of many chemicals as probable human carcinogens.[45] Positive associations have been obtained in either rats or mice for half of 214 chemicals tested. However, results were consistent across these two genetically similar species only 70 percent of the time. If it is assumed that rodent bioassays have the same sensitivity and selectivity with respect to human carcinogens as they do between rodent species, and it is further assumed that 10 percent of all chemicals are in fact human carcinogens, then 27 of every 100 randomly selected chemicals would be misclassified as probable human carcinogens. Only three chemicals would be misclassified as noncarcinogens. Thus, "false positives" would be 9 times more common than "false negatives."[46]

Of course, this ratio of false positives to false negatives reflects highly conservative "upper-bound" assumptions concerning sensitivity and selectivity. Given the high degree of similarity between rats and mice and the limited resemblance between rodents and humans, the sensitivity of rodent bioassays with respect to human carcinogenicity is probably much lower than 70 percent. Furthermore, other research indicates that selectivity may be as low as 5 percent.

---

[43] See *EPA Carcinogen Risk Assessment Guidelines*, p. 33997 (data from long-term animal studies showing the greatest sensitivity should generally be given the greatest emphasis).

[43] See, e.g., Ames *et al.*, *(op. cit.)*, pp. 276–277.

[44] *OSTP Guidelines*, Guideline 25, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, p. 34003 (responding to comments on the draft guidelines and affirming agreement with OSTP Guideline 25).

[45] Lester B. Lave, Fanny K. Ennever, Herbert S. Rosenkranz, and Gilbert S. Omenn, "Information Value of the Rodent Bioassay," *Nature*, Vol. 336 (December 15, 1988), pp. 631–633.

[46] *False negatives* occur when a test fails to detect effects when they are in fact present. *Sensitivity* refers to the capacity of a test to minimize false negatives. *False positives* occur when a test appears to detect effects that in fact are absent. *Selectivity* refers to a test's ability to minimize false positives. The 9 to 1 ratio of false positives to false negatives calculated by Lave *et al.* assumes that both selectivity and sensitivity equal about 70%.

Adjusting only for this lower selectivity suggests that false positives are almost 30 times more common than false negatives. This raises serious questions concerning the practical utility of the current approach to animal bioassays for the purpose of quantitative risk assessment.[47]

Other factors should also be considered when relying upon animal bioassay results as the primary basis for quantitative risk assessments. For example, certain substances are toxic or even carcinogenic by one pathway but not by others. Nevertheless, animal bioassay protocols often emphasize the most sensitive pathway. As long as human exposure is likely to arise the same way, then this choice may be reasonable. However, the pathway to which the test species is sensitive sometimes reflects an exposure route that is implausible or irrelevant for humans. For example, formaldehyde causes nasal tumors in rats at 12 times the rate observed in the next most sensitive animal species. This extreme sensitivity may be related to the fact that rats breathe only through the nose.

There may be important differences between animals and humans that make specific tumors irrelevant. For example, some chemicals cause cancer in the zymbal gland of the rat; because humans lack such a gland it is unclear whether these results matter in estimating human health risk. Other substances induce cancer through biochemical mechanisms not found in humans.

A greater controversy surrounds the question whether the same weight should be given to benign and malignant tumors. The scientific consensus is that benign and malignant tumors should be aggregated only when it is scientifically defensible to do so.[48] In practice, however, benign and malignant tumors are routinely aggregated unless a strong case can be made *against* the practice.[49] The difference between these default assumptions is significant: One approach counts only carcinomas that *are* present, whereas the other counts tumors that *might become* carcinomas. In an extreme case, a substance that promotes benign tumors but never causes cancer could be classified as a probable human carcinogen simply because benign and malignant tumors are treated equally.

In addition, tumor incidence is commonly pooled across sites to obtain a total estimate of carcinogenic effects.[50] This implicitly assumes that cancer induction is independent across sites and not the result of either metastasis or the same biological mechanism. Given the extreme sensitivity of test species and the regular use of MTD administration, other explanations for tumors occurring at multiple sites appear just as plausible.

The Choice of Dose-Response Model

No single mathematical model is accepted as generally superior for extrapolating from high to low doses.[51] Consequently, Federal agencies often use a variety of different models. Rather than being a scientific footnote to the risk-assessment process, however, the choice of model is actually an important policy issue. The multistage model appears to be the most commonly used method for estimating low-dose risks from chemicals, and there are two major sources of bias embedded in this choice: its inherent conservatism at low doses, and the routine use of the "linearized" form in which the 95 percent upper bound is used instead of the unbiased estimate.

The *multistage model* essentially involves fitting a polynomial to a data set, with the number of "stages" identified by the number of terms in the polynomial. Since animal bioassays rarely have more than three dose levels, it is unusual to see applications of the multistage model with more than two stages. Although the multistage model enjoys some scientific support because it is compatible with multistage theories of carcinogenesis, in practice the model fails to include enough stages, due to the absence of sufficient alternative exposure cohorts.

The multistage model typically yields low-dose risk estimates that are higher than most other models. For example, when five different dose-response models were analyzed in a recent risk assessment of cadmium, estimates of cancer risks at moderate doses varied by a factor of 100. This difference among

[47] Lave *et al.*, *(op. cit.)*, p. 631. Adjusting also for less sensitivity reduces the ratio of false positives to false negatives. For example, if sensitivity is only 10 percent and all other parameters remain unchanged, then this ratio declines to 9.5 to 1. However, this implies that both types of statistical errors are rampant, which raises questions concerning the practical utility of animal bioassays. This is, in fact, precisely the concern raised by Lave *et al.*, *(op. cit.)*, who conclude that such tests are cost-effective investments in information only under extraordinary conditions.

[48] *OSTP Guidelines*, p. 10376.

[49] *EPA Carcinogen Risk Assessment Guidelines*, p. 33997.

[50] *Id.*

[51] *OSTP Guidelines*, Guideline 26, p. 10378; Ames *et al.*, *(op. cit.)*, p. 276.

estimates widened as doses declined toward the very low levels within the range of regulatory concern. At very low doses, two of the five models predicted excess lifetime cancer risks greater than one in one thousand (10^{-3}), a risk oftentimes regarded by policymakers as unacceptable. However, two other equally plausible models predicted essentially no excess cancer risk at all. Since none of the five models offers a scientifically superior basis for deriving low-dose risks, the choice of model is therefore a pivotal policy decision. The accepted practice under these circumstances is to develop a subjectively-derived "best" estimate while fully informing decisionmakers as to the extent of uncertainty surrounding it.[52] In the cadmium case, as in most others, this practice was not followed: Estimates of the number of statistical cancers that would be prevented by regulation were presented based only on the multistage model.[53]

The *linearized multistage model (LMS)* is a special version of the multistage model in which the 95 percent upper confidence limit of the linear term is used instead of the unbiased estimate. That is, the model identifies the largest value for the linear term that cannot be rejected at the 95 percent confidence level and uses it in place of the unbiased estimate. Assuming that the model has been correctly specified, there is only a 5 percent chance that the true risk exceeds this level.

The LMS has become the preferred statistical approach because estimates derived from it appear to be more "stable" than estimates obtained from the ordinary multistage model. The "stability" issue originally arose because unbiased estimates of low-dose risks are very sensitive to the maximum-likelihood estimate (MLE) of the value of the linear term. When the MLE of the linear term is positive, it dominates estimated risks at low doses. In some instances, however, the MLE of the linear term is zero, and low-dose risk estimates decline precipitously. Using the 95 percent upper confidence limit ensures that the linear term is always positive, thus eliminating the inherent "instability" of low-dose risk estimates derived from the multistage model.[54]

Another often-cited advantage of the LMS procedure is that it provides a "yardstick" for comparing potencies across chemicals.[55] A uniform risk-assessment procedure such as the LMS, it is argued, enables policymakers to better understand the relative significance of a broad array of chemical hazards and set regulatory priorities accordingly.

Finally, the LMS is often defended on the ground that it is prudent to err on the side of caution when dealing with potentially carcinogenic chemicals. Because the LMS generates upper-bound risk estimates, policymakers can be confident that actual risks are likely to be lower.

None of these purported advantages of the LMS approach has a sound statistical basis. It is a fundamental axiom of statistics that unbiased estimates are generally preferred to biased ones. Using the upper confidence limit instead of the unbiased estimate exaggerates underlying specification errors instead of eliminating them. "Instability" is overcome, but at the cost of greater errors in specification.

The inherent instability of the multistage model reflects a generalized misspecification of dose-response—that is, the real human dose-response relationship is often very different from what the multistage model constrains it to be. The model is extremely sensitive to small differences in observed tumor incidence, which can cause dramatic changes in estimated low-dose risks. The LMS procedure eliminates this sensitivity without remedying the underlying specification error. Proper statistical procedure requires correcting model misspecification, not masking its symptoms behind biased parameter estimates.

The LMS procedure inflates low-dose risk estimates by a factor of two or three when the MLE of the linear term is positive. However, it increases low-dose risk estimates by orders of magnitude when the MLE of the linear term is zero.[56] This means that the degree of hidden conservative bias is substantially greater for what are demonstrably lower risks.

By its very nature, the LMS cannot serve as a useful yardstick for comparing the relative risk of a variety of potential carcinogens. If a given statistical procedure generated identical biases across substances tested,

[52] See, e.g., *OSTP Guidelines*, Guidelines 27, 29, and 31, p. 10378; *EPA Carcinogen Risk Assessment Guidelines*, pp. 33999, 34003.

[53] Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 FR 4076 (February 6, 1990).

[54] Albert L. Nichols and Richard J. Zeckhauser, "The Dangers of Caution: Conservatism in Assessment and the Mismanagement of Risk," Chapter 3 in *Advances in Applied Micro-Economics, Volume 4: Risk, Uncertainty, and the Valuation of Benefits and Costs*, V. Kerry Smith, ed., Greenwich, CT: JAI Press, 1986, pp. 55–82, esp. pp. 62–63. A nontechnical version of this paper is available by the same authors as "The Perils of Prudence: How Conservative Risk Assessments Distort Regulation," *Regulation*, November/December 1986, pp. 13–24.

[55] U.S. Environmental Protection Agency, *A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD*, EPA/600/6-88/007Aa, June 1988 (hereinafter, *Dioxin Risk Assessment*), pp. 45–46.

[56] Nichols and Zeckhauser, *op. cit.*, pp. 62–63.

then it would still yield an accurate rank-ordering of theoretical hazards. Similarly, if the procedure added a stochastic bias from a uniformly distributed random variable, the resulting rank-ordering would still be accurate on an expected-value basis. The problem with the LMS is that it generates biases that intensify with the degree to which the multistage model misspecifies the true dose-response relationship. Even if the multistage model provided an accurate rank-ordering of hazards, the LMS could not do so, because it injects biases that are systematic with statistical misspecification.

The LMS procedure (and the multistage model itself) is also fatally flawed as a yardstick for regulatory priority setting because it fails to take account of human exposure in the calculation of unit risks. Regardless of the procedure's capacity to accurately rank-order *hazards*, failing to adjust unit risks by relative human *exposure* virtually guarantees that regulatory priorities will be misordered. Resources tend to be focused on reducing the greatest theoretical *hazards* rather than the most significant human health *risks*.[57]

Finally, the "margin of safety" argument in favor of the LMS unequivocally contradicts the widely recognized need to distinguish science from policy.[58] The LMS introduces into each risk assessment a conservative bias of varying but unknown magnitude. This practice fundamentally alters regulatory decisionmaking. Instead of leaving policy decisions to policymakers, the LMS disguises fundamental policy decisions concerning the appropriate margin of safety behind the veil of science.

In summary, the LMS cannot be justified as a method of scientific risk assessment. The "yardstick" defense implicitly asserts that scientific advancements in risk-assessment methodology should take a back seat to the preservation of an outdated and misguided statistical procedure. The "margin of safety" argument tacitly usurps from policymakers the authority and responsibility for risk-management decisions. Finally, the statistical "instability" overcome by the LMS is an artifact of specification error, not any scientific theory of human carcinogenesis that warrants the intentional use of biased parameter estimates. The habitual reliance upon either the multistage model or its LMS descendant cannot be supported by sound scientific principles.

Alternative models are available, of course, and they have been applied in many quantitative risk assessments. Because proper model specification is the foundation of applied statistical methodology, alternatives to the multistage model should be expected and encouraged. Indeed, innovation is the hallmark of scientific inquiry; policies that institutionalize any particular model specification effectively stifle scientific advancement.

Unfortunately, models other than the multistage model are often discouraged in practice.[59] Agencies may require substantial scientific evidence in support of an alternative model before allowing it to be used. Alternative models thus face a burden of demonstrating scientific plausibility that the multistage model cannot satisfy. Even in the extraordinary case in which this burden can be satisfied, estimates may be required from the linearized multistage model anyway.[60]

The potential human health threat posed by dioxins provides an excellent example of the problem of model selection. Using the same linearized multistage model, EPA, the Centers for Disease Control (CDC), and the Food and Drug Administration (FDA) have arrived at upper-bound risk estimates that span an order of magnitude.[61] Depending on the data and assumptions used, the linearized multistage model predicts unit risk factors that vary by as much as 1,200, with the

[57] Some scientists have attempted to devise alternative indexes of relative human health risk that explicitly account for variations in human exposure. Ames *et al.*, (*op. cit.*), pp. 272–273, describe one such alternative (the Human Exposure/Rodent Potency index, or HERP) and report index values for 36 substances. Because the HERP index is based on a relative rather than absolute scale, the distorting effect of conservative biases embedded in the underlying risk assessments has been significantly reduced. Many substances suspected of being environmental carcinogens rank very low on the HERP index, suggesting that regulatory priorities have been seriously misdirected.

[58] See, *e.g.*, *NAS Risk Management Study*, p. 161; *OSTP Risk Assessment Guidelines*, Principle 29, p. 10378; and *EPA Carcinogen Risk Assessment Guidelines*, p. 34001.

[59] See, *e.g.*, Ames *et al.*, (*op. cit.*), p. 276 (continued reliance on linear models despite the accumulation of evidence against linearity); and Lester B. Lave, "Health and Safety Risk Analysis: Information for Better Decisions," *Science*, Vol. 236, April 17, 1987, pp. 291–295, esp. p. 292 (agencies often resist modeling improvements and data that yield lower risk estimates).

[60] *EPA Carcinogen Risk Assessment Guidelines*, pp. 33997–33998. "In the absence of adequate information to the contrary, the linearized multistage procedure will be employed. . . . Considerable uncertainty will remain concerning responses at low doses; therefore, in most cases, an upper-limit risk estimate using the linearized multistage procedure should also be presented."

[61] *Dioxin Risk Assessment Appendix A*, p. 13. Unbiased risk estimates vary by a similar factor.

three risk estimates mentioned earlier clustered at the high end of the range.[62] Risk assessments based on different models have led other governments to establish unit risk factors that are a thousand times less stringent than the most commonly used of these three; one study suggests that this particular estimate overstates the most likely risk estimate by a factor of almost 5,000.[63]

Conversion from Animals to Humans

Once risk has been extrapolated to low doses in rodents, scientists must convert them to human dose-equivalents. The two most common approaches involve the use of body-weight or surface-area conversions, and there are scientific reasons for choosing either approach in individual cases. The surface-area approach leads to estimates of risk that are between 7 and 12 times greater than those based on the body-weight method, depending upon the test species. Despite the ambiguity of the underlying science, the more conservative surface-area method is often applied reflexively.[64]

ISSUES ARISING FROM HUMAN EXPOSURE ESTIMATES

In addition to developing estimates of the dose-response function, agencies must estimate the likely level of human exposure. This section examines some of the issues and problems that arise in conducting an exposure assessment.

It is a generally accepted principle of exposure assessment that estimates should be based on the most likely scenario, with appropriate consideration of uncertainty.[65] Nevertheless, agencies often use conservative assumptions for exposure when real-world data are unavailable. When each of these assumptions tends to overstate likely human risks, the multiplicative effect of even a small overstatement at each stage in an exposure assessment will yield a substantial overestimate of actual exposure. For example, the multiplicative effect of overstating risk by a factor of two at five different points in an exposure assessment will overstate actual risk by a factor of thirty-two.

Worst-Case Environmental Conditions

When data are available they often relate to unusually sensitive environments or highly contaminated conditions. When estimating regional or nationwide exposures, agencies often use data from these local "hot spots" in developing more general national estimates of health risks. However, such data are never representative and estimates extrapolated from them are generally unreliable and misleading.

In addition, chemicals often degrade naturally after they have been released to the environment. In some cases, degradation occurs very quickly, whereas in others the process may take many years or even decades. A common practice in exposure assessment modeling is to assume that exposures remain constant over time—that is, chemicals are assumed never to degrade, or degradation by-products are assumed to pose identical risks.

The Maximum-Exposed Individual

In addition to estimating the amount of a substance that may actually be present in the environment, a risk analysis must also consider the conditions under which humans may be exposed. Actual risks vary considerably depending on location, mobility, and a host of other factors. Nevertheless, estimates often are based on the upper-bound lifetime cancer risk to the maximum-exposed individual (MEI), the hypothetical person whose exposure is greater than all others. Sometimes, risks to the entire population are estimated by assuming that everyone is exposed at the MEI level. Because environmental regulations are often justified using MEI-based risk assessments, actual risks may be substantially lower than what decisionmakers and the general public perceive them to be.

---

[62] *Dioxin Risk Assessment*, pp. 46–49. 10-6 risk-specific doses (RsDs) derived from the linearized multistage model span the range from 0.001 to 1.2 picogram/kg/day. The RsDs of EPA, CDC, and FDA are 0.006, 0.03, and 0.06 pg/kg/day, respectively.

[63] *Dioxin Risk Assessment*, p. 4.

[64] *EPA Carcinogen Assessment Guidelines*, p. 33998. "EPA will continue to use this [surface area] scaling factor unless data on a specific agent suggest that a different scaling factor is justified."

[65] EPA guidance documents have historically called for unbiased estimates of exposure. See, e.g., U.S. Environmental Protection Agency, "Guidelines for Exposure Assessment," 50 FR 34042–34054 (September 24, 1986, hereinafter, *EPA Exposure Assessment Guidelines*); U.S. Environmental Protection Agency, *Superfund Public Health Evaluation Manual*, OSWER Directive 9285.4–1, October 1986; and U.S. Environmental Protection Agency, *Superfund Exposure Assessment Manual* (Revised Draft), OSWER Directive 9285.5–1, December 1986. EPA recently abandoned the calculation of unbiased exposure estimates for Superfund sites on the ground that it was insufficiently conservative. EPA's new protocol requires the estimation of "reasonable maximum exposure" instead of the average and upper-bound estimates. Reasonable maximum exposure constitutes a new term of art that EPA intends to be "well above the average case" but not as extreme as the upper-bound. It provides a new opportunity for embedding conservative assumptions into exposure assessment and exaggerating estimates of actual human-health risk at Superfund sites. See *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A), Interim Final*, EPA/540/1-89/002, December 1989, Chapter 6, pp. 5, 47–50.

In developing the MEI risk level, analyses invariably assume that the level of exposure is continuous over a 70-year lifetime. This assumption overstates actual risks, because people are mobile, encounter a constantly changing portfolio of daily risks to life and health, and can take actions that reduce risk.

Assumptions vs. Real-World Exposure Data

The thread that connects these exposure assessment issues is that simple constructs which overstate exposure are typically used in lieu of real-world data, often because such data are unavailable. The risk estimates generated by these models depend on the validity of their assumptions; even small biases in exposure assessment assumptions can result in a substantial overstatement of risk.

For example, regulatory agencies may not have statistically reliable real-world data on pesticide residues in agricultural products. They also may not know the proportion of a given crop that has been treated with a particular pesticide. A common resolution of these uncertainties is to assume that residues are equal to the regulatory "tolerance"—the maximum level allowed to be present in food sold in interstate commerce—and that 100 percent of the relevant crop has been treated. Both assumptions overstate actual exposure, but are encouraged by agency guidance as a way to instill conservatism in risk assessment.[66] When data are available, however, the extent of this conservative bias becomes evident. In a recent special review for the pesticide Captan, for example, EPA reduced its earlier upper-bound lifetime cancer risk estimate by two orders of magnitude when it replaced the original conservative assumptions with real-world data. Even with these improvements, EPA still reported that upper-bound risks were probably overstated. For example, field tests were performed based on applications at the maximum legal rate and as close to harvest as the label permits. Similarly, feeding studies assumed that animal diets were dominated by feedstuffs that happened to contain high residues relative to other feedstuffs, such as almond hulls and raisin waste. As EPA noted, even if these assumptions accurately represented typical animal diets, they would do so only for portions of California where these crops are grown; nationwide extrapolations based on these "hot-spots" would very likely overstate exposure.[67] Since two of the highest product-specific risks were attributed to milk and meat, these remaining conservative biases can be expected to be significant.

IMPLICATIONS OF CONSERVATIVE RISK ASSESSMENT FOR RISK MANAGEMENT AND REGULATORY DECISIONMAKING

The primary purpose of risk assessment is to provide data as a basis for risk management decisions. Providing useful data requires the synthesis of information concerning risks and exposure levels into a coherent package that can be used to develop regulatory options. Decisionmakers then can use these risk estimates in evaluating regulatory alternatives. Unfortunately, the way in which risk information is characterized tends to overstate risks, making them appear much greater than they are likely to be. As a result, decisionmakers may make regulatory choices that are very different from the ones they would make if they were fully informed.

Quantification of Uncertainty

In accordance with the recommendations of the National Academy of Sciences, the *OSTP Guidelines* explicitly call for the quantification of uncertainty, particularly as it arises in the selection of dose-response models and exposure assumptions.[68] Unfortunately, Federal regulatory proposals that utilize risk assessment rarely provide this information, nor do they analyze the implications of uncertainty for decisionmaking. Instead, many risk assessments only identify a lifetime upper-bound level of risk.[69]

The differences between upper-bound and expected-value estimates may be considerable. As we indicated earlier, the upper-bound risk estimate for dioxin may be 5,000 times greater than the most likely estimate. Plausible risk estimates for perchloroethylene (the primary solvent used in dry cleaning) vary by a factor of about 35,000.[70]

In some instances, decisionmakers may not be informed that risk estimates differ because of policy choices hidden in the risk-assessment methodology. In EPA's proposed rule limiting emissions from coke

[66] *EPA Exposure Assessment Guidelines*, p. 34053. "When there is uncertainty in the scientific facts, it is Agency policy to err on the side of public safety."

[67] See, e.g., U.S. Environmental Protection Agency, "Captan: Intent to Cancel Registrations; Conclusion of Special Review," 54 FR 8127–8128 (February 24, 1989).

[68] *OSTP Guidelines*, (Guideline 27), p. 10378.

[69] See, e.g., *EPA Carcinogen Risk Assessment Guidelines*, p. 33998.

[70] Nichols and Zeckhauser, *(op. cit.)*, pp. 64–65.

ovens, for example, cancer risks were estimated based on the LMS model—a model that is designed to yield upper-bound estimates of risk. In previous rules involving similar types of risks, however, EPA used the unbiased maximum likelihood estimate. To the extent that decisionmakers were not informed that the higher estimate of risk was largely due to a different low-dose extrapolation procedure, regulatory decisions based on this risk assessment were likely to reflect misunderstanding rather than science.[71]

Plausible estimates of likely cancer risk can often be found buried in regulatory background documents. However, *Federal Register* rulemaking notices seldom present such estimates alongside upper-bound estimates. This practice overstates baseline human health threats, as well as the amount of risk reduction that may be accomplished by regulation. Policymakers and the public are misled because they typically see only the upper-bound estimates of the threat.

The prevalent Federal agency practice is to calculate the benefits of Federal regulatory initiatives based solely on upper-bound estimates of risk and exposure. In a recent proposal to reduce occupational exposure to cadmium, for example, the Occupational Safety and Health Administration (OSHA) developed risk estimates based on five alternative models for animal data, and two alternative models for human data. Across these seven data/model combinations, estimated excess lifetime cancer risk at the least stringent of the two proposed exposure standards varied from 0 to 153 cases per 10,000 workers occupationally exposed for 45 years. OSHA based its proposed exposure standards on *one* of these data/model combinations—the multistage model applied to animal data. This data/model combination predicted an excess lifetime cancer risk of 106 per 10,000 exposed workers, and was used to estimate aggregate cancer incidence and the risk-reduction benefits attributable to the new standard. Uncertainties in the underlying risk assessment, which span several orders of magnitude, were not carried forward through the exposure assessment and benefit calculation stages. This analytic error effectively obscured the uncertainty surrounding the true incidence of cadmium-induced lung cancer, and resulted in benefit estimates that may exceed actual reductions in occupational illness by several orders of magnitude.[72]

Misordered Priorities, Perverse Outcomes

Logically, one would expect that the routine overstatement of likely risks would lead to inefficient regulatory choices. Decisionmakers, convinced that a certain substance or activity poses a significant threat to public health, might well take actions that they would otherwise resist. Alternatively, they might take actions that address the wrong real-life risks.

To the extent that risk assessments differ in the degree to which they adopt conservative assumptions, it is difficult to determine which activities pose the greatest risks and hard to establish reasonable priorities for regulatory action. Because conservatism in risk assessment is especially severe with respect to carcinogens, it is reasonable to expect that other health and safety risks tend to receive relatively less attention and weight. As a result, society may actually incur greater total risk, because of misordered priorities caused by conservative biases in cancer risk assessment.[73]

A perverse and unfortunate outcome of using upper-bound estimates based on compounded conservative assumptions is that the practice may actually increase risk, even in situations where cancer is the only concern. Regulatory actions taken to address what are in fact insignificant threats may implicitly tolerate or ignore better known, documented risks that are far more serious. For example, before it was banned, ethylene dibromide (EDB) was used as a grain and soil fumigant to combat vermin and molds. Vermin transmit disease, and molds harbor the natural and potent carcinogen aflatoxin B. The estimated human cancer risk from the aflatoxin contained in one peanut butter sandwich is about 75 times greater than a full day's dietary risk from EDB exposure. On this basis alone, it might have been appropriate to accept a small increase in cancer risk from EDB to reduce the much larger cancer risk from aflatoxin. By eliminating the relatively small hazard from EDB, Federal risk managers may have intensi-

[71] Letter from Wendy Gramm (Administrator of the Office of Information and Regulatory Affairs) to Lee Thomas (Administrator of the Environmental Protection Agency), August 12, 1986, p. 3.

[72] Occupational Safety and Health Administration, "Occupational Exposure to Cadmium; Proposed Rule," 55 *Federal Register* 4076, 4080, 4093.

[73] This is precisely the policy issue raised by Nichols and Zeckhauser, (*op. cit.*), pp. 69–71, who note that EPA's 1985 decision to limit lead in gasoline was threatened by concerns about potential increases in benzene exposure. Any tradeoff between lead and benzene risks would have been biased against lead, as estimates of benzene risks are more conservative simply because it is a carcinogen, whereas lead is not.

fied the relatively potent threat of aflatoxin associated with an increase in the prevalence of mold contamination.[74]

The emphasis on risks faced by the maximum-exposed individual may also cause a perverse result by increasing overall population risks. For example, EPA's proposed regulation of the disposal of sewage sludge would probably create more public health risk than it eliminates. The proposal outlines a regulatory scheme that would shift disposal from generally safe practices to relatively risky alternatives. Thus, setting sludge quality standards to achieve an MEI upper-bound lifetime cancer risk of one in 100,000 (10^{-5}) would prevent 0.2 statistical cancer cases resulting from monofilling and land application. However, it would cause 2.0 additional statistical cancers by forcing a shift away from these disposal approaches toward incineration.[75]

These problems can be addressed by providing decisionmakers with the full range of information on the risks of a substance or an activity. Thus, decisionmakers should be given the likely risks as well as estimates of uncertainty and the outer ranges of the potential risk. Then, if regulatory decisionmakers want to choose a very cautious risk management strategy, they can do so and a margin of safety can be applied explicitly in the final decision. This approach is superior to one in which the expected risk and an unknown margin of safety are hidden behind the veil of a succession of upper-bound estimates adopted at key points in the risk-assessment process.

The public and affected parties also benefit from knowing both the expected risk and the margin of safety rather than being given upper-bound estimates that are probably very different from actual risks. People are likely to have a better intuitive understanding of the significance of averages than they have of unlikely extremes. To the extent that a margin of safety is appropriate—perhaps to protect unusually sensitive subpopulations—the magnitude of this margin can be more readily communicated if made explicit. In addition, providing information in this way should help improve public confidence in quantitative risk assessment as the basis for decisionmaking.

AVOIDING CONSERVATIVE BIASES IN RISK ASSESSMENT

Risk assessment remains a powerful and useful scientific tool for estimating many of the risks that arise in a technologically advanced society. Unfortunately, it is also susceptible to hidden biases that may undermine its scientific integrity and the basis for policymakers' reliance on such information in risk management decisions. For policymakers and the public to continue to rely on risk assessment in the development of regulatory initiatives, a renewed effort must be made to separate science from policy and provide risk information that is both meaningful and reliable.

Expected Value Estimates

Perhaps the most important current need in regulatory decisionmaking is for carefully prepared and scientifically credible estimates of the likely risks involved. Relying on worst-case analysis based on extremely conservative risk assessment and exposure models leads to widespread misunderstanding on the part of both Government officials and individual citizens. Decisionmakers at all levels need unbiased and impartial risk information so they can focus their attention on significant problems and avoid being distracted by minutiae.[76]

Weight-of-Evidence Determinations

Similar procedures are needed for assigning weight to each relevant study in the risk-assessment literature. Current practice gives undue weight to studies that show positive relationships. Resulting risk classifications are thus conservatively biased estimates derived from samples of similarly biased observations.

Full Disclosure

Efficient and responsible decisionmaking requires that policymakers and the public be fully informed about the implications of the regulatory alternatives among which they must choose. Meeting this requirement demands a careful discrimination between science and policy. When risk estimates depend on assumptions and judgments instead of data, the meaning and implications of these nonscientific parameters must be clearly articulated.

Avoiding Perverse Outcomes

Careful attention needs to be paid to the likely results of regulatory alternatives, with an eye toward avoiding choices that have the perverse effect of increasing net risk. All human activity involves risk.

---

[74] Ames *et al.*, *(op. cit.)*, p. 273.

[75] U.S. Environmental Protection Agency, "Standards for the Disposal of Sewage Sludge; Proposed Rule," 54 FR 5746–5902 (February 6, 1989).

[76] Nichols and Zeckhauser, *op. cit.*, pp. 72–76.

Decisionmakers need to be sure that specific actions taken in the name of risk-reduction in one area do not make matters worse elsewhere. Quantitative risk assessment can help in this regard so long as the methods applied are not inherently biased in a way that undermines comparisons across alternatives, each of which entails some degree of risk.

Our discussion has covered only the highlights of risk-assessment methods, yet we have identified several independent places at which conservative assumptions are commonly used. Individually, each of these assumptions might appear to be prudent responses to scientific uncertainty. In combination, however, they result in a distortion equal to the product of the individual conservative biases. To illustrate, suppose that there are ten independent steps in a risk assessment and prudence dictates assumptions that in each instance result in risk estimates two times the expected value. Such a process would yield a summary risk estimate that is more than 1,000 times higher than the most likely risk estimate. Because there are usually many more than ten steps, and many of them will incorporate conservative biases that exceed an order of magnitude, risk estimates based on such practices will often exceed the most likely value by a factor of one million or more.

When risk assessments contain hidden value judgments, their scientific credibility is inevitably compromised. To the extent that policymakers and the public fail to understand the magnitude of the margin of safety embedded in quantitative risk assessments, policy choices are distorted from the course that would have been selected if decisionmakers had been better informed of the actual risks. Ironically, these policy decisions may actually increase total societal risk. Too much attention is focused on relatively small hazards that have been exaggerated by conservative risk assessments, leaving alone larger risks that have been estimated using unbiased procedures.

Information as an Alternative Regulatory Strategy

Federal regulation was initiated to deal with economic problems caused by monopoly and so-called "excess competition." Subsequent events have shown that, in general, economic regulation—fixing prices, establishing restrictive terms of trade, and erecting barriers to entry—is usually inefficient and detrimental to innovation. In response to these lessons, Federal regulation of this type has been under increasing criticism. As indicated above, however, much more needs to be done to reform economic regulation and restore competition.

Federal regulation has more recently been initiated to deal with what economists call externalities, situations in which participants in voluntary market transactions do not bear the full costs or capture all of the benefits of these exchanges. Common examples of externalities include environmental pollution and traffic congestion, common property resources such as fisheries and public forests, and "public goods" such as basic scientific research. In each of these instances, regulation may be an appropriate mechanism to modify or restore distorted market processes, or to establish markets where heretofore they have not existed, to maximize net social benefits (including environmental, health, and safety benefits). The key ingredient is the determination that existing markets are, in some significant manner, failing to perform efficiently.

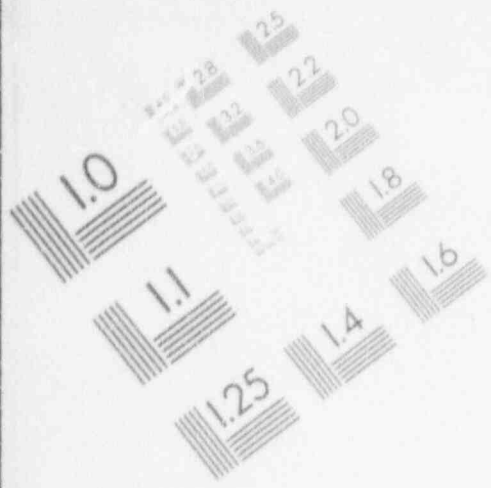
The traditional regulatory approach to externalities has been the promulgation of standards. Because this approach often remedies existing externalities by creating new ones, economic incentive instruments are becoming an increasingly popular alternative to standards. The principal attraction of economic incentives is that they rely on market forces rather than attempt to suppress them.

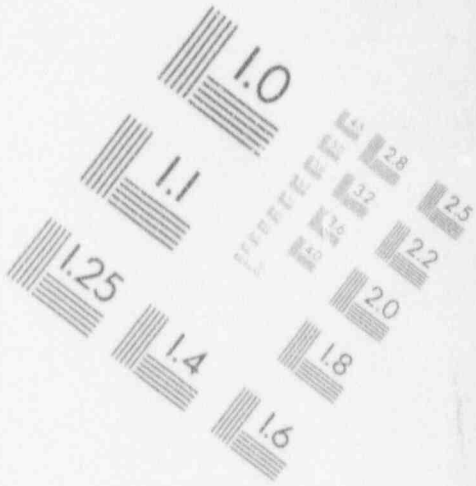
This section explores another alternative regulatory strategy—the production, provision, or mandated disclosure of information. The first subsection briefly summarizes the economics of information as it relates to regulatory decisionmaking. Three points stand out in this discussion. First, because information is costly to acquire and the capacity to process it is limited, there is an optimal level of information for every market transaction. Second, differences in the amount and quality of information between buyers and sellers are normal and do not necessarily indicate market failure. Rather, these differences generally reflect variations in the costs and benefits that are attributable to information. Third, competitive markets provide powerful incentives for buyers and sellers to reveal relevant information. Market processes, not government regulations, provide the dominant motivation for generating, acquiring, and disclosing information. The role of government regulation thus should be to supplement these processes when they prove to be inadequate, not to supplant them when they work well.

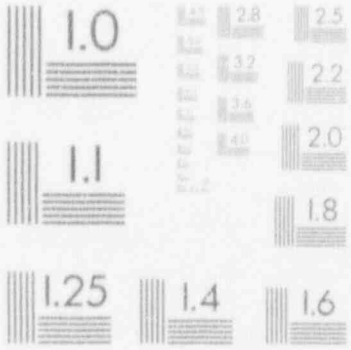
The second subsection identifies three rationales for government intervention in the production or mandated disclosure of information. Two of these are economic—the public-good character of some types of

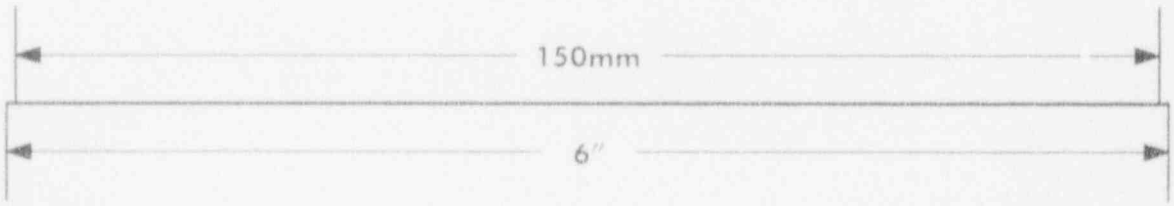
1

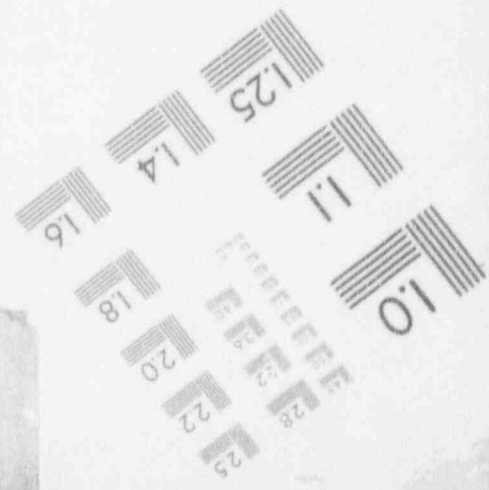
IMAGE EVALUATION TEST TARGET (MT-3)





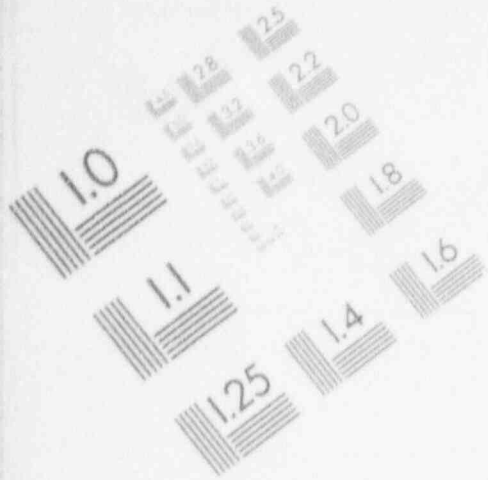


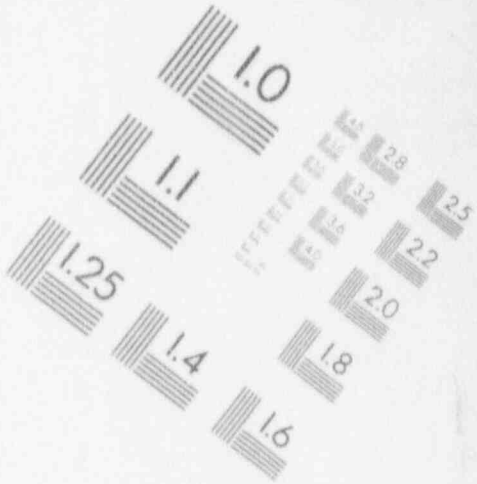


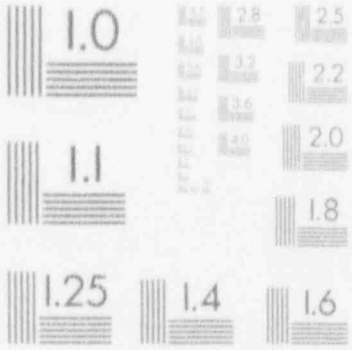


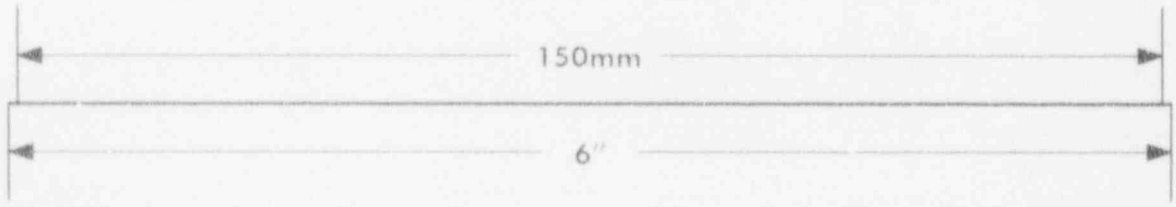
1

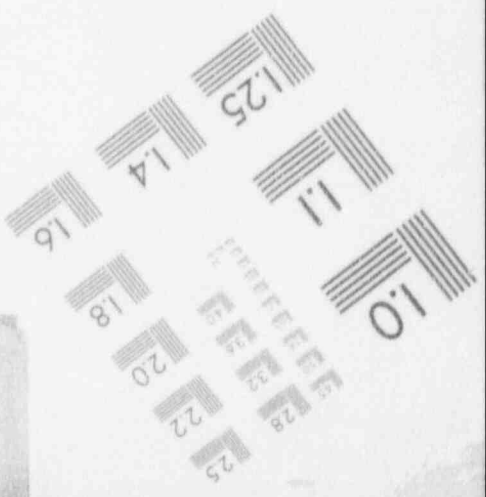
IMAGE EVALUATION TEST TARGET (MT-3)





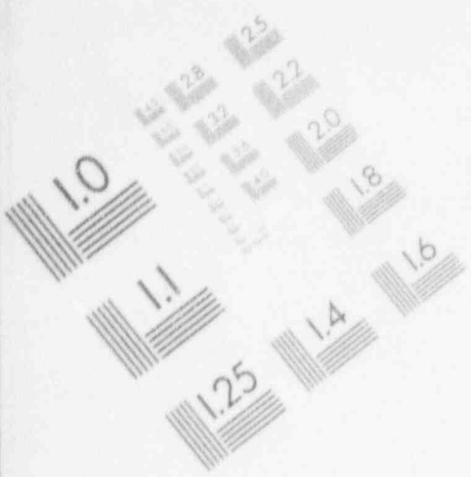


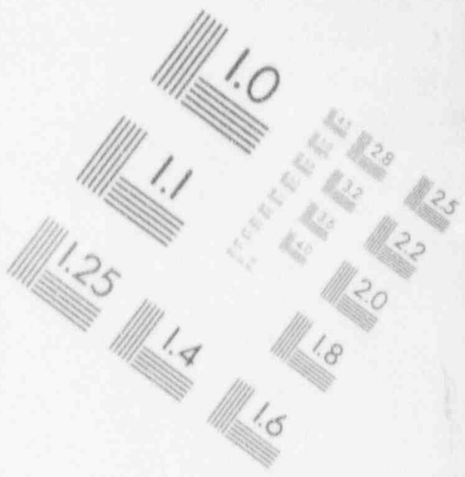


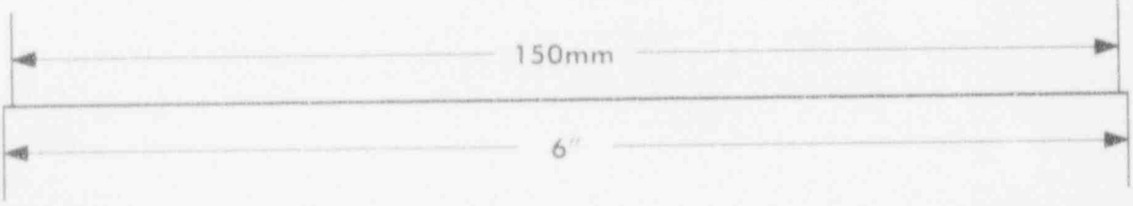


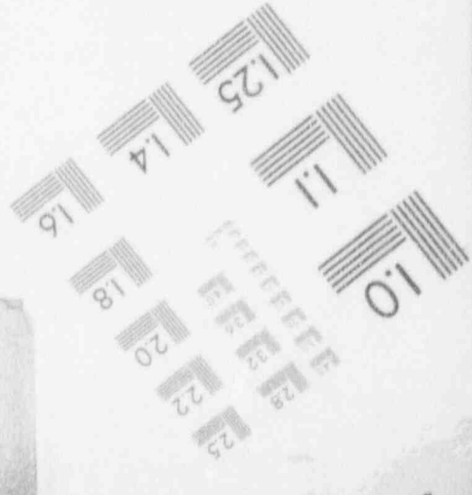
1

IMAGE EVALUATION TEST TARGET (MT-3)









APPENDIX V

Regulatory Impact Analysis Guidance

A Regulatory Impact Analysis (RIA) should demonstrate that a proposed regulatory action satisfies the requirements of Section 2 of Executive Order No. 12291. To do so, it should show that:

- There is adequate information concerning the need for and consequences of the proposed action;
- The potential benefits to society outweigh the potential costs; and
- Of all the alternative approaches to the given regulatory objective, the proposed action will maximize net benefits to society.

The fundamental test of a satisfactory RIA is whether it enables independent reviewers to make an informed judgment that the objectives of Executive Order No. 12291 are satisfied. An RIA that includes all the elements described below is likely to fulfill this requirement. Although variations consistent with the spirit and intent of the Executive Order may be warranted for some rules, most RIAs should include these elements.

The guidance in this document is not in the form of a mechanistic blueprint, for a good RIA cannot be written according to a formula. Competent professional judgment is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphases in analysis. For one proposed regulation, the crucial issue may be the question of whether a market failure exists, and much of the analysis may need to be devoted to that key question. In another case, the existence of a market failure may be obvious from the outset, but extensive analysis might be necessary to estimate the magnitude of benefits to be expected from proposed regulatory alternatives. The amount of analysis (whether scientific, statistical, or economic) that a particular issue requires depends on how crucial that issue is to determine the best alternative and on the complexity of the issue.

Regulatory analysis inevitably involves uncertainties and requires informed professional judgments. Whenever an agency has questions about such issues as the appropriate analytical techniques to use or the alternatives that should be considered, it should consult with the Office of Management and Budget as early in the analysis stage as possible.

This document is written primarily in terms of proposed regulatory changes. However, it is equally applicable to the review of existing regulations. In the latter case, the regulation under review should be compared to a baseline case of no regulation and to reasonable alternatives.

Elements of a Regulatory Impact Analysis

Preliminary and final Regulatory Impact Analyses of major rules should contain five elements. They are: (1) a statement of the potential need for the proposal, (2) an examination of alternative approaches, (3) an analysis of benefits and costs, (4) the rationale for choosing the proposed regulatory action, and (5) a statement of statutory authority. These elements are explained in Sections I–V below.

I. STATEMENT OF POTENTIAL NEED FOR THE PROPOSAL

In order to establish the potential need for the proposal, the analysis should demonstrate that (a) market failure exists that is (b) not adequately resolved by measures other than Federal regulation.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. Once such market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure. The three major types of market failure are externality, natural monopoly, and inadequate information.

1. *Externality.* An externality occurs when one party's actions impose uncompensated benefits or costs on another outside the marketplace. Environmental problems are a classic case of externality. Another example is the case of common property resources that may become congested or overused, such as fisheries or the broadcast spectrum. A third example is a "public good," such as defense or scientific research, whose distinguishing characteristic is that it is inefficient, or impossible, to exclude individuals from its benefits.

2. *Natural monopoly.* Natural monopoly exists where a market can be served at lowest cost only if production is limited to a single producer. Local telephone, gas, and electricity services are examples.

3. *Inadequate information.* The optimum, or ideal, level of information is not necessarily the maximum possible amount, because information, like other goods, should not be produced when the costs of doing so exceed the benefits. The free market does not

necessarily supply an optimal level of information, because information, once generated, can be disseminated at little or no marginal cost, and because it is commonly infeasible to exclude nonpayers from reaping benefits from the provision of information by others. Where market failure due to inadequate information is the rationale for government intervention, a regulatory action to improve the availability of information will ordinarily be the preferred alternative.

The current state of knowledge about the economics of information is not highly developed. Therefore, regulatory intervention to address an information problem should only be undertaken where there is substantial reason to believe that private incentives to provide information are seriously inadequate and that the specific regulatory intervention proposed will provide net benefits for society.

In many circumstances, the availability of information, while perhaps not optimal, is reasonably adequate, so that attempts to regulate information are as likely to make things worse as to make them better. Information about a particular characteristic of a product, for example, would be reasonably adequate if buyers could determine the existence of the characteristic by inspection of the product before purchase or (in the case of a frequently purchased product) by use of the product. Even if the characteristic could not be determined by buyers, government intervention would not be warranted where sellers have incentives to reveal the existence of the characteristic to buyers. Sellers will have substantial incentives to supply information about any characteristic that is important to buyers and valued positively by them, particularly if the level of the characteristic varies between the products of one seller and another. In these circumstances, sellers whose products rank highly in the valued characteristic can increase their sales by informing buyers of the superiority of their products. If the level of the characteristic does not vary between the products of one seller and another, individual sellers have less incentive to inform buyers about the characteristic. Even so, the incentives of individual sellers or of a trade association to supply information may be substantial.

Sellers are least likely to supply adequate information about a particular characteristic of their product where the characteristic is negatively valued by consumers and the level of the characterstic does not vary between the products of one seller and those of another (e.g., cholesterol in eggs). Even in such circumstances, substantial information about the characteristic may be available to buyers. For example, sellers of rival products may supply the information (e.g., while sellers of butter may have no incentive to tell buyers about cholesterol in butter and its possible consequences, sellers of margarine do have such an incentive). Where the negative characteristic involves a health or safety hazard, the threat of future product liability lawsuits may give sellers adequate incentives to reveal information about the potential hazard. News media, consumer groups, public health agencies, and similar services may supply information not supplied by sellers. In summary, while it is possible to identify situations in which market failure due to inadequate information is more likely to warrant regulatory intervention, each situation must be examined on a case-by-case basis.

There should be a presumption against the need for certain types of regulatory actions, except in special circumstances. A particularly demanding burden of proof is required to demonstrate the potential need for any of the following types of regulations:

- Price controls in competitive markets
- Controls on production or sales in competitive markets
- Mandatory uniform quality standards for goods or services, unless they have hidden safety or other defects and the problem cannot be adequately dealt with by voluntary standards or information disclosing the hazard to potential buyers or users
- Controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

B. Alternatives to Federal Regulation

Even where a market failure exists, there may be no need for Federal regulatory intervention if other means of dealing with the market failure resolve the problem adequately or better than the proposed Federal regulation would. Among the alternative means that may be applicable are the judicial system (particularly liability cases to deal with health and safety), antitrust enforcement, and workers' compensation systems.

An important alternative that may often be relevant is regulation at the State or local level. In determining whether there exists a potential need for a proposed Federal regulation, the analysis should examine whether regulation at the Federal level is more appropriate than regulation at the State or local level. This analysis may support regulation at the Federal level where rights of national citizenship (such as legal equality among the races) or considerations of interstate commerce are involved. If interstate commerce is involved the analysis should attempt to determine whether the burdens on

interstate commerce arising from different State and local regulations are so great that they outweigh the advantages of diversity and local political choice. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, pollution that spills across state lines (such as acid rain whose precursors are transported widely in the atmosphere) is probably best controlled by Federal regulation, while localized pollution (such as garbage truck noise) is probably more efficiently handled by local government regulation.

In general, because demands among localities for different governmental services differ and because competition among governmental units for taxpayers and citizens may encourage efficient regulation, the smallest unit of government capable of correcting the market failure should be chosen. This must, however, be balanced against the possibility of higher costs because national firms would be required to comply with more than one set of regulations and because administering similar regulations in more than one governmental unit involves some costs of duplication. Thus, some analysis may be necessary to determine which level of government can most efficiently regulate a specific market failure.

If the analysis does suggest a potential need for a Federal action, it should also consider alternatives of nonregulatory Federal measures. For example, as an alternative to requiring an action or the use of a particular product, it may be more efficient to subsidize it. Similarly, a fee or charge may be a preferable alternative to banning or restricting a product or action. An example would be an effluent discharge fee, which has been recommended as an efficient way to limit pollution, because it causes pollution sources with different marginal costs of abatement to control effluents in an efficient manner. In addition, legislative measures that make use of economic incentives, such as changes in insurance provisions or changes in property rights, should be considered.

II. AN EXAMINATION OF ALTERNATIVE APPROACHES

The RIA should show that the agency has considered the most important alternative approaches to the problem and must provide the agency's reasoning for selecting the proposed regulatory change over such alternatives. Ordinarily, it will be possible to eliminate some alternatives by a preliminary analysis, leaving a manageable number of alternatives to be evaluated by quantitative benefit-cost analysis according to the principles to be described in Section III. The number and choice of alternatives to be selected for detailed benefit-cost analysis is unavoidably a matter of judgment. There must be some balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis.

Alternative regulatory actions that should be explored include the following:

1. *More performance-oriented standards for health, safety, and environmental regulations.* Performance standards are generally to be preferred to engineering or design standards because they allow the regulated parties to achieve the regulatory objective in the most cost-effective way. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should also be applied as broadly as possible without creating too much variation in regulatory benefits; for example, by setting emission standards on a plant-wide or firm-wide basis rather than source by source. It is misleading and inappropriate, however, to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard.

2. *Different requirements for different segments of the regulated population.* For example, there might be different requirements for large and small firms. If such a differentiation is made, it should be based on perceptible differences in the costs of compliance or in the benefits to be expected from compliance. For example, some worker safety measures may exhibit economies of scale, that is, lower costs per worker protected in large firms than in small firms. A heavier burden should not be placed on one segment of the regulated population on the grounds that it is better able to afford the higher cost; this is a sure formula for loading disproportionate costs on the most productive sectors of the economy.

3. *Alternative levels of stringency.* In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although costs will eventually increase more rapidly than benefits). It is important to consider alternative levels of stringency to better understand the relationship between stringency and benefits and costs. This approach will increase the information available to the decisionmaker on the option that maximizes net benefits.

4. *Alternative effective dates of compliance.* The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially over different compliance dates for an industry that requires a year or more to plan its production runs efficiently. In this instance, a regulation whose requirements provide

sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

5. *Alternative methods of ensuring compliance.* Compliance alternatives include the appropriate entity (local, State, or Federal) enforcing compliance, whether compliance is enforced by on-site inspection or periodic reporting, and structuring compliance penalties so that they provide the most appropriate incentives.

6. *Informational measures.* Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hot-lines, or public interest broadcast announcements). If intervention is necessary to address a market failure arising from inadequate information, informational remedies will generally be the preferred approaches. As an alternative to a mandatory standard, a regulatory measure to improve the availability of information has the advantage of being a more market-oriented approach. Thus, providing consumers information about concealed characteristics of consumer products gives consumers a greater choice than banning these products (for example, consumers are likely to benefit more from information on energy efficiency than from a prohibition on sale of appliances or automobiles falling below a specified standard of energy efficiency).

Except for prohibiting indisputably false statements (whose banning can be presumed beneficial), specific informational measures must be evaluated in terms of their benefits and costs. Paradoxically, the current state of knowledge does not generally permit the benefits and costs of informational remedies to be measured very accurately. Nonetheless, it is essential to consider carefully the costs and benefits of alternative informational measures, even if they cannot be quantified very precisely. Some effects of informational measures can easily be overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product include not only the obvious cost of gathering and communicating the required information, but also the loss of any net benefits of information displaced by the mandated information, the cost of any inaccurate consumer interpretation of the mandated information, and any inefficiencies arising from the incentive that mandatory disclosure of a particular characteristic gives to producers to overinvest in improving that specific characteristic of their products.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, as will often be the case, the least intrusive alternative, sufficient to accomplish the regulatory objective, should be chosen. For example, it will often be sufficient for government to establish a standardized testing and rating system without mandating its use, because firms that score well according to the system will have ample incentive to publicize the fact.

7. *More market-oriented approaches.* In general, alternatives that provide for more market-oriented approaches, with the use of economic incentives replacing command-and-control requirements, should be explored. Market-oriented alternatives that may be considered include fees, subsidies, penalties, marketable rights or offsets, changes in liabilities or property rights, and required bonds, insurance or warranties (in many instances, implementing these alternatives will require legislation).

III. ANALYSIS OF BENEFITS AND COSTS

A. General Principles

The preliminary analysis called for by Sections I and II should have narrowed the number of alternatives to be considered by quantitative benefit-cost analysis to a workable number. Ordinarily, one of the alternatives will be to promulgate no regulation at all, and this alternative will commonly serve as the base from which increments in benefits and costs are calculated for the other alternatives. Even if alternatives such as no regulation are not permissible statutorily, it is often desirable to evaluate the benefits and costs of such alternatives to determine if statutory change would be desirable. Departments and agencies bear a similar burden when they perform environmental impact statements in which alternatives that lie outside their statutory authority must be considered.

In some cases, the desirability of specific alternatives outside the scope of the agency's regulatory authority may be determined by use of basic economic concepts in light of the principles enumerated in Section I. In other instances, however, only a quantitative benefit-cost analysis can resolve the question, and such alternatives will need to be included in the analysis of this section. In addition, alternative forms of agency regulation will need to be evaluated by quantitative benefit-cost analysis.

1. *Evaluation of Alternatives.* Except where prohibited by law, the primary criterion for choice among alternatives is expected net benefit (benefits minus costs). Other criteria may sometimes produce equivalent results, but they must be used with care to avoid

the potentially serious pitfalls to be explained in Part B of this section and in Section IV. Both benefits and costs should be expressed in discounted constant dollars. Appropriate discounting procedures are discussed in the following section.

The distinction between benefits and costs in benefit-cost analysis is somewhat arbitrary, since a positive benefit may be considered a negative cost, and vice versa, without affecting the net benefit (benefits minus costs) decision criterion. This implies that the considerations applicable to benefit estimates also apply to costs and vice versa. The different issues are considered separately under benefits or costs in Sections B and C below according to where they most often arise.

If the proposed regulation is composed of a number of distinct provisions, it is important to evaluate the benefits and costs of the different provisions separately. The interaction effects between separate provisions (such that the existence of one provision affects the benefits or costs arising from another provision) may complicate the analysis but does not eliminate the need to examine provisions separately. In such a case, the desirability of a specific provision may be appraised by determining the net benefits of the proposed regulation with and without the provision in question. Where the number of provisions is large and interaction effects are pervasive, it is obviously impractical to analyze all possible combinations of provisions in this way. Some judgment must be used to select the most significant or suspect provisions for such analysis.

2. *Discounting.* The monetary values of benefits and costs occurring in different years should be discounted to their present values so that they are comparable. This is not the same as correcting for inflation. An inflation adjustment is made with a price index, whereas discounting to present value is done with a discount rate. Benefits and costs expressed in constant (i.e., unaffected by inflation) dollars must further be discounted to present values before benefits and costs in different years can be added together to determine overall net benefits. As an equivalent alternative to discounting nonmonetized benefits, the RIA may use the discount rate to annualize (amortize) costs over a period that corresponds to the occurrence of the benefits. Regardless of the discounting procedure selected, the RIA must contain a schedule indicating when the benefits and costs occur.

Discounting takes account of the fact that resources (goods or services) in a given year are worth more than identical resources in a later year. The underlying reason for this is that resources can be invested so as to return more resources later. Partly because of this productivity of investment, individuals value consumption in earlier years higher than consumption in later years.

Modern analysis of discounting for public programs stresses the distinction between two rates of return:

- The *before-tax* rate, also known as the opportunity cost of capital. This is the real rate of return to marginal private investments. Estimates of the opportunity cost of capital in the U.S. economy vary substantially. The 10 percent discount rate specified by OMB Circular A–94 for use in evaluating government programs is intended to represent the opportunity cost of capital.
- The *after-tax* rate, also known as the consumption rate of interest. This represents the rate at which consumers would be willing to exchange present for future consumption, that is, the rate at which consumers must be compensated for postponing their consumption. As with the opportunity cost of capital, alternative estimates of the consumption rate of interest vary significantly. A rate of 4 percent is reasonably representative of the range of alternative estimates and consistent with a 10 percent before-tax rate of return.

The basic concept underlying the academic literature on public-sector discounting is that economic welfare is ultimately determined by consumption and only indirectly by investment. Therefore, the value of investment must be measured by the value of the subsequent increase in consumption it permits. Any effect that a government program has on investment must be converted to an equivalent time-stream of consumption before being discounted. In practice, this results in a complex procedure that uses the before-tax and after-tax discount rates, a "shadow price of capital," and the impacts of benefits and costs on investment. It is recommended that agencies continue to use the well-understood procedure of discounting by a single rate (as specified by OMB Circular A–94) and, when appropriate, perform additional analysis using the more complex shadow-price-of-capital methodology.

There are two circumstances when it is important to perform sensitivity analysis using the shadow price of capital approach:

(a) Where the costs of the regulation are almost entirely current costs borne by consumers. In such circumstances, a low rate close to 4 percent is called for. (This assumes, as is normally the case, that the benefits are all in the form of disposable income or other benefits directly to individuals.)

(b) Where some of the costs are capital costs financed out of saving *and* there is a long period between the time when most costs are incurred and the time when most benefits accrue. In general, the

smaller the fraction of costs that are capital costs financed out of saving and the *longer* the time period between costs and benefits, the greater the likelihood that the shadow price of capital approach will be correct.

It is conceptually incorrect to adjust the discount rate as a device to account for the uncertainty of expected future benefits and costs. This procedure will virtually never lead to a correct adjustment of benefits and costs. Therefore, risk and uncertainty should be dealt with according to the principles in Section 3 below and not by changing the discount rate.

3. *Treatment of Risk and Uncertainty.* Where uncertainties exist about important parameters affecting the expected benefits or costs of an alternative under consideration, it is essential to carry out a *sensitivity analysis* to determine the effect on net benefits of plausible variations in the value of the parameters. One form of sensitivity analysis involves calculation of the "switch-point" value of the parameter under examination, that is, the value of the parameter at the break-even point at which the net-benefit decision criterion switches over from favoring one alternative to favoring another. When this break-even point of the parameter value is determined, the analysis may then consider the probability that the true parameter value is above or below the break-even value. For example, if the major uncertainty about a proposed regulation were its cost, the analysis could calculate how high the cost would need to be in order to reduce the net benefit of the proposal to zero. If it is judged to be highly unlikely that the actual cost would be that high or higher, it may be concluded that the choice of the proposed alternative is not sensitive to uncertainties about its cost.

A primary objective of sensitivity analysis is to identify where additional analysis may be most needed. If the choice of a specific regulatory action is sensitive to alternative parameter values that are about equally likely to be true, more research to better determine the true parameter value could be very valuable.

Wherever parameter estimates are uncertain, for either benefits or costs, expected-value estimates should be presented. Hypothetical best-case or worst-case estimates may be presented as alternatives for sensitivity analysis. Where possible, information about the probability distribution of the parameter estimate should be presented.

A common situation that arises in estimating both benefits and costs is that a number of different studies may exist which together provide a range of different estimates for a particular parameter. In general, it is not appropriate to use the midpoint of the range of extreme values provided by the studies. Such a technique ignores the information provided by all studies except those providing the extreme values, which may be the least reliable. The preferred approach to deriving an expected-value estimate of a particular parameter in this situation would be to derive it as a weighted average of the estimates of the individual studies, with the weight of each estimate being based on the reliability (in the best judgment of the agency) of the study that produced it.

Where expected future benefits or costs are uncertain, their value to those who receive them may be different from their value if they were certain. (Often, but not always, a certain future benefit is worth more to people than an uncertain future benefit with the same expected value.) As noted in the previous section, it is incorrect to adjust the discount rate as a device to account for the riskiness of future benefits or costs. Any allowance for risk should be made by adjusting the monetary values (for the year in which they occur) of the uncertain benefits and costs so that they are expressed in terms of their "certainty-equivalents."

For an uncertain benefit in future year X, the certainty-equivalent is the number of certain dollars in year X that the uncertain benefit is worth to its recipient. For example, suppose that a particular regulation reduces the probability of fire in a particular type of facility. As part of a benefit-cost analysis for this regulation, the dollar value of the expected reduction in fire loss would be calculated. The owners of the protected facilities place a higher dollar value on the risk of a fire than the expected dollar value of the loss. This is demonstrated by their willingness-to-pay for fire insurance. Therefore, their relative net cost (the percentage difference between insurance premiums and insurance company claim payments) for fire insurance can be used to increase the expected dollar value of the reduction in fire loss to its certainty-equivalent value.

In the example of the preceding paragraph, the adjustment for risk would involve an increase in the value of the benefit, whereas uncertainty of a benefit is normally thought to reduce its certainty-equivalent value. The reason is that even though this benefit by itself is uncertain, it acts to reduce the overall level of risk that would prevail in the absence of the regulation. This illustrates the important principle that what matters is not the variability or riskiness of a regulation's net benefits by themselves but the regulation's effect on risk and uncertainty overall.

While an adjustment to account for risk may be called for in the fire-risk example given, a similar adjustment for the value of reductions in fatalities and injuries would not be appropriate. Assuming that

the values of fatalities and injuries have been derived by the willingness-to-pay methodology recommended in Section B.2 below, they would already represent the certainty-equivalent value of the uncertain risk. This is because the estimated dollar values represent the certain dollar amounts that individuals would sacrifice to reduce these risks.

Probably, in most cases, it will not be advisable to adjust for risk and uncertainty. As a theoretical matter, no adjustment for risk is necessary wherever the net benefits are widely dispersed among many individuals and are not correlated with disposable income. And in cases where this does not apply, risk may be relatively unimportant or may already be taken into account by use of the willingness-to-pay methodology. In other cases, there may be no practical way to quantify the value of changes in risk.

4. *Assumptions.* Where benefit or cost estimates are heavily dependent on certain assumptions, it is essential to make these assumptions explicit and, where alternative assumptions are plausible, to carry out sensitivity analyses based on plausible alternative assumptions. If the decision criterion proves to be sensitive to alternative plausible assumptions, this may necessitate further research to develop more evidence on which of the alternative assumptions is the most appropriate. Because the adoption of a particular estimation methodology sometimes implies major hidden assumptions, it is important to analyze estimation methodologies carefully to make hidden assumptions explicit.

5. *International Trade Effects.* In calculating the benefits and costs of a proposed regulatory action, generally no explicit distinction needs to be made between domestic and foreign resources. If, for example, compliance with a proposed regulation requires the purchase of specific equipment, the opportunity cost of that equipment is ordinarily best represented by its domestic cost in dollars, regardless of whether the equipment is produced domestically or imported. The relative value of domestic and foreign resources is correctly represented by their respective dollar values, as long as the foreign exchange value of the dollar is determined by a free exchange market. Nonetheless, an awareness of the role of international trade may be quite useful for assessing the benefits and costs of a proposed regulatory action. For example, the existence of foreign competition usually makes the demand curve facing a domestic industry more elastic than it would be otherwise. Elasticities of demand and supply frequently can significantly affect the magnitude of the benefits or costs of a regulation.

A regulation that discriminates unjustifiably against foreign exporters is a form of economic protectionism. The economic loss to the U.S. due to the fact that protectionism is economically inefficient will be reflected in the net benefit estimate of any properly conducted benefit-cost analysis. However, a benefit-cost analysis will generally not be able to measure the potential U.S. loss from the threat of future retaliation by foreign governments. Therefore, special attention should be given to any possibility that a regulation would unjustifiably discriminate between domestic and foreign producers and consumers—both discrimination against foreigners and discrimination in favor of foreigners.

The fact that a regulation has a differential effect on foreigners as compared to Americans does not necessarily constitute discrimination. If, for example, an automobile safety standard could be complied with less expensively by large cars than by small cars, such a standard would be more favorable to American car producers, who produce relatively more large cars compared to the fleet mix of foreign producers. Nonetheless, such a differential effect would not be discriminatory if the difference in compliance cost between large and small cars was necessary to achieve legitimate regulatory objectives in the most efficient way.

If a regulation has an adverse differential effect on foreign producers or consumers relative to domestic producers and consumers that is not necessary to realize regulatory goals efficiently, then a discriminatory effect on foreign trade exists. The RIA should identify any substantial differential effect on international trade and explain why it is necessary to achieve legitimate regulatory goals in the most efficient way. One means for reducing the likelihood of international discrimination would be for a U.S. product standard for an internationally traded good to be based on an international standard, wherever an international standard exists and is compatible with the health, safety, or environmental needs of the U.S. International harmonization can be beneficial for regulations directly setting standards for internationally traded goods or services. For example, it would be appropriate to consider international harmonization in setting safety standards for automobiles. There is no similar advantage to international harmonization where a regulation does not directly affect the quality of an internationally traded good or service, even if it indirectly affects its costs (e.g., environmental controls for automobile plants).

6. *Distributional Effects.* Those who bear the costs of a regulation and those who enjoy its benefits often are not the same persons. Benefits and costs of regulation may also be distributed unevenly over time, perhaps spanning several generations. There is no generally accepted way to monetize potential

distributional effects. Attempts to incorporate distributional concerns in benefit-cost analysis require the establishment of unequal weights for different groups in society. Because positive economics treats equally the willingness-to-pay of all individuals, any alternative weighting would undermine the objective character of the analysis. Policymakers may wish, however, to take account of the distributional effects of various regulatory alternatives. Therefore, where there are potentially important differences between those who stand to gain and those who stand to lose under alternative regulatory options, the RIA should identify these groups and indicate the nature of the differential effects. The RIA should also present information on the streams of benefits and costs over time as well as present value estimates, particularly where intergenerational effects are concerned.

B. Benefit Estimates

The RIA should state the beneficial effects of the proposed regulatory change and its principal alternatives. In each case, there should be an explanation of the mechanism by which the proposed action is expected to yield the anticipated benefits. An attempt should be made to quantify all potential real incremental benefits to society in monetary terms to the maximum extent possible. A schedule of monetized benefits should be included that would show the type of benefit and when it would accrue; the numbers in this table should be expressed in constant, undiscounted dollars. Any expected incremental benefits that cannot be monetized should be explained.

The RIA should identify and explain in detail the data or studies on which benefit estimates are based. Where benefit estimates are derived from a statistical study, the RIA must provide sufficient information so that an independent observer can determine the representativeness of the sample, whether it was extrapolated from properly in developing aggregate estimates, and whether the results are statistically significant.

For regulations addressing health and safety risks, the calculation of potential benefits should derive from the agency's estimate of the mean expected value of the reduction in risk attributable to the standard. Estimates of the prevailing level of risk and of the reduction in risk to be anticipated from a proposed standard should be unbiased expected-value estimates rather than hypothetical worst-case estimates. Extreme safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, to the extent possible, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit margin of safety, where required, in final decisions. If a margin of safety is to be provided, the proper place for it is the final stage of the decision-making process, not by adjusting the risk or benefit estimates in a conservative direction at the information-gathering or analytical stages of the process. Conservative estimates should be presented as alternatives to best estimates for sensitivity analysis but should not substitute for them.

It is important to guard against double-counting of benefits. For example, if a regulation improved the quality of the environment in a community, the value of real estate in the community might rise, reflecting the greater attractiveness of living in the improved environment. It would ordinarily be incorrect to include the rise in property values among the benefits of the regulation. Ordinarily, the value of environmental benefits (e.g., reduced health risks, scenic improvements) will already be included among the benefits. The rise in property values reflects the capitalized value of these improvements. Therefore, to count as benefits both the value of the environmental improvements and the corresponding increase in property values is to count the same benefits twice. Only where a direct estimate of the benefits has not been included would it be appropriate to include the increase in property values among the benefits.

1. *General Considerations.* The concept of "opportunity cost" is the appropriate construct for valuing both benfits and costs. The principle of "willingness-to-pay" captures the notion of opportunity cost by providing an aggregate measure of what individuals are willing to forgo so as to enjoy a particular benefit. Market transactions provide the richest database for estimating benefits based on willingness-to-pay, so long as the goods and services affected by a potential regulation are traded in markets. Estimation problems arise in a variety of instances, of course, where prices or market transactions are difficult to monitor. Markets may not even exist in some instances, forcing regulatory analysts to develop appropriate proxies that simulate market exchange. Indeed, the analytical process of deriving benefit estimates by simulating markets may suggest alternative regulatory strategies that create such markets.

Willingness to pay always provides the preferred measure of benefits. Estimates of willingness-to-pay based on observable and replicable behavior deserve the greatest level of confidence. Considerably less confidence should be conferred on benefit estimates that are neither derived from market transactions nor based on behavior that is observable or replicable. Of course, innovative benefit estimation method-

ologies may be necessary in some cases, and should be encouraged. However, reliance upon such methods intensifies the need for quality control to ensure that estimates derived conform as closely as possible to what would be observed if markets existed.

2. *Principles for Valuing Directly Observable Benefits.* Ordinarily, goods and services are to be valued at their market prices. However, in some instances, the market value of a good or service may not reflect its true value to society. If a regulatory alternative involves changes in such a good or service, its monetary value for purposes of benefit-cost analysis should be derived using an estimate of its true value to society (often called its "shadow price"). For example, suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant will be the value of the crop saved as a result of the controls. If the price of that crop is held above the free-market equilibrium price by a government price-support program it will overstate the value of the benefit of controlling the pollutant if the crop saved were valued at the market price established by the support program. The social value of the benefit should be calculated using a shadow price for crops subject to price supports. The estimated shadow price should reflect the value to society of marginal uses of the crop (e.g., the world price if the marginal use is for exports). If the marginal use is to add to very large surplus stockpiles, the shadow price would be the value of the last units released from storage minus storage cost. Therefore, where stockpiles are large and growing, the shadow price is likely to be low and could well be negative.

3. *Principles for Valuing Benefits that are Indirectly Traded in Markets.* In some important instances, a benefit corresponds to a good or service that is indirectly traded in the marketplace. Important examples include reductions in the health-and-safety risks, the use-value of environmental amenities and scenic vistas, and savings in time. To estimate the monetary value of such an indirectly traded good, the willingness-to-pay valuation methodology is still conceptually superior, because the amount that people are willing to pay for a good or service is the best measure of its value to them. As noted in Sections 4 and 5 immediately following, alternative methods may be used where there are practical obstacles to the accurate application of direct willingness-to-pay methodologies.

A variety of methods have been developed for estimating indirect benefits. Generally, these methods apply statistical techniques to distill from observable market transactions the portion of willingness-to-pay that can be attributed to the benefit in question. Examples include estimates of the value of environmental amenities derived from travel-cost studies, hedonic price models that measure differences or changes in the value of land, and statistical studies of occupational-risk premiums in wage rates.

Contingent-valuation methods have become increasingly popular for estimating indirect benefits, but they suffer from the fact that survey instruments have a limited capacity to simulate real-world market behavior. Benefit estimates derived from contingent-valuation studies thus have a greater burden of analytical care to ensure that they represent in an unbiased manner what actually occurs in the marketplace.

4. *Principles and Methods for Valuing Benefits that are Not Traded Directly or Indirectly in Markets.* Some types of goods, such as the social benefit of preserving environmental amenities apart from their use and direct enjoyment by people, are not traded directly or indirectly in markets. The practical obstacles to accurate measurement are similar to (but generally more severe than) those arising with respect to indirect benefits, principally because there are not market transactions to provide data for willingness-to-pay estimates.

Contingent-valuation methods provide the only analytical approaches currently available for estimating the benefits of such untraded goods. The absence of observable and replicable behavior with respect to the benefit in question, combined with the difficulties of avoiding bias in contingent-valuation studies, argues for great care and circumspection in the use of such methods. This means, for example, that estimates of willingness-to-pay must incorporate the variety of alternative means individuals have of expressing value for untraded goods. Moreover, analyses must faithfully capture individuals' budget constraints, which restrict their willingness-to-pay for untraded as well as traded goods and services. Benefit analyses derived from contingent valuation and similar methods thus require considerable analytic rigor in design and careful execution. Absent such efforts, analyses based heavily on the benefits of untraded goods and services ordinarily would fail the test of a satisfactory RIA.

5. *Methods for Valuing Health and Safety Benefits.* For health and safety benefits, a distinction should be made between risks of nonfatal illness or injury and fatality risks.

(a) *Nonfatal illness and injury.* Although the willingness-to-pay approach is conceptually superior, the current state of empirical research in the area is not sufficiently advanced to assure that estimates derived by this method are necessarily superior to direct-cost valuations of reductions in risks of nonfatal illness or injury. Any injury-value estimate from a willingness-

to-pay study is necessarily an average over a specific combination of injuries of varying severity. If the average injury severity in such a study is greatly different from that for the regulatory action under study, then the study's estimated injury value may not be appropriate for evaluating that action. Accordingly, the agency should use whichever approach it considers most appropriate for the decision at hand. The primary components of the direct-cost approach are medical costs and the value of lost production. Possibly important costs that may be omitted by the use of the direct-cost approach are the value of pain and suffering and the value of time lost from leisure and other activities that are not economically directly productive.

(b) *Fatality.* Reductions in fatality risks are best monetized according to the willingness-to-pay approach. The value of changes in fatality risk is sometimes expressed in terms of the "value of life." This is something of a misnomer since the value of a life really refers to the sum of many small reductions in fatality risk. For example, if the annual risk of death is reduced by one in a million for each of two million people, that represents two "statistical lives" saved per year (two million × one millionth = two). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives saved. The conclusion that the fatality risk reductions in these two cases are equivalent implies an assumption. The implicit assumption—that equal increments in risk are valued equally—allows different risk increments to be added together and compared directly. As a different example, suppose there are two alternative reductions in the annual risk faced by an individual:

A: from $.10 \times 10^{-6}$ to $.09 \times 10^{-6} = .01 \times 10^{-6}$
B: from 1.00×10^{-6} to $.99 \times 10^{-6} = .01 \times 10^{-6}$

Since in both cases the reduction in annual risk is the same ($.01 \times 10^{-6}$), the value of A and B should be considered the same.

The assumption that equal increments in fatality risk are of equal value is a legitimate one, so long as the level of fatality risk is below 10^{-4} annually. There is evidence that the willingness-to-pay value for increments in fatality risk does not change significantly over a wide range of risk exposure below 10^{-4} annually.

For levels of annual risk exposure of 10^{-4} and above cannot be assumed that equal increments of risk are valued equally. At these higher risk levels, it is particularly important to distinguish between situations of voluntary risk assumption and those of involuntary risk. Where the high risk is involuntary, it is appropriate to value reductions in risk from that high level more highly than equal risk reductions at lower risk levels. In general, the greater the risk that an individual bears, the higher will be the value the individual places on marginal changes in risk. On the other hand, where a high risk is chosen voluntarily those assuming the risk tend to be persons who place a relatively low value on averting safety risks. Empirical studies of risk premiums in high-risk occupations suggest that reductions in voluntarily assumed high risks should be valued less than equal risk reductions at ordinary risk levels.

Estimates of the value of fatality risks refer only to changes in an uncertain risk of death. They have no application to the certain prevention of the death of an identifiable individual.

6. *Alternative Methodological Frameworks for Estimating Health and Safety Benefits.* Several alternative ways of incorporating fatality risks into the framework of benefit-cost analysis may be appropriate. These may involve either explicit or implicit valuation of fatality risks.

One acceptable explicit valuation approach would be for the agency to select a single value for reductions in fatality risk at ordinary risk levels (below 10^{-4} annually) and use this value consistently for evaluating all its programs that affect ordinary fatality risks. Another acceptable explicit valuation approach would be to use a range of values for reductions in fatality risk and apply sensitivity analysis as with other parameters that have alternative plausible values. The range of alternative values should be a reasonable one, not one that includes the most extreme upper and lower values of fatality risk reduction that have been estimated. Extreme values are more appropriate for instances of extraordinarily high risks (above 10^{-4} annually), with the extreme low values being appropriate where voluntary assumption of high risk leads to self-selection and the extreme high values being appropriate where the high risk is involuntarily assumed.

Where the analysis uses a range of alternative values for reductions in fatality risk, it may be useful to calculate break-even values, as in other sensitivity analyses. This requires calculating the borderline value of reductions in fatality risk at which the net benefit decision criterion would switch over from favoring one alternative to favoring another (i.e., the value of fatality risk at which the net benefits of the two alternatives are equal). This method will frequently be infeasible because of its computational demands or because alternatives are continuous rather than discrete (e.g., alternative stringencies for exposure levels), but where appropriate, it is a useful supplement to the sensitivity analysis.

An implicit valuation approach could entail calculations of the cost per unit of reduction in fatality risk (cost per "statistical life saved"), with costs defined as costs minus monetized benefits. This must be used with care since there is a serious potential pitfall: It is *not* correct to choose between two mutually exclusive alternatives by selecting the alternative with lowest cost per statistical life saved. The alternative with higher cost per life saved may nonetheless be the alternative with the higher net benefit to society.

The way to avoid this pitfall while retaining the implicit valuation approach is to make all calculations of cost per life saved in terms of increments between alternatives. Alternatives should be arrayed in order of their total reduction in expected fatalities and the incremental cost per life saved calculated between each adjacent pair of alternatives. In contrast to explicit valuation approaches, this avoids the necessity of specifying in advance a value for reductions in fatality risks. However, a range of values will be implied by the final selection of an alternative. This range should be consistent with estimated values of reductions in fatality risks calculated according to the willingness-to-pay methodology.

Another way of expressing reductions in fatality risks is in terms of life-years saved. For example, if a regulation protected individuals whose average remaining life expectancy was 40 years, then a risk reduction of one fatality would be expressed as 40 life-years saved. Such a refinement may be desirable for regulations that disproportionately protect young people (e.g., motor vehicle safety regulations) or elderly people (e.g., regulations controlling carcinogens). To derive the value of a life-year saved from an estimate of the value of life, first determine the average remaining life expectancy of the sample population in the study from which the estimate was drawn. Assuming that the average age of the sample population is known, the average remaining life expectancy may be derived from actuarial tables giving life expectancy in relation to age. Using standard compound interest tables, the value of a life-year saved can then be determined as the estimated value of life annualized over a period equal to the number of years of remaining average life expectancy.

C. Cost Estimates

1. *General Considerations.* The opportunity cost of an alternative is the value of the benefits foregone as a consequence of that alternative. For example, the opportunity cost of banning a product (e.g., a drug, food additive, or hazardous chemical) is the foregone net benefit of that product. It is measured by changes in producers' and consumers' surpluses. (Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the distance between the price and the supply curve for that unit. Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the distance between the price and the demand curve for that unit.) As another example, even if a resource required by regulation does not have to be paid for because it is already owned by the regulated firm, nonetheless, the use of that resource to meet the regulatory requirement has an opportunity cost equal to the net benefit it would have provided in the absence of the requirement. Any such foregone benefits for an alternative should be monetized wherever possible and either added to the costs or subtracted from the benefits of that alternative. Any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

All costs calculated should be incremental, that is, they should represent changes in costs that would occur if the regulatory alternative is chosen compared to costs in the base case (ordinarily no regulation or the existing regulation). Future costs that would be incurred even if the regulation is not promulgated, as well as costs that have already been incurred (sunk costs), are not part of incremental costs. If marginal cost is not constant for any component of costs, incremental costs should be calculated as the area under the marginal cost curve over the relevant range.

Costs include private-sector compliance costs, government administrative costs, and costs of reallocating workers displaced as a result of the regulation. Costs that are not monetary outlays must be included and should be attributed a monetary value wherever possible. Such costs may include the value (opportunity cost) of benefits foregone, losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time. A schedule of monetized costs should be included that would show the type of cost and when it would occur; the numbers in this table should be expressed in constant, undiscounted dollars. Any expected incremental costs that cannot be monetized should be explained. An important type of cost that often cannot be quantified is a slowing in the rate of innovation or of adoption of new technology. For example, regulations re..ig a costly and time-consuming approval process for new products or new facilities may have such costs, as may regulations setting much more stringent standards for new facilities than existing ones.

Two accounting cost concepts that should not be counted as costs in benefit-cost analysis are interest and depreciation. The time value of money is already accounted for by the discounting of benefits and costs. Depreciation is already taken into account by the time distribution of benefits and costs; the only legitimate use for depreciation calculations in benefit-cost analysis is to estimate the salvage value of a capital investment.

2. *Real Costs versus Transfer Payments.* An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not genuine costs but payments for which no real good or service is received in return. Several examples of problems that may arise from the confusion between transfer payments and real costs (or benefits) may help identify situations in which further analysis of the problem may be warranted. Monopoly profits, insurance payments, government subsidies and taxes, and distribution expenses are four potential problem areas.

(a) *Monopoly profits.* If, for example, sales of a competitively produced product were restricted by a government regulation so as to raise prices to consumers, the resulting monopoly profits are not a benefit of the rule, nor is their payment by consumers a cost. The real benefit-cost effects of the regulation would be represented by changes in producers' and consumers' surpluses.

(b) *Insurance payments.* Potential pitfalls in benefit-cost analysis may also arise in the case of insurance payments, which are transfers. Suppose, for example, a worker safety regulation, by decreasing employee injuries, led to reductions in firms' insurance premium payments. It would be incorrect to count the amount of the reduction in insurance premiums as a benefit of the rule. The proper measure of benefits is the value of the reduction in worker injuries, monetized as described previously, plus any reduction in real costs of administering insurance (such as the time of insurance company employees needed to process claims) due to the reduction in worker insurance claims. Reductions in insurance premiums that are matched by reductions in insurance claim payments are changes in transfer payments, not benefits.

(c) *Indirect taxes and subsidies.* A third instance where special treatment may be needed to deal with transfer payments is the case of indirect taxes (tariffs or excise taxes) or subsidies on specific goods or services. Suppose a regulation requires firms to purchase a $10,000 piece of imported equipment, on which there is a $1,000 customs duty. For purposes of benefit-cost analysis the cost of the regulation for each firm ordinarily would be $10,000, not $11,000, since the $1,000 customs duty is a transfer payment from the firm to the Treasury, not a real resource cost. This approach, which implicitly assumes that the equipment is supplied at constant costs, should be used except in special circumstances. Where the taxed equipment is not supplied at constant cost, the technically correct treatment is to calculate how many of the units purchased as a result of the regulation are supplied from increased production and how many from decreased purchases by other buyers. The former units would be valued at the price without the tax and the latter units would be valued at the price including tax. This calculation is usually difficult and imprecise because it requires estimates of supply and demand elasticities, which are often difficult to obtain and inexact. Therefore, this treatment should only be used where the benefit-cost conclusions are likely to be sensitive to the treatment of the indirect tax. While costs ordinarily should be adjusted to remove indirect taxes on specific goods or services as described here, similar treatment is not warranted for other taxes, such as general sales taxes applying equally to most goods and services or income taxes.

(d) *Distribution expenses.* The treatment of distribution expenses is also a source of potential error. For example, suppose a particular regulation raises the cost of a product by $100 and that wholesale and retail distribution expenses are on average 50 percent of the factory-level cost. It would ordinarily be incorrect to add a $50 distribution markup to the $100 cost increase to derive a $150 incremental cost per product for benefit-cost analysis. Most real resource costs of distribution do not increase with the price of the product being distributed. In that case, either distribution expenses would be unchanged or, if they increased, the increase would represent distributor monopoly profits. Since the latter are transfer payments, not real resource costs, in neither case should additional distribution expenses be included in the benefit-cost analysis. However, increased distribution expenses should be counted as costs to the extent that they correspond to increased real resource costs of the distribution sector as a result of the change in the price or characteristics of the product.

D. Expenditure Rules

Regulations establishing terms or conditions of Federal grants, contracts, or financial assistance call for a different form of regulatory analysis than do other types of regulation. In some instances, a full-blown benefit-cost analysis may be appropriate to inform Congress and the President more fully about the desirability of the program, but this would not ordinarily be required in a Regulatory Impact Analy-

sis. The primary function of the RIA for this type of regulation should be to verify that the terms or conditions are the minimum necessary to achieve the purposes for which the funds were appropriated. They should not contain conditions in pursuit of goals that are not germane to the purpose for which the funds were authorized and appropriated. Beyond controls to prevent abuse and to ensure that funds appropriated to achieve a specific purpose are channeled efficiently toward that end, maximum discretion should be allowed in the use of Federal funds, particularly when the recipient is a State or local government.

IV. RATIONALE FOR CHOOSING THE PROPOSED REGULATORY ACTION

The RIA should include an explanation of the reasons for choosing the selected regulation. Ordinarily, the regulatory alternative selected should be the one that achieves the greatest net benefits. If legal constraints prevent this choice, they should be identified and explained, and their net cost should be estimated.

Where uncertainties are substantial or a large proportion of benefits cannot be monetized, other methods of summarizing the benefit-cost analysis may sometimes be appropriate. When alternative forms of presentation are used, the objective must continue to be the maximization of net benefits (except where prohibited by law). Alternative criteria must be used with care because of the potential for errors or misinterpretation.

Agencies need not calculate the internal rate of return for a regulation. The internal rate of return is often difficult to compute and is problematical when multiple rates exist. It must not be used as a criterion for choosing between mutually exclusive alternatives. As a criterion for choosing between alternatives that are not mutually exclusive, it has no advantages over the criterion of maximizing the present value of net benefits.

Benefit-cost ratios, if used at all, must be used with care to avoid a common pitfall. It is a mistake to choose among mutually exclusive alternatives by selecting the alternative with the highest ratio of benefits to costs. An alternative with a lower benefit-cost ratio than another may have the higher net benefits. Whether a regulation's benefits are greater (or less) than its costs can be determined by whether its benefit-cost ratio is greater (or less) than one. The benefit-cost ratio may be used as a very simplified indicator of the likely sensitivity of the result: If the benefit-cost ratio is much greater than one, the conclusion that the regulation's benefits exceed its costs probably is not sensitive to likely alternative parameter values. If the ratio is only slightly greater than one, the conclusion probably is sensitive. The benefit-cost ratio may sometimes be acceptable as a rough substitute for genuine sensitivity analysis where it is not feasible to carry out a full sensitivity analysis (e.g., if the number of regulatory parameters to be tested by sensitivity analysis is large). When so used, the benefit-cost ratio should be recognized as only a crude approximation to a genuine sensitivity analysis and the analyst should be aware of its limitations (e.g., the benefit-cost ratio is sensitive to the arbitrary classification of an item as a benefit or an averted cost).

Where the benefits of proposed regulatory alternatives include reductions in fatality risks, an acceptable alternative to direct calculation of net benefits is the indirect approach of calculating incremental costs per life saved between adjacent alternatives. This is done by ranking all the alternatives according to the number of lives they save and then calculating the change in costs and the change in lives saved between each alternative and the one with the next highest number of lives saved. If the alternative selected is the one whose incremental cost per life saved is closest to the willingness-to-pay value of life, this decision criterion is analytically equivalent to that of maximizing net benefit.

In cases where important benefits cannot be assigned monetary values, cost-effectiveness analysis should be used where possible to evaluate alternatives that generate equivalent nonmonetizable benefits. Costs should be calculated net of monetized benefits. Between two alternatives with equivalent nonmonetizable benefits, the alternative with the lower net costs should be selected. Cost-effectiveness analysis should also be used to compare regulatory alternatives in cases where the level of benefits is specified by statute.

V. STATUTORY AUTHORITY

The RIA should include a statement of determination and explanation that the proposed regulatory action is within the agency's statutory authority.

Further Reading

Edith Stokey and Richard Zeckhauser, *A Primer for Policy Analysis*. Chapters 9 and 10 provide a good introduction to basic concepts.

E. J. Mishan, *Economics for Social Decisions: Elements of Cost-Benefit Analysis*. Assumes some knowledge of economics. Chapters 5–8 should be helpful on the important subjects of producers' and consumers'

surpluses (not discussed extensively in this guidance document).

W. Kip Viscusi, *Risk By Choice*. Chapter 6 is a good starting point for the topic of valuing health and safety benefits. Other more technical sources are given in the bibliography.

Robert Cameron Mitchell and Richard C. Carson, *Using Surveys to Value Public Goods: The Contingent Valuation Method*. Provides a valuable discussion on the potential pitfalls associated with the use of contingent-valuation methods.

V. Kerry Smith, Ed., *Advances in Applied Microeconomics: Risk, Uncertainty, and the Valuation of Benefits and Costs*.

Judith D. Bentkover, Vincent T. Covello, and Jeryl Mumpower, Eds., *Benefits Assessment: The State of the Art*.

OCT 1 1991

Mr. David A. Ward, Chairman
Advisory Committee on Reactor Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Ward:

Your letter of July 19, 1991, to the Chairman identified concerns of the ACRS about the consistent use of probabilistic risk assessment by the NRC staff. The letter notes a number of symptoms of what you identify as more general problems, the lack of a coherent policy on the use of PRA by the staff, and the limited number of staff experts in PRA.

With respect to the general problems you have identified, we have the following observations:

- The level of sophistication of staff PRAs and of internal and external reviews clearly varies among applications. This is entirely appropriate, recognizing that certain analyses require more detailed consideration than others and that the underlying technical issues vary in potential safety significance. For example, more PRA resources have been assigned to reviews of advanced reactor design submittals and to certain key generic issues (e.g., station blackout) than to the analysis of other generic issues. Further, the lack of adequate data has influenced our use of PRA in many applications.

- The policy of the staff is to make best estimates of risks and costs. Where possible, this means using realistic assumptions and statistical means. However, in many analyses the data are sparse and the best that can be done are point estimates. In other cases, no data are available and only conservative estimates are possible. Where such departures are taken from the ideal, they are to be clearly displayed and their effect on the proposed decision explained.

- The level of sophistication of uncertainty analysis also varies among applications of PRA. Such variation is appropriate because of variations in the significance of safety issues and the availability of supporting data. While the recent completion of NUREG-1150 has made the issue of uncertainty analysis much more apparent, the staff has not completely studied its implications for a more general implementation in the regulatory process. One important aspect of such a study would be the development of improved methods for generating the data needed in such analyses.

- The staff is well aware of the uncertainty and unreliability of PRA results, particularly reliance on bottom line numbers. Assessing this uncertainty and unreliability is an important part of any decision. However, I don't believe that it is practical at this time to employ a decision-making algorithm with a prescribed confidence level as you suggest. With a few possible exceptions the data required to implement such a method is simply not available.

- Substantial effort is being expended to improve the PRA knowledge of the NRC staff. During FY 92, a total of 20 4-day duration PRA courses ranging from introductory to advanced level are scheduled for presentation to appropriate staff. In addition, NRC management has recognized a need for a "cultural shift" in staff understanding of risk and PRA considerations. Beginning in 1990, the NRC Technical Training Center staff were provided PRA training and during 1991 have subsequently revised the reactor technology lesson plans to specifically address risk perspectives as each topic or system is discussed. The objective is to inculcate risk perspectives and appropriate application of PRA insights into NRC personnel as they proceed through the technical training program.

- The staff has noted previously (e.g., in SECY 91-161 [on advanced reactor review schedules]) that available personnel with the requisite backgrounds in probabilistic analysis and accident phenomenology are at a premium.

  Efforts have been made to expand the staff's capabilities, with moderate success; these efforts are continuing. The staff's ability to recruit PRA experts and persons with the potential to become PRA experts has been hampered by competition with other federal agencies and private industry. In this circumstance, the available staff resources must be carefully prioritized to optimize their influence. In many cases, contractors have been used to supplement the staff, with varying degrees of success.

- We agree that the issue of obtaining additional staff expertise is not limited to the PRA field. The staff is now working to recruit, for example, people with expertise in digital instrumentation and control systems.

Thus, while it does not appear that major problems now exist in the use of probabilistic risk assessment by the staff, I believe that a review of the staff's PRA activities is appropriate. This review will consider what additional guidance to the staff would assure the consistent development, content and use of PRA within the NRC. Since all of the program offices have an interest in the application of PRA, an interoffice group will be established to conduct such a review. I would expect that a review could be

completed in a few months and will keep the Committee informed of its work and findings.

Sincerely,

Original Signed By:
James M. Taylor
James M. Taylor
Executive Director
for Operations

cc: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
SECY

* SEE PREVIOUS CONCURRENCE SHEET
** CONCURRED BY TELEPHONE

PRAB	DSR	DSR	DSIR	RES	RES	NRR
CUNNINGHAM	MURPHY	SHERON	MINNERS	SPEIS	BECKJORD	MURLEY
8/9/91*	8/9/91*	8/9/91*	9/13/91*	9/18/91*	9/18/91*	9/25/91**

NMSS	AEOD	EDO	EDO
BERNERO	JORDAN	SNIEZEK	TAYLOR
9/16/91**	9/30/91	9/ /91	10/ /91

(Document Name: G:\groups\dsir\WARD9-13)

POLICY ISSUE
(Notation Vote)

February 22, 1993 SECY-93-043

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: REGULATORY ANALYSIS GUIDELINES OF THE U.S. NUCLEAR REGULATORY COMMISSION

Purpose: To seek Commission approval to publish a Federal Register Notice (Enclosure 1) announcing the availability of the proposed Regulatory Analysis Guidelines for public comment.

Summary: This paper describes a proposed revision to the Nuclear Regulatory Commission's Guidelines for preparing regulatory analyses and discusses the major issues which need to be resolved in order to finalize these Guidelines. This paper also responds to parts of three Staff Requirements Memoranda (SRM). Item 3 of the first SRM, dated June 15, 1990, concerns the establishment of a formal mechanism to routinely consider safety goals in future regulatory initiatives. Item 1 of the second SRM, dated December 20, 1991, concerns the treatment of averted onsite costs in NRC regulatory analyses. In the last item of the third SRM, dated February 21, 1992, Commissioner Remick asked about the staff's reexamination of the $1000 value of person-rem averted and the implications on current regulations and past regulatory decisions of revising that value. This latter item is not addressed herein since the dollar per person-rem valuation is still under staff review and evaluation.

Background: By memorandum dated May 1, 1991, SECY-91-114, the staff informed the Commission on the status and plans for

Contact:
Brian Richter, RES
301-492-3763

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

improving regulatory analysis guidance. One of the tasks referred to in that document was the revision of the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (Guidelines), Draft NUREG/BR-0058, Rev. 2 (Enclosure 2). This revision reflects: (1) the NRC's accumulated experience with implementing the previous Guidelines; (2) changes in NRC regulations and procedures since 1984, especially the backfit rule (10 CFR 50.109) and the Policy Statement on Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028, August 21, 1986); (3) advances and refinements in regulatory analysis techniques; (4) regulatory guidance for Federal agencies issued by the Administrative Conference of the United States and the Office of Management and Budget (OMB); and (5) procedural changes designed to enhance NRC's regulatory effectiveness.

Review comments on early versions of the proposed Guidelines were provided by an ad-hoc group of NRC regulatory analysis practitioners. The Regulatory Analysis Steering Group (RASG), a group comprised of senior-level management from the various NRC program offices, reviewed subsequent versions of the proposed Guidelines, and recommended policy direction on a number of controversial issues. This document has also been reviewed by the Committee to Review Generic Requirements (CRGR) and the Advisory Committee on Reactor Safeguards (ACRS). Subject to Commission approval, the proposed Guidelines will be published for public comment, revised as necessary, and revisited by the RASG, relevant NRC offices, CRGR, ACRS, the PRA Working Group, and the Commission prior to being published as final. In many respects, this process is consistent with the development of an NRC rule or policy statement. The staff is also involved in the revision of a Handbook to replace A Handbook for Value Impact Assessment, (NUREG/CR-3568). The new Handbook will set forth systematic procedures for performing value impact assessments. The development of the Handbook has purposely lagged the Guidelines because it is largely dependent on the policy positions adopted in the Guidelines.

Discussion: The proposed Guidelines (Enclosure 2) represents the NRC's policy-setting document with respect to regulatory analyses. A regulatory analysis is performed by the NRC to support numerous NRC actions affecting power reactor and non-power reactor licensees alike. As such, the document contains a number of policy decisions that have broad implications for the NRC and its licensees. There are a range of views within the staff on these policy issues. It is hoped that issuance of this draft will allow the Commission an opportunity to hear from the public and industry on some of these key issues.

Some of the positions taken in the proposed Guidelines either represent departures from current practice, have never been formalized before, or differ from positions recommended by industry. In this regard, the staff has identified the following issues for specific attention:

(1) Guidance for addressing safety goal considerations in the regulatory analysis. The position taken in the proposed Guidelines is consistent with the approach described in SECY-91-270. The guidance responds to the Commission's request, in the SRM dated June 15, 1990, for a formal mechanism to routinely consider the safety goals for future regulatory initiatives affecting power reactors. In a June 12, 1992, letter from the ACRS to the Chairman concerning the staff's proposed procedure to account for safety goal considerations, the ACRS continued to express concern that there is not an overall safety goal implementation strategy. There is no argument with the ACRS that these Guidelines do not present an overall NRC safety goal implementation strategy (they were intended to implement the safety goals in a practical manner in accord with our traditional rulemaking and generic requirements development process). However, this fact should not preclude issuing the proposed Guidelines with its treatment of safety goal considerations. The staff recognizes that this implementation procedure may be subject to revision due to a number of considerations, including for example, a final conclusion on the large release definition.

(2) Quantification of values (benefits) in the regulatory analysis. The document provides additional guidance on the quantification of values, particularly for those regulatory actions in which PRAs are not available to estimate averted person-rem.

(3) The treatment of voluntary actions in NRC regulatory analyses. Voluntary licensee actions or programs may already be in-place which, to some degree, already achieve some of the objectives sought by the proposed regulatory initiative. The approach taken in the proposed Guidelines is to encourage industry voluntary initiatives, but to recognize that there may be cases where good cause exists to consider codification of such safety practices.

For the purpose of performing the regulatory analysis weighing of values and impacts for such actions, the proposed Guidelines include the position that, with

certain exceptions, no credit should be given for the voluntary actions taken by licensees. The intent of this position is that the regulatory policy should not inhibit regulatory requirements to be established when voluntary programs are non-uniform across all licensees or when such programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and thus values and impacts associated with the proposed regulatory action are reduced, meaningful health and safety improvements could remain uncodified and voluntary in nature. Absent a significant safety concern, these initiatives would not be subject to enforcement on the part of the NRC. When the base case value-impact results take no credit for voluntary actions, a sensitivity analysis is to be performed and the value-impact results also displayed with credit for voluntary actions. The staff recognizes voluntary actions that are a part of an overall industry commitment with appropriate follow-up evaluations could be subject to special treatment on a case by case basis.

(4) The interest rate (or discount rate) to be used in present worth calculations. The position taken in the proposed Guidelines is that under most circumstances the discount rate specified in the latest version of OMB Circular A-94 should be used in NRC regulatory analyses. This circular was most recently updated on November 10, 1992 and specifies the use of a 7 percent real (i.e., inflation adjusted) discount rate. The staff recommends the use of a 3 percent real rate for sensitivity analysis purposes. Finally, in unique circumstances where the regulatory analysis considers consequences that occur over a timeframe in excess of 100 years, the staff recommends that a 7 percent interest rate not be used. In these instances, the NRC regulatory analysis should display results to the decision maker in two ways. First, on a present worth basis using a 3 percent real rate, and second, by displaying the values and impacts at the time in which they are incurred with no present worth conversion.

(5) Analyses and information necessary to satisfy the backfit rule and/or CRGR review. The position taken in the proposed Guidelines is that a regulatory analysis prepared in conformance with the Guidelines meets the needs of the backfit rule and provisions of the CRGR charter without a need to prepare separate submissions.

(6) The treatment of averted onsite costs in NRC regulatory analyses. Industry has challenged the inclusion of averted onsite costs and has argued that it can distort the validity of the value-impact ratio. The position taken in the draft Guidelines is that averted onsite costs should be included in the value-impact analysis as a positive attribute in a net value formulation (value minus impact), or as a cost offset when results are displayed as a ratio. The staff believes this position is consistent with Commission policy as stated in item (7) of the SRM dated June 15, 1990. The position taken in the proposed Guidelines is to express the result on a net value basis which is consistent with an OMB recommendation. In the past, industry has had difficulty with inclusion of averted onsite costs, believing that utility economics should not be NRC's concern. The staff believes such an approach would be inconsistent with current backfit rule determinations which include the consideration of all costs, including utility costs, by NRC in appropriate circumstances.

In an SRM dated December 20, 1991, the Commission directed that the staff evaluate the various arguments for how averted onsite costs should be treated in cost-benefit analyses. Enclosure 3 has been prepared in response to this request and contains the detailed underpinnings for the position adopted in the proposed Guidelines.

(7) The present worth valuation of future health and safety effects in NRC regulatory analyses. The position taken in the proposed Guidelines is that future health and safety effects should be subject to present worth considerations in the same manner and at the same rate as impacts. The objective is to determine the amount of money needed today that is equivalent (taking account of return on investment) to the dollar value of future health and safety effects such that all such effects, regardless of when they occur, are equally valued throughout the regulatory analysis. In recognition that this is contrary to NRC's historic practice and is a subject of some controversy, Enclosure 4 elaborates on this staff position.

(8) The dollar/person-rem value to be used in NRC regulatory analyses. A recommendation on the $/person-rem value has not yet been developed and further review and analysis is necessary. In the interim, the position taken in the proposed Guidelines

is that continued use of $1000/person-rem (1993 dollars) is acceptable as a conversion factor for all offsite consequences of severe power reactor accidents, and as a reference point or baseline in applications where offsite consequences are not involved such as for occupational exposure, non-power reactor accidents, and in ALARA determinations associated with cleanup of contaminated sites. In the document the staff recommends that alternative values can also be used to portray the range of values which reasonably could be selected as the $/person-rem conversion factor.

In an SRM of February 21, 1992, Commissioner Remick requested that, the staff consider the potential impact on current regulations and past regulatory decisions of their reevaluation of the $/person value. Given that the $1000 evaluation has been retained as an interim value and the staff's review and evaluation is still on-going, a response to Commissioner Remick's question has been deferred until this issue is finally resolved.

Coordination: The Office of the General Counsel (OGC) has reviewed this paper and has found no legal objection to the staff's proposal. The Advisory Committee on Reactor Safeguards also reviewed the Guidelines package. In a November 12, 1992 letter to the EDO (Enclosure 5), the ACRS identified a number of specific issues and concerns. The staff generally agrees with the ACRS' comments and has revised the Guidelines in response to their concerns. The ACRS recommended that the proposed Guidelines be reviewed again by ACRS prior to issuance for public comment. However, in view of the policy nature of the Guidelines, the staff believes that the development of the document can best be served by early review by the Commission and the public. The staff plans to resubmit the Guidelines to the CRGR and ACRS for review and comment before final consideration by the Commission.

Recommendation: That the Commission:

1. Approve publication of the announcement of the proposed Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Draft NUREG/BR-0058, Revision 2 for public comment along with Enclosures 3 and 4.

2. Note that:

(a) The Federal Register Notice (Enclosure 1) will be published in the Federal Register, for a 90-day public comment period;

(b) A public announcement (Enclosure 6) will be issued when the Federal Register Notice is filed with the Office of the Federal Register for publication;

(c) The supporting (draft) Handbook providing additional detailed implementation guidance continues under development. It will be available upon request after April 30, 1992, during the public comment period, and will reflect positions established in the proposed Guidelines. A copy will be provided to the Commission for information when available.

(d) The staff believes that portions of the framework outlined in Chapter 3 of the proposed Regulatory Analysis Guidelines, such as those related to the "substantial additional protection" criterion, have potential to be useful in reaching plant specific backfitting decisions. The staff plans to explore the feasibility of this option on a trial use basis but in doing so, will be attentive to the Commission's June 15, 1990 SRM guidance on safety goals.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. Federal Register Notice
2. Proposed Regulatory Analysis Guidelines
3. Averted Onsite Costs
4. Present Worth Valuation of Future Health and Safety Effects
5. ACRS Ltr., November 12, 1992
6. Public Announcement

RECORD NOTE: A draft copy of this package was sent to OIG for information on February 5, 1993.

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Monday, March 8, 1993.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, March 1, 1993, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

DISTRIBUTION:
Commissioners
OGC
OCAA
OIG
OPA
IP
OCA
OPP
EDO
ACRS
ACNW
ASLBP
SECY

Enclosure 1

Federal Register Notice

[7590-01]

NUCLEAR REGULATORY COMMISSION

Regulatory Analysis Guidelines

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice

SUMMARY: The Nuclear Regulatory Commission is making available for public comment its proposed "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 2 (Guidelines). This document, last issued in 1984, is the Commission's policy-setting document with respect to regulatory analyses. The objectives of the Guidelines are to incorporate:

(1) the NRC's accumulated experience with implementing the previous Guidelines;

(2) changes in NRC regulations and procedures since 1984, especially the backfit rule (10 CFR 50.109) and the Policy Statement on Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028, August 21, 1986);

(3) advances and refinements in regulatory analysis techniques;

(4) regulatory guidance for Federal agencies issued by the Administrative Conference of the United States and the Office of Management and Budget (OMB); and

(5) procedural changes designed to enhance NRC's regulatory effectiveness.

DATES: The comment period expires on [insert a date to allow 90 days for public comment], 1993. Comments received after this time will be considered if it is practical to do so, but assurance of consideration cannot be given except for comments received on or before this date.

ADDRESSES: To receive a copy of the proposed, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission", NUREG/BR-0058, Revision 2, contact Brian Richter, Office of Nuclear Regulatory Research, Mail Stop NLS-129, U. S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492-3763. A copy is also available for inspection and/or copying at the NRC Public Document Room, 2120 L Street, N.W., (Lower Level), Washington, DC.

Mail written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to One White Flint North, 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays. Comments may also be delivered to the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC between 7:45 am and 4:15 pm on Federal workdays.

FOR FURTHER INFORMATION CONTACT: Brian Richter, Office of Nuclear Regulatory Research, Mail Stop NLS-129, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492-3763.

SUPPLEMENTARY INFORMATION:

Background

The reissuance of the Guidelines is meant to fulfill the objectives identified above. The NRC plans to publish the Guidelines in both proposed and final form, in many respects employing a process consistent with the development of a rule or policy statement. Since this is the NRC's policy-setting document with respect to regulatory analyses, it contains a number of policy decisions that have broad implications. As a result, issuance of this draft will allow the Commission a chance to hear from the public on these implications and issues.

Discussion

Some of the positions taken in the proposed Guidelines either represent departures from current practice, have never been formalized, or differ from positions industry has taken. In recognition of this, the NRC has identified the following issues for specific attention and would welcome public comment on each of these issues:

(1) Guidance for addressing safety goal considerations in the regulatory analysis. The position taken in the proposed Guidelines is consistent with the approach described in SECY-91-270, "Interim Guidance on Staff Implementation of the Commission's Safety Goal Policy," of August 27, 1991. The proposed procedure is based on the use of a change in core damage probability rather than an absolute number and involves certain criteria for staff action.

(2) The treatment of voluntary actions in NRC regulatory analyses.

Voluntary licensee actions or programs may already be in place which, to some degree, already achieve some of the objectives sought by the proposed regulatory change. The approach taken in the proposed Guidelines is to encourage industry voluntary initiatives, but to recognize that there may be cases where good cause exists to consider codification of such safety practices.

For the purpose of performing the regulatory analysis weighing of values and impacts for such actions, the proposed Guidelines include the position that with certain exceptions, no credit should be given for the voluntary actions taken by licensees. The intent of this position is that the regulatory policy should not inhibit regulatory requirements to be established when voluntary programs are non-uniform across all licensees or when such programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and thus values and impacts associated with the proposed regulatory action are reduced, meaningful health and safety improvements could remain uncodified and voluntary in nature. Absent a serious safety concern, these initiatives would not be subject to enforcement on the part of the NRC. When the base case value-impact results take no credit for voluntary actions, a sensitivity analysis is to be performed and value-impact results also displayed with credit for voluntary actions. The staff recognizes voluntary actions that are a part of an overall industry commitment with appropriate follow-up evaluations could be subject to special treatment on a case by case basis.

(3) The interest rate (or discount rate) to be used in present worth calculations. The position taken in the proposed Guidelines is that under most circumstances the discount rate specified in the latest version of OMB Circular A-94 should be used in NRC regulatory analyses. This circular was most recently updated on November 10, 1992 and specifies the use of a 7 percent real (i.e., inflation adjusted) discount rate. The NRC recommends the use of a 3 percent real rate for sensitivity analysis purposes. Finally, in unique circumstances where the regulatory analysis considers consequences that occur over a timeframe in excess of 100 years, the NRC recommends that a 7 percent interest rate not be used. In these instances, the NRC regulatory analysis should display results to the decision maker in two ways. First, on a present worth basis using a 3 percent real rate, and second, by displaying the values and impacts at the time in which they are incurred with no present worth conversion.

(4) Analyses and information necessary to satisfy the backfit rule and/or CRGR review. The position taken in the proposed Guidelines is that preparation of a regulatory analysis in conformance with the Guidelines meets the needs of the backfit rule and the provisions of the CRGR charter without a need to prepare separate submissions.

(5) The treatment of averted onsite costs in NRC regulatory analyses. In the past, industry has challenged the inclusion of averted onsite costs and has argued that it can distort the meaning of the value-impact ratio. The position taken in the proposed Guidelines is that averted onsite costs should be included in the value-impact analysis as a positive attribute in a net value formulation (value minus impact), or as a cost offset when results are displayed as a ratio.

(6) The present worth valuation of future health and safety effects in NRC regulatory analyses. The position taken in the proposed Guidelines is that future health and safety effects should be subject to present worth considerations in the same manner and at the same rate as impacts. The objective is to determine the amount of money needed today that is equivalent (taking account of return on investment) to the dollar value of future health and safety effects such that all such effects, regardless of when they occur, are equally valued throughout the regulatory analysis.

(7) The dollar/person-rem value to be used in NRC regulatory analyses. A recommendation on the $/person-rem value has not yet been developed and further review and analysis is necessary. In the interim, the position taken in the proposed Guidelines is that continued use of $1000/person-rem (1993 dollars) is acceptable as a conversion factor for all offsite consequences of severe power reactor accidents, and as a reference point or baseline in applications where offsite consequences are not involved such as for occupational exposure, non-power reactor accidents, and in ALARA determinations associated with cleanup of contaminated sites. In the document the staff recommends that alternative values can also be used to portray the range of values which reasonably could be selected as the $/person-rem conversion factor.

Public Comment

NRC is interested in receiving public comment on any aspect of the proposed Guidelines. To facilitate the public comment process, the staff has also prepared the following supplemental documents which will be provided along with copies of the proposed Guidelines. The first is a paper which

discusses the various arguments for the treatment of averted onsite costs, and the second discusses the present worth valuation of health and safety effects.

A draft of the "Regulatory Analysis Technical Evaluation Handbook" (Handbook), a replacement for "A Handbook for Value-Impact Assessment," NUREG/CR-3568, will also be made available upon request after April 30, 1993. The Handbook provides detailed guidance on performing regulatory analyses and should be useful in better understanding how NRC policy will be applied in regulatory analyses. The Handbook, which will reflect positions established in the proposed Guidelines, is in an earlier developmental stage and will be finalized upon receiving public comments on the proposed Guidelines.

Dated at Rockville, Maryland, this _____ day of _____ 1993.

For the Nuclear Regulatory Commission.

_____

Samuel J. Chilk,
Secretary of the Commission.

Enclosure 2

Proposed Guidelines Revision 2

NUREG/BR-0058
Revision 2

United States

Nuclear Regulatory Commission

REGULATORY ANALYSIS GUIDELINES

OF THE

U.S. NUCLEAR REGULATORY COMMISSION

_____, 1992

Office of the Executive Director for Operations

TABLE OF CONTENTS

ACRONYMS

ACRS	Advisory Committee on Reactor Safeguards
ACNW	Advisory Committee on Nuclear Waste
BWR	Boiling water reactor
C/B	Cost/Benefit
CCFP	Conditional containment failure probability
CDF	Core damage frequency
CFR	Code of Federal Regulations
CRGR	Committee to Review Generic Requirements
EDO	Executive Director for Operations
EIS	Environmental Impact Statement
EO	Executive Order
FR	Federal Register
FSAR	Final Safety Analysis Report
INPO	Institute of Nuclear Power Operations
NRC	U.S. Nuclear Regulatory Commission
NUMARC	Nuclear Management and Resources Council
OMB	Office of Management and Budget
PRA	Probabilistic risk analysis
PWR	Pressurized water reactor
RA	Regulatory Analysis
U.S.C.	United States Code
V/I	Value/Impact

1. INTRODUCTION

The Regulatory Analysis Guidelines ("Guidelines") will be used in the evaluation of proposed actions by the Nuclear Regulatory Commission (NRC) that may be needed to protect public health and safety. The evaluation is intended to aid the staff and the Commission in determining whether the proposed actions are needed, to provide adequate justification, and to provide a clear and well-documented explanation of why a particular action was recommended. These Guidelines establish a framework for: (1) analyzing the need for and consequences of a proposed regulatory action, (2) selecting a preferred alternative, and (3) documenting the analysis in an organized and understandable format. The resulting document is referred to as a Regulatory Analysis.

Although the NRC does not have a statutory mandate to conduct regulatory analyses, it voluntarily began performing these types of analyses in 1976. The intent in conducting regulatory analyses is to ensure that the NRC's decisions which impose regulatory burdens on licensees are based on adequate information regarding the extent of these burdens and the resulting values (benefits), and that a systematic and disciplined process is followed which is also open and transparent. The ultimate objective of this regulatory process is to ensure that all regulatory burdens are needed, justified, and minimal to achieve the regulatory objectives.

The regulatory analyses prepared before 1983 were termed value-impact analyses and were prepared according to value-impact guidelines issued in final form in December 1977 (SECY-77-388A). In February 1981, President Reagan issued Executive Order 12291 which directs all executive agencies to prepare a Regulatory Impact Analysis for all major rules and states that regulatory actions are to be based on adequate information concerning the need for and consequences of proposed actions. Moreover, the Executive Order directs that actions are not to be undertaken unless there is a positive net value to society. NRC, as an independent agency, is not required to comply with the Order. However, the Commission noted that its established procedures for the review of its regulations included an evaluation of proposed and existing

rules in a manner consistent with the Regulatory Impact Analysis provisions of the Executive Order. The Commission determined that the clarification and formalization of the NRC value-impact procedures then in place for analysis of regulatory actions would enhance the effectiveness of NRC regulatory actions and further meet the spirit of EO 12291. In performing a regulatory analysis, as in all Federal activities relating to the protection of the public's health and safety, the NRC adheres to the Principles of Good Regulation as delineated by former Chairman Carr in his January 17, 1991, announcement to NRC employees.[1] These principles, which serve to guide the agency's decision making process, are Independence, Openness, Efficiency, Clarity, and Reliability.

The original version of these Guidelines (NUREG/BR-0058) was issued in January 1983. In December 1983 NRC issued A Handbook for Value-Impact Assessment, NUREG/CR-3568.[2] The basic purpose of the 1983 Handbook was to set out systematic procedures for performing value-impact assessments. Revision 1 to NUREG/BR-0058 was issued in May 1984 to include appropriate references to NUREG/CR-3568. This revision (Revision 2) is being issued to reflect: (1) the NRC's accumulated experience with implementing the previous Guidelines; (2) changes in NRC regulations and procedures since 1984, especially the backfit rule (10 CFR 50.109) and the Policy Statement on Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028, August 21, 1986); (3) advances and refinements in regulatory analysis techniques; (4) regulatory guidance for Federal agencies issued by the Administrative Conference of the United States and the Office of Management and Budget (OMB); and (5) procedural changes designed to enhance NRC's regulatory effectiveness.[3]

---

[1]The principles are set out at p. 3 in the 1990 NRC Annual Report, NUREG-1145, Vol. 7, July 1991.

[2]This document is currently undergoing revision and will tentatively be titled the Regulatory Analysis Technical Evaluation Handbook. The revised document is referred to as the "Handbook."

[3]Certain regulatory actions are subject to the backfit rule and to the analysis and information requirements of the Committee to Review Generic Requirements (CRGR). It is the NRC's intent that, for these actions, the

Subsequent to publication of NUREG/CR-3568 and revision of NUREG/BR-0058, the Commission issued its Policy Statement on Safety Goals for the Operation of Nuclear Power Plants. This policy statement presents a risk-based philosophy to be used by the NRC staff as part of their regulatory analysis process for proposed actions that may have an impact on commercial nuclear power reactors. The Commission's safety goal policy provides a "safety first" test that gives added strength to the regulatory decision making process for new requirements that are considered and justified as safety enhancements applicable to more than one nuclear power reactor. Specifically, application of this philosophy will minimize the number of occasions that resources are spent on conducting extensive regulatory analyses that later determine a proposed action is not justified because the incremental safety benefits would not substantially improve upon the existing level of plant safety. By defining a clear level of incremental safety for nuclear power plants, the safety goal evaluation to be included in the regulatory analysis provides the staff with direction in deciding where no further backfits are warranted. Thus, the safety goal evaluation can truncate the need for further analysis. Therefore, the safety goal analysis discussed in Chapter 3 of this document is to be addressed as early as possible in the regulatory analysis process for safety enhancement initiatives.

This document is comprised of five chapters which are further subdivided into several sections. Chapter 2 of this document discusses the purpose and coverage of the Guidelines. The discussion includes information on when a regulatory analysis must be prepared for a proposed regulatory action, the role of regulatory analysis in NRC decision making, and special requirements for proposed regulatory actions involving backfits. Chapter 3 discusses the relationship of NRC's safety goals for nuclear power plant operations to regulatory analyses. Chapter 4 discusses the format that should be followed in preparing a regulatory analysis document. This chapter includes summary guidance on estimating and evaluating the values and impacts of alternative

---

analysis performed in accordance with the Guidelines meets the needs of the backfit rule and the provisions of the CRGR charter without a need to prepare separate submissions.

regulatory actions and selection of the proposed action. Information is also included in Chapter 4 on regulatory analysis content requirements for proposed generic backfits and for actions subject to review by the Committee to Review Generic Requirements (CRGR). Chapter 5 discusses certain procedural requirements that relate to the regulatory analysis process including the impact of the Paperwork Reduction Act of 1980 and the Regulatory Flexibility Act of 1980.

2. DISCUSSION

2.1 Purpose of Regulatory Analysis

The statutory mission of the NRC is to ensure that civilian uses of nuclear materials in the United States--in the operation of nuclear power plants and related fuel cycle facilities or in medical, industrial, or research applications--are carried out with proper regard and provision for the protection of the public health and safety, property, environmental quality, common defense and security, and in accordance with applicable antitrust laws. Accordingly, the principal purposes of a regulatory analysis are to help ensure that:

- NRC's regulatory decisions made in support of its statutory responsibilities are based on adequate information concerning the need for and consequences of proposed actions.
- Appropriate alternative approaches to regulatory objectives are identified and analyzed.
- There is no clearly preferable alternative to the proposed action.
- Proposed actions subject to the backfit rule (10 CFR 50.109) [and not within the exceptions at 10 CFR 50.109(a)(4)] provide a substantial increase in the overall protection of the public health and safety or the common defense and security and that the direct and indirect costs of implementation are justified in view of this substantial increase in protection.

The regulatory analysis is intended to be an integral part of NRC decision making that will systematically provide complete disclosure of the relevant information supporting a regulatory decision.[4] The process should begin when it becomes apparent that some type of action to address an identified problem may be needed.

---

[4]The conclusions and recommendations included in a regulatory analysis document are neither final nor binding, but rather are intended to enhance the soundness of decision making by NRC management and the Commission.

The regulatory analysis process is not to be used to produce after-the-fact rationalizations to justify decisions already made, nor should it be used to unnecessarily delay regulatory actions. Initial efforts should be focused on the nature, extent, and magnitude of the problem being addressed, why NRC action is required, and identification of alternative solutions. Detailed information gathering and analysis activities should be focused on the most promising alternatives.

2.2 General Coverage

Regulatory Analyses are performed by the NRC to support numerous NRC actions affecting reactor and materials licensees. The "Regulatory Impact Analysis Guidelines" of Executive Order 12291 require that a regulatory analysis be prepared for all major proposed and final rules.[5] NRC policy requires regulatory analyses for a broader range of regulatory actions than for those that would be covered by EO 12291. In general, each NRC Office should ensure that all mechanisms used by NRC staff to establish or communicate generic requirements, guidance, requests, or staff positions, which would result in the use of resources by licensees and staff of the NRC or an Agreement State, include an accompanying regulatory analysis. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions, and standard technical specifications.

Regulatory analysis requirements for a given action may be eliminated at the discretion of the Commission, the EDO or a Deputy Executive Director, or the responsible NRC Office Director. A factor that could influence this decision for example is the degree of urgency associated with the regulatory action. For example, urgent NRC bulletins and orders may need to be issued without regulatory analyses. In addition, in other regulatory applications, case

---

[5] EO 12291 defines a major rule as any regulation that is likely to result in: (1) An annual effect on the economy of $100 million or more; (2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or (3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

specific circumstances could justify the preparation of a more limited regulatory analysis. A regulatory analysis should be limited only in terms of depth of discussion and analysis, not in reduction of the scope of the regulatory analysis nor in the need to justify the proposed action.

Generic actions[6] that may not need a regulatory analysis include notices, policy statements, and generic letters that only forward information and do not present new or revised staff positions, impose requirements, or recommend action. Generic information requests issued under 10 CFR 50.54(f) require a specific justification statement and are reviewed by the CRGR, but do not require the type of regulatory analysis discussed in this document. The content of such a justification statement is available in NRC Management Directive 8.4. New requirements affecting certified plant designs would be justified through the notice and comment rulemaking process. Also, regulatory analyses are not required for requirements arising out of litigation, such as discovery in a licensing proceeding.

2.3 Proposed Actions Subject to the Backfit Rule and CRGR Review

Regulatory actions that are subject to the backfit rule and/or CRGR review require that specific questions and issues be addressed. These Guidelines have been developed so that the preparation of a regulatory analysis in conformance with these Guidelines will meet the requirements of the backfit rule and provisions of the CRGR Charter (Revision 5, April 1991). However, it should be noted that relaxations of requirements are not subject to the backfit rule nor to the safety goal analysis process and criteria contained in Section 3. Relaxations do need to have presentations of effects on values and cost savings, but no balance is required. With respect to the values, that side of the equation does not need to be shown. What needs to be shown is that the relaxation does not adversely affect the public health and safety and that the protection continues to be adequate.

---

[6]In these Guidelines, the term generic actions refers to those actions that affect all, several, or a class of licensees.

The CRGR has the responsibility to review and recommend to the EDO approval or disapproval of requirements or staff positions to be imposed by NRC on one or more classes of power reactors. Section IV of the CRGR Charter specifies the information to be submitted to the CRGR as part of its review process. This information is incorporated in Chapter 4 of these Guidelines.

Additionally, the Regulatory Analysis Technical Evaluation Handbook, NUREG-XXXX, provides a standard table of contents for a regulatory analysis and indicates where each item of information required by the CRGR Charter may be found in a regulatory analysis.

When a regulatory analysis has been prepared in accordance with these Guidelines and the associated Handbook, it will not be necessary to prepare a separate document to address the information required for CRGR review, except for the CRGR requirement relating to the concurrence of affected program offices, or an explanation of any nonconcurrences. This exception may be addressed in the transmittal memorandum forwarding the matter to the CRGR for review.

After a regulatory analysis has been prepared and printed, it may become necessary to revise or supplement some of the material. It may be appropriate to address the supplement or revision in the transmittal memorandum to the CRGR (and include as an enclosure) rather than reprinting the regulatory analysis.

Special requirements apply to regulatory analyses prepared in conjunction with proposed backfitting of production or utilization facilities.[7,8,9]

---

[7]The backfit rule [cf. 10 CFR 50.109(a)(2)] prescribes the preparation of an analysis for both proposed plant-specific and generic backfits. The required analysis for generic backfits is to be considered a regulatory analysis and should be prepared according to these Guidelines. In addition, plant specific backfits require justification statements similar in nature to a regulatory analysis. To the extent to which the Guidelines are applicable to plant-specific requirements, it should be applied in these circumstances as well.

[8]The term "backfitting" is defined at 10 CFR 50.109(a)(1).

Backfitting can apply to one facility ("plant-specific backfitting") or to multiple facilities ("generic backfitting"). These Guidelines are intended for both generic and plant specific backfits. Proposed plant-specific backfits are subject to the requirements in NRC Management Directive 8.4 (Manual Chapter 0514-043). This Directive contains plant-specific regulatory analysis requirements that must be adhered to, and as a result, when preparing a plant-specific analysis this Directive should be consulted.

Backfitting can arise through a variety of mechanisms including rulemakings, bulletins, generic letters, and regulatory guides. Further description of the backfitting process is in Backfitting Guidelines, NUREG-1409. NRC Management Directive 8.4 is included as Appendix B in NUREG-1409.

A regulatory analysis involving a value-impact determination is necessary for all proposed plant-specific and generic backfits except when one of the three conditions identified at 10 CFR 50.109(a)(4) applies, i.e.,

i. That a modification is necessary to bring a facility into compliance with a license, a Commission requirement, or a written commitment by the licensee; or
ii. That regulatory action is necessary to ensure that the facility provides adequate protection[10] to the health and safety of the public and is in accord with the common defense and security; or
iii. That the regulatory action involves defining or redefining what level of protection to the public health and safety or common

---

[9]The terms "production facility" and "utilization facility" are defined at 10 CFR 50.2. A nuclear power reactor is a utilization facility. Production facilities include reactors designed or used for the formation of plutonium or uranium-233, uranium enrichment facilities, and nuclear material reprocessing facilities.

[10]The level of protection constituting "adequate protection" is to be determined on a case-by-case basis. The determination should be based on plant and site-specific considerations and the body of NRC's regulatory requirements.

defense and security is regarded as necessary for adequate protection.

For backfits meeting one of these exception criteria, costs are not to be considered in justifying the proposed action. A documented evaluation is prepared which includes the objectives of and reasons for the backfit, and the reasons for invoking the particular exception [10 CFR 50.109(a)(6)]. Procedural requirements for preparation and processing of the documented evaluation are in NRC Management Directive 8.4 for plant-specific backfits and Section IV(B)(ix) of the CRGR Charter for generic backfits.

A regulatory analysis may also be prepared in these instances as a management decision. In particular, if there are two or more ways to achieve compliance or reach a level of adequate protection, and should it be necessary or appropriate for the Commission to specify a way, then costs may be a factor in that decision. A regulatory analysis that explores the cost effectiveness of the various alternatives under consideration could therefore be valuable to a decision maker.

3. SAFETY GOAL CONSIDERATIONS

Assessing the risk or potential changes to public safety has always been a fundamental part of regulatory decision making. In the early development of regulations, this assessment was based on qualitative analysis, simple reliability principles and practices (such as worst case analysis), defense-in-depth and the single failure criterion. The likelihood or probability of the hazard was an explicit factor, primarily because the overall state-of-the-art of probabilistic risk assessment (PRA) technology was not sufficiently advanced and accepted. Currently, due to the advancements made and an increased confidence in PRA, regulatory activities have progressively relied more on the insights and results from probabilistic assessment. The safety goals, which are expressed in an August 1986 Commission policy statement, are a clear example of this change and established a guide for regulatory decision making.

The safety goal analysis is designed to answer the threshold backfit question as to when a regulation or regulatory decision should not be imposed because the risk is already acceptable and a lower risk should not be required whether or not justified on a value-impact (V/I) basis.

The following discussion provides guidance on: (1) when a regulatory analysis must include a safety goal evaluation, (2) criteria for judging conformance to the safety goals, and (3) the sequence for performing the analysis.

3.1 Criteria

NRC's safety goal policy addresses a level of acceptable residual individual risk from operation of power reactors judged to be lower than that associated with adequate protection, that is the risk level above which continued operation would not be allowed. As a result, the safety goal analysis as discussed in this section, is applicable only to regulatory initiatives considered to be generic safety enhancement backfits as defined in the backfit rule (50.109). If the proposed safety goal criteria are satisfied, it is to

be presumed that the substantial additional protection standard of 10 CFR 50.109(a)(3) is met for the proposed action.

As discussed in Section 2.3, relaxations of requirements are not backfits and thus do not fall within the scope of the backfit rule. As a result, relaxations or the elimination of requirements are not subject to the analysis or criteria of this section. Additionally, it should be noted that the Commission's safety goals reflect a "mean" value for a class or all U.S. reactors as a whole. In this regard, the Commission specified in an SRM dated June 15, 1990, that "Safety goals are to be used in a more generic sense and not to make specific licensing decisions."

In justifying a proposed backfit under the backfit rule, the burden is on the staff to make a positive showing that a generic safety problem actually exists, and that the proposed backfit will both address the problem effectively and provide a substantial safety improvement in a cost beneficial manner.

3.2 Procedure

The staff must first determine whether the subject regulatory action needs to consider safety goals. The discussion in Section 3.1 provides guidance for making this determination. If safety goal considerations are required, the results of the safety goal evaluation will establish whether a regulatory analysis should be done (Figure 3.1). If the proposed regulatory action meets the specified criteria, the regulatory analysis should include the results of the safety goal evaluation, as well as the follow-on value-impact analysis. Figure 3.1 depicts all steps performed in a regulatory analysis that is subject to a safety goal evaluation. Depending on the results of steps C and/or D, the regulatory analysis can be terminated. In performing steps C and D, a PRA should be relied upon to quantify both the risk reduction and corresponding values of the proposed action. However, it is recognized that not all regulatory actions are amenable to a quantitative PRA type assessment, and thus certain evaluations may require reliance on expert opinion, engineering/regulatory judgement, or qualitative analysis. Additional

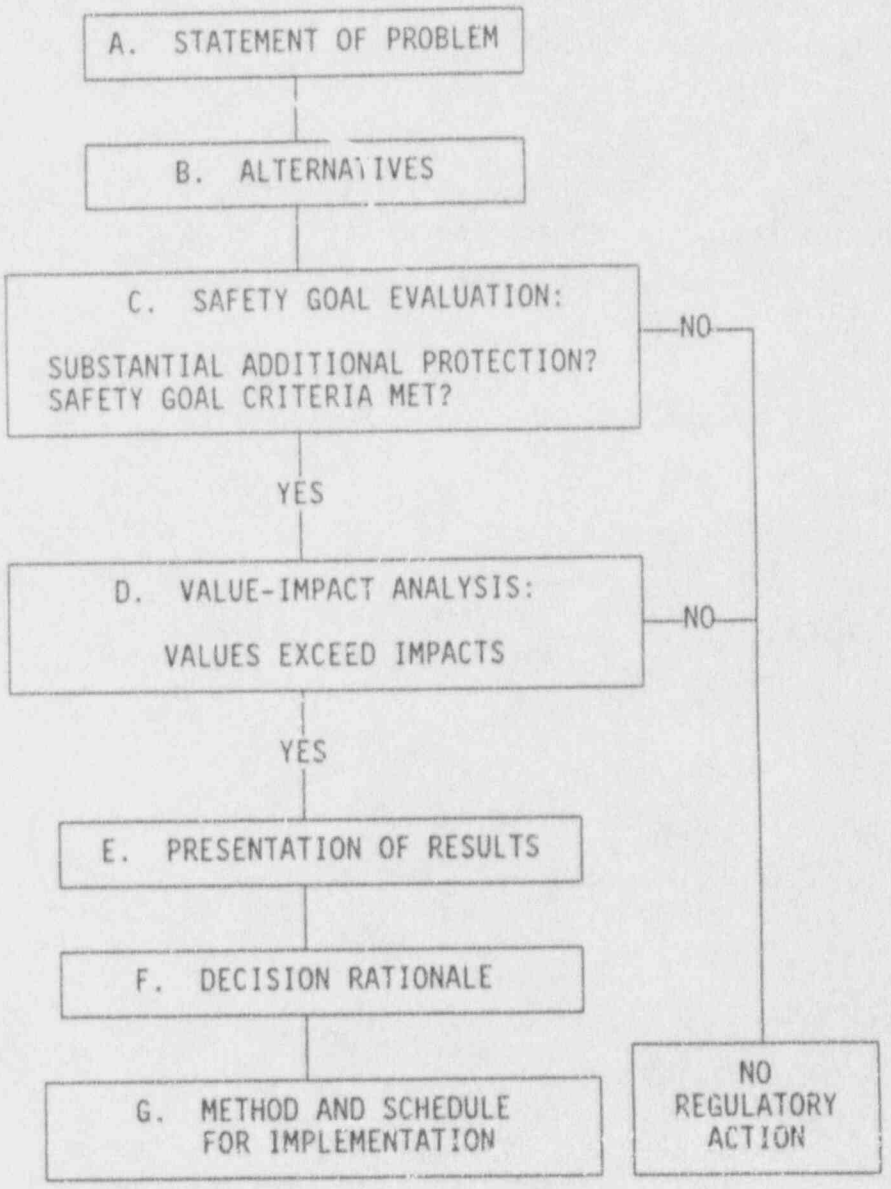
insights are available in the Handbook beyond the implementation guidance which follows.

3.3 Interim Guidance for Implementation

This interim guidance is to allow the staff to gain experience in the application of the safety goals and to permit consideration of the goals to the extent practical, pending availability of additional data and decisions to permit more structured decision making. This guidance will be revised as experience and new information dictates. Factors that will be considered include: (1) availability of PRA's reflecting both internally and externally initiated accidents and the current design of all U.S. plants, and (2) approval of a large release definition.

FIGURE 3.1

REGULATORY ANALYSIS FOR REACTOR SAFETY ENHANCEMENTS



In summary, the approach to safety goal considerations is based upon the following broad guidelines:

- Safety goal objectives are to be applied only to safety enhancements and evaluated for the affected class of plants. Safety goals are to be used as a reference point in ascertaining the need for safety enhancements. (Note: Consideration of uncertainties is important in order not to overlook or dismiss potentially risk significant issues prematurely.) However, the safety goals are not requirements and, with the Commission's approval, safety enhancements that otherwise comply with the Commission's rules may be implemented without strict adherence to the Commission's safety goal policy statement.

- The approach is to be implemented in conjunction with the "substantial additional protection" criterion contained in the backfit rule [10 CFR 50.109(a)(3)] and applies to § 50.109 analyses associated with safety enhancements for nuclear power plants.

- The analysis should take into consideration that there are a number of limitations and uncertainties involved with estimating risk at operating plants. These uncertainties relate to the quantitative measurement of certain types of human actions (e.g., errors of commission and heroic recovery actions); variations in licensees' organization/management safety commitments; failure rates of equipment, especially to common-cause effects such as maintenance, environment design and construction errors, or from aging, and external events such as seismic and tornado effects, and incomplete understanding of the physical progression and consequences of severe accidents.

- Evaluation of proposed regulatory initiatives for consistency with safety goals should identify and integrate related issues under study. Such integration is essential to the efficient application

of staff and industry resources. The overall objective is to avoid piecemeal evaluation of issues.

The regulatory philosophy involves the concept of defense-in-depth and a balance between prevention and mitigation. This traditional defense-in-depth approach and the accident mitigation philosophy require reliable performance of containment systems. The following guidance was developed to establish consistency between new regulatory initiatives and the overall "mean" frequency of a large release of radioactive materials to the environment from a reactor accident of less than 1 in 1,000,000 per year of reactor operation. A "mean" core damage frequency of 1 in 10,000 per reactor year has been used as a subsidiary benchmark.

3.3.1 Prevention of Core Damage Accidents--Comparison With Subsidiary Goal for Core Damage "Mean" Frequency of 10^{-4}/Reactor Year

For proposed regulatory actions to prevent or reduce the likelihood of sequences that can lead to core damage events, the change in the estimated Core Damage Frequency[11] (CDF) per reactor year needs to be evaluated and addressed in the regulatory analysis. The objective is to assure that emphasis is placed on preventing core damage accidents.

This calculation should be computed on a generic basis for the class of affected plants. The resulting change in CDF should be representative for the affected class of plants. The selection of the PRA model (or models) and the associated data base must be identified and justified as representative of the class. For example, if the class of affected plants is exclusively "older BWRs," one or more PRAs from IPE submittals or that have been conducted for older BWRs should be selected [see for example NUREG 1150]. The Handbook which complements these Guidelines includes a table listing all currently available PRAs along with some basic attributes of each (e.g., plant type and

---

[11]Core Damage Frequency is defined as the likelihood of an accident involving the loss of adequate cooling to reactor fuel elements up to and including major damage to a reactor core with consequent release of fission products, but not necessarily involving a breach of the reactor vessel.

year of commercial operation). As a minimum, the merit of the proposed actions should be explored and displayed using best available PRA and actual data for multiple plants within the class. This will result in identification and assessment of the range of reduction in CDF as well as an estimation of the representative change for the class. Uncertainties and limitations should be addressed qualitatively and, to the extent practical, quantitatively in the supporting documentation for the proposed regulatory action. This would include, for example, plant-to-plant variabilities within a class of plants and the use of point estimates for PRAs that do not have an uncertainty analysis. (In this latter case, sensitivity analyses, whereby individual parameter values are increased/decreased one at a time, may be used in lieu of uncertainty analysis.)

In comparing the estimated resulting change in CDF for the affected class of plants, contributions from both internal and external events should be considered to the extent that information is available and pertinent to the issue. However, the uncertainties associated with external event risk contributions (especially seismic) can be relatively large. Therefore, to supplement any available quantitative information, qualitative insights should be used for issues involving external events.

For the purpose of evaluating regulatory initiatives against safety goal objectives, the magnitude of the change in CDF should be considered in concert with the determination of whether the substantial additional protection criterion of the backfit rule is met. Specifically, a single, common criterion is to be used for determining whether a regulatory initiative involving a reduction in CDF (1) meets the "substantial additional protection" standard identified in the backfit rule, and (2) is appropriate from the subsidiary safety goal perspective on CDF of 10^{-4}/reactor year.

In light of the inherent uncertainties of current PRA analysis, and during the initial period of trial use, a reduction in CDF will be considered to be "substantial" if the reduction is 10 percent or more of the subsidiary safety goal CDF objective of 10^{-4}/reactor year. As discussed below and as illustrated in Figure 3.2, this means that, with certain exceptions, as

discussed later, regulatory initiatives involving actions to prevent core damage should result in a reduction of at least 1×10^{-5} in the estimated mean value or best estimate CDF (i.e., the CDF prior to the proposed regulatory change should exceed the CDF after the change by at least 1×10^{-5}) in order to justify proceeding with further analyses. This screening criterion was selected to provide some assurance that the PRA and data limitations and uncertainties, as well as the variabilities among plants, will not eliminate issues warranting regulatory attention. In this regard, the effect of uncertainties should be considered and discussed. Because full scope PRAs are not available for all plants, the evaluation of change in CDF may be based on the best available information from those PRAs which include estimates of CDF. This allows a specific focus on the sequence(s) of concern and allows considerable savings in staff resources.

After the risk significance has been determined as measured by the estimated reduction in CDF of the proposed action for the affected class of plants, guidance on further staff action is as follows:

Estimated Reduction In CDF		Staff Action
$> 10^{-4}$	(approximately)	• Proceed directly to V/I portion of the regulatory analysis on high priority basis.
10^{-4}-10^{-5}		• The decision whether to proceed to V/I portion of the regulatory analysis is to be made by the responsible Division Director. (see Figure 3.2).
$< 10^{-5}$	(approximately)	• Terminate further analysis unless the Office Director directs otherwise based upon strong engineering or qualitative justification (see Figure 3.2).

The evaluation of CDF reduction provides a calibration on the significance of the proposed regulatory action. If the initiative results in a small change in CDF (less than 1×10^{-5}/reactor year), the regulatory analysis should in general proceed only if an alternative justification for the proposed action

can be formulated. One class of accident sequencing which should receive further consideration even if the reduction in CDF is less than 1×10^{-5}/reactor year is that involving the potential for early containment failure or containment bypass (see Section 3.3.2, below). However, there may be other special circumstances which should be analyzed. The staff should forward the issue (and include sufficient supporting information) for Office Director review.

If it is not possible to develop quantitative supporting information with acceptably small uncertainties for the proposed action, a qualitative analysis and perspective should be provided. To the extent practical, these points and insights should be related to the proposed criteria provided above. For example, how does the proposed initiative affect the CDF and to what extent? How should a measure or estimation of the risk and the expected improvement be done?

The safety goal objectives are in terms of a "mean" for the class of plants. However, the range within the class of the risk reduction is also important. Consequently, when performing safety goal analyses, if specific plants are identified as "outliers," this situation should be flagged for specific regulatory follow-up, (e.g., for evaluations regarding potential plant-specific backfits).

3.3.2 Mitigation of Core Damage Accidents--Determine the Potential for Early Containment Failure or for Bypassing Containment

The NRC's regulatory philosophy involves the concept of defense-in-depth including the requirement of a capable and reliable containment. Consequently, the potential for early failure or bypass of containment needs to be assessed given the conditions that may be present in the event of a core damage accident. Further, potential modifications or improvements to the containment system may be proposed as a regulatory initiative which also may need to be assessed.

The potential for failure or bypass of containment should be determined, if practical, by estimating the conditional containment failure probability (CCFP).[12] This calculation should be computed on a generic basis as representative for the affected class of plants using models and data from previous analysis such as IPE evaluations or from NUREG 1150 studies. If such an analysis cannot be performed with reasonable levels of certainty, then a qualitative assessment should be made. For example, if the CCFP or the change in CCFP given a postulated change in containment design cannot be reasonably estimated, then engineering judgement of relevant factors affecting the potential for early containment failure or bypass sequence would be an adequate basis for proceeding further.

The mitigation of core damage accidents needs to be assessed in comparison with the large release frequency guideline of 10^{-6}/reactor year. Such mitigation initiatives would normally fall within the following three categories:

1. The assessment of the potential for early failure or bypass of the containment given the conditions of a specific core damage accident sequence.

2. Accident management programs including activities to prevent or minimize the probability of sequences that result in large-scale fuel melting and breach of the reactor vessel (given a core damage accident), or

3. Postulated modification to the containment system that would prevent or minimize the probability of sequences that could lead to an early failure or bypass of containment.

---

[12]CCFP in this context is a probability of early containment failure or bypass given core melt. In NUREG-1150, early containment failure is defined as: "Those containment failures occurring before or within a few minutes of reactor vessel breach for PWRs and those failures occurring before or within 2 hours of vessel breach for BWRs. Containment bypass failures (e.g. interfacing-system loss-of-coolant accidents) are categorized separately from early failures."

When considering sequences which may bypass containment, the following three types should be included in the evaluation:

(a) a failure resulting in a direct pathway to the environment such as in an interfacing system;
(b) pre-existing opening in, or failure to isolate, the containment; and
(c) bypassing of the mitigative function of the containment, such as loss of suppression pool scrubbing, coupled with a release path to the environment.

Following evaluations of the potential for bypass of the containment, the following criteria listed below should be used regarding subsequent staff action.

Estimated Reduction in Likelihood of Containment Bypass with Core Damage Accidents	Staff Action
$> 10^{-6}$	• Proceed to V/I portion of the regulatory analysis.
10^{-6} (approximately)	• Division Director decides if further regulatory analysis is justified.
$< 10^{-6}$	• Terminate further analysis unless the Office Director directs otherwise based upon strong engineering or qualitative justification.

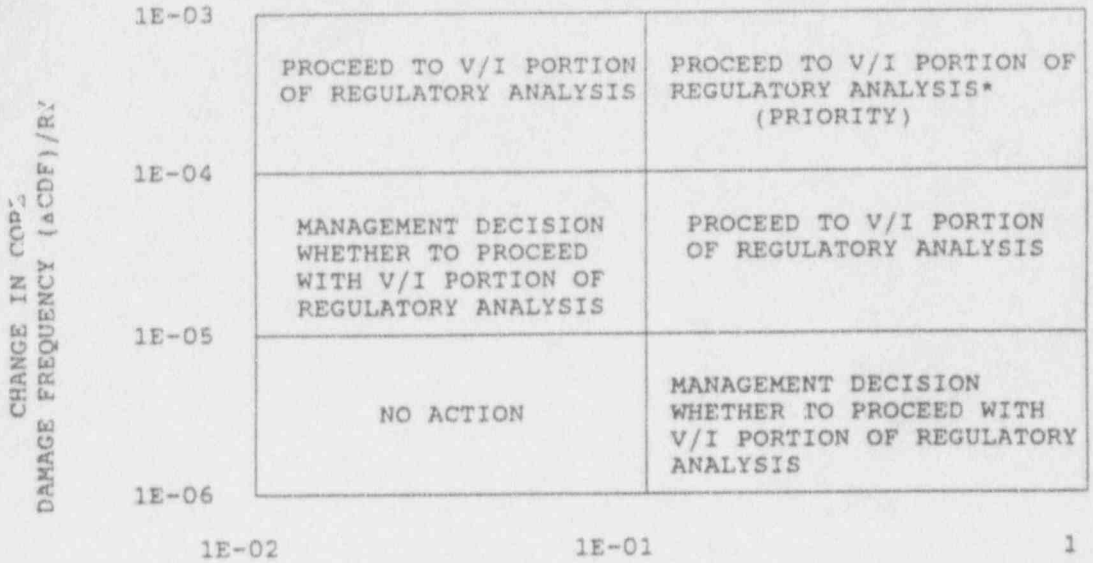
After the potential for bypass of containment has been determined, guidance on further staff action with regard to early containment failure is as follows:

Estimated ΔCDF and CCFP	Staff Action
ΔCDF is 10^{-4}-10^{-5} and CCFP is > 10^{-1}	• Proceed to V/I portion of the regulatory analysis.
ΔCDF is 10^{-4}-10^{-5} and CCFP is 10^{-1}-10^{-2}	• Division Director decides if further regulatory analysis is justified.
ΔCDF is 10^{-5}-10^{-6} and CCFP is > 10^{-1}	• Division Director decides if further regulatory analysis is justified.
ΔCDF is 10^{-5}-10^{-6} and CCFP is < 10^{-1}	• Terminate further analysis unless the Office Director directs otherwise based upon strong engineering or qualitative justification.

3.3.3 Summary of Implementation Guideline

The detailed staff action criteria discussed in the previous sections has been summarized in Figure 3.2. which graphically illustrates the above criteria and provides guidance as to when staff should proceed to the value-impact portion of the regulatory analysis, and when a management decision is needed.

FIGURE 3.2 SAFETY GOAL IMPLEMENTATION GUIDANCE



* A determination is needed regarding adequate protection or compliance; as a result a value-impact analysis may not be appropriate.

**Conditional upon core damage accident which releases radionuclides into the containment (see Section 3.3.2).

Responsible management should review the results and the overall uncertainty and sensitivity of these estimates. A judgment should be made whether substantial additional protection would be provided and whether continuation of the regulatory analysis is therefore warranted. Such judgments should consider the merits of either further reductions in the estimated CDF or potential actions to reduce the CCFP.

3.3.4 Value-Impact Analysis

If the safety goal evaluation of the proposed regulatory action results in a favorable determination, the analyst may presume that the substantial additional protection standard of § 50.109 has been met. The initiative should then be assessed in accordance with Section 4.3 (Estimation and Evaluation of Values and Impacts) of these Guidelines. Should the impacts not

be justified, further activities and analyses should be terminated unless there is a strong qualitative justification for proceeding further.

4. REQUIRED ELEMENTS FOR PREPARING A REGULATORY ANALYSIS

This section discusses the specific elements to be included in a regulatory analysis document. These elements include:

(1) A statement of the problem and NRC objectives for the proposed regulatory action.

(2) Identification and preliminary analysis of alternative approaches to the problem.

(3) Estimation and evaluation of the values and impacts for selected alternatives including consideration of the uncertainties affecting the estimates.

(4) The conclusions of the value-impact analysis, and when appropriate, the safety goal evaluation.

(5) The decision rationale for selection of the proposed regulatory action.

(6) A tentative implementation schedule for the proposed regulatory action.

A regulatory analysis should be organized to address each of these elements and should also include an executive summary, a list of acronyms, and identification of the references used. More detailed guidance for the preparation of regulatory analysis documents is available in the Handbook. The Handbook includes methodological tools and generic estimates for the quantification of selected attributes that are typically included in the NRC value-impact analyses.

Regulatory analyses are reviewed within the NRC and made publicly available. Reviewers include NRC technical staff and management and formal groups such as the CRGR and the Advisory Committee on Reactor Safeguards, and the Advisory Committee on Nuclear Waste. Reviewers typically focus on the appropriateness of assumptions, the selection and elimination of alternatives, estimation

techniques, evaluation methods, any limitations in the data used, and the decision rationale. To facilitate this review, as well as review by those outside the NRC, staff should carefully document both the assumptions made and the sources of information used in preparing the regulatory analysis. Information obtained from outside the NRC, including any from interested parties to a proposed regulatory action, may be used in the preparation of the regulatory analysis after the staff has assured itself of the reasonableness of such information.

It is the intent of this guide to ensure uniformity in the scope or elements to be included in a regulatory analysis. But, the appropriate level of detail that the staff should include in a regulatory analysis can vary depending on the particular circumstances. Factors that staff should consider in determining the appropriate level of detail should include:

- The complexity and policy significance of the particular problem being addressed
- The magnitude and likelihood of values and impacts
- The relative amount by which projected values exceed impacts[13]
- The immediacy of the need for a regulatory action and time constraints imposed by legislation or court decisions
- Any supplemental direction provided by the Commission, the Office of the EDO, or an NRC Office Director.

The emphasis in implementation of the Guidelines should be on simplicity, flexibility, and common sense, in terms of the type of information supplied and in the level of detail provided. The level of treatment given to a particular issue in a regulatory analysis should reflect how crucial that issue is to the bottom line recommendation of the regulatory analysis. In all cases, regulatory analyses must be sufficiently clear and contain sufficient

---

[13] Proposed actions where values and impacts are estimated to differ by a relatively small amount should normally be analyzed in greater detail than actions where values and impacts differ by a substantial amount.

detail to enable NRC decision makers and other interested parties to easily recognize:

- The problem defined within the context of the existing regulatory framework
- The proposed regulatory action
- The conclusions reached and the associated bases
- The specific data and analytical methods used and the logic followed that led to the conclusion that the proposed action was appropriate and justified
- The sources and magnitude of uncertainties which might affect the conclusions and the proposed action
- The sensitivity of the conclusions to changes in underlying assumptions and considerations.

4.1 Statement of the Problem and Objective

The statement of the problem should be a concise summary of the problems or concerns that need to be remedied, defined within the context of the existing regulatory framework. The statement should provide the reader with a clear understanding of exactly what the problem is and why it exists, the extent of the problem and where it exists, and why it requires action. In this context, a measure of its safety importance needs to be presented on either a qualitative or quantitative basis. The focus of this section is to clearly demonstrate that the problem requires action, and the implications of taking no action.

For certain regulatory issues there may be existing regulatory requirements or guidance, industry programs, or voluntary efforts directed at the same or similar problem. These activities, and any variations in industry practice and commitments among licensees, must be identified and discussed. The need for regulatory action must be justified within the context of what would prevail if the proposed action were not adopted which requires assumptions as to whether, and to what degree, voluntary practices may change in the future.

In general, the no action alternative or base case is central to the estimation of incremental values and impacts. Additional guidance is available in Section 4.3.

The problem statement should identify the specific class or classes of licensees, reactors, or other facilities affected by the problem, as appropriate. Any distinctions between impacted licensees (e.g., NRC and Agreement State, BWR and PWR) should be noted, as well as any differences in facility type, age, design, or other relevant considerations.

A background discussion of the problem should be included. The background discussion should cover, as applicable:

(1) A brief history of the problem and the outcome of past efforts (if any) to alleviate it.
(2) Any legislation or litigation[14] that directly or indirectly addresses the problem.
(3) The extent (if any) to which the immediate problem is part of a larger problem.
(4) The relationship of the problem to other ongoing studies or actions, (Note, it is important this action be reviewed in the proper context of other regulatory requirements that apply to the same problem, such as to NRC's prioritized generic safety issues (NUREG-0933) or other identified safety issues meriting NRC's attention).
(5) The objective(s) of the proposed action and the relationship of the objective(s) to NRC's legislative mandates, safety goals for the operation of nuclear power plants, and policy and planning guidance (e.g., NRC's Five-Year Plan).
(6) Identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness.

---

[14]Could come from court cases, decisions by an Atomic Safety and Licensing or Appeal Board, or Commission decisions in cases under litigation.

(7) Constraints or other cumulative impacts which work against solutions to the problem.

(8) Draft papers or other underlying staff documents supporting the requirements or staff positions.

4.1.1 Backfit Rule Concerns

For problems or concerns within the scope of the backfit rule (10 CFR 50.109), the type of backfit needs to be identified. Specifically, depending on whether the action is being initiated for adequate protection or compliance and not as a safety enhancement, the need for a regulatory analysis may not exist, or at a minimum, its scope or focus should be markedly different (see Section 2.3). Thus, it is important for the preparer of the regulatory analysis to address this issue early in the regulatory analysis process. Further, for any single action, more than one type of backfit may be involved. Under these circumstances, the population of plants should be separately identified and assessed for each type of backfit.

4.2 Identification and Preliminary Analysis of Alternative Approaches

Once the need for action has been identified, the regulatory analysis should focus on identifying reasonable alternatives that have a high likelihood of resolving the problems and concerns, and meeting the objectives identified under Section 4.1. The initial list of alternatives should be identified and analyzed as early in the analysis process as possible. For certain rulemakings, an options paper may be needed to identify and delineate substantive issues and to facilitate early consensus on the resolution of those issues. This analysis forces early consideration and documentation of alternatives, and identifies an initially preferred option.

The list of alternatives should be reasonably comprehensive to ensure that the range of all potentially reasonable and practical approaches to the problem are considered. The no-action alternative will normally serve as the base case for analysis. In essence, it functions as a default approach which will occur if none of the action alternatives is justified. Its primary value is

to establish the baseline condition from which all incremental values and impacts can be calcula ed. Alternatives generally focus on or explore alternatives to a series of hypothetical questions: What, who, how, and when.

Accordingly, in defining alternatives, when applicable, consideration should be given to the following types of issues:

- What action should be taken? - It may be appropriate to identify alternative ways to resolve the problem. This would typically account for viable alternatives based on variability in the physical and technical requirements needed to address the problem at-hand. This could also include varying the scope of requirements and number of licensees affected.

- Whose responsibility should it be to take action? - Different entities may be capable, and, therefore, can assume responsibility for resolving the problem. For example, initiatives by licensees and industry support groups may constitute a viable alternative to some NRC initiative.

- How should it be done? - It may be appropriate to consider the various mechanisms (e.g. generic letter, rule, policy statement) available to the NRC to accomplish the change.

- When should it become effective? - It may be appropriate to consider alternative implementation schedules and compliance dates.

The selection of alternatives for any given regulatory analysis will largely depend on the specific circumstances at-hand. For some regulatory analyses, alternatives covering the full range of considerations may be appropriate. For others, circumstances may dictate that the alternatives be confined to only one of the categories identified above. For example, Congressional or court rulings could prescribe an NRC action with such specificity that the only alternatives open to the NRC are implementation mechanisms.

Where the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirement should merely specify the objective or result to be attained, rather than prescribing to the licensee how the objective or result is to be attained. In other words, requirements should be performance based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary.

After the initial list of alternatives is identified, a preliminary analysis of the feasibility, values, and impacts of each alternative usually eliminates some alternative approaches. The elimination of alternatives from further analysis can be based on such factors as (1) clearly exorbitant impacts in relation to values, (2) technological impracticality, or (3) severe implementation difficulties. As information is generated as part of the preliminary analysis of alternatives, the initial set of alternatives should be refined. For each alternative that survives the preliminary screening, a general description of the activities required of licensees and the NRC to implement the alternative should be provided.[15] In certain circumstances this preliminary screening of alternatives may eliminate most of the alternatives under consideration. In such cases, the subsequent value-impact assessment need only address the limited set of remaining alternatives.

The alternatives section of the regulatory analysis document should list all significant alternatives considered by the staff. A brief explanation of the reason for elimination should be included for alternatives not selected for further study.

---

[15]Inclusion of this information will satisfy the requirements of 10 CFR 50.109(c)(2) for proposed generic backfits, NRC Management Directive 8.4 for proposed plant-specific backfits, and section IV(B)(vii)(b) of the CRGR Charter for proposed actions subject to CRGR review.

4.3 Estimation and Evaluation of Values and Impacts

The section of the regulatory analysis document covering the estimation and evaluation of values and impacts needs to analyze the alternatives that survive the screening process of Section 4.2. The level of detail need not be equivalent for all alternatives. For example, less detail is needed when one alternative can be shown to be clearly superior to the others. Nevertheless, this section will often be the longest and most complex portion of the document. For the purpose of these Guidelines the following definitions are adopted:

Values — The public values that NRC is directed to seek by Congress (e.g., The Atomic Energy Act of 1954 as amended) as interpreted by the Federal courts and the NRC Office of the General Counsel are as follows: (1) protection of the public health and safety, including protection of workers in the licensed nuclear industry, against the hazards of radiation, (2) protection of offsite property (i.e., property not owned or leased by a licensee), (3) assurance of the common defense and security, and (4) upholding and supporting the laws and agreements of the United States including antitrust and environmental laws and international agreements.

Impacts — The consequences of a proposed regulatory action that are not values.

Staff should consult the Handbook and any relevant NRC reports or documents issued subsequently to the preceding document for additional guidance on estimating and evaluating values and impacts. General principles to be followed are discussed in this section.

Categories of groups affected by the proposed regulatory action should be identified. Groups may include (but are not limited to) the general public, units of state and local government, licensees, employees of licensees,

contractors and vendors, and the NRC. Within each affected group further differentiation, i.e., licensee suppliers or contractors, may be necessary if the proposed action affects segments of the group differently. Under these circumstances, separate estimates and evaluations of values and impacts should be made for each distinct category. The categorization of licensees may be appropriate for a variety of reasons. For example, the effects of a new requirement can be markedly different between newer facilities which may have had safety features installed during construction that were not included in older facilities.

For each affected group, the attributes that can be used to characterize the consequences of the proposed action should be identified. The Guidelines and Handbook should be reviewed before selecting appropriate attributes. For each identified attribute, values and impacts are to be estimated on a net basis.[16]

Value and impact estimates are to be incremental, best estimates relative to the baseline case, which is normally the no action alternative.[17] When possible, best estimates should be made in terms of the "mean", or "expected-value." However, other acceptable estimates could include median and point estimates depending upon the level of detail available from the data sources employed in the value-impact analysis. However, the rationale for use of estimates other than "mean" values should be provided. The definition of the baseline case requires specific attention to ensure against double counting of either the values or impacts in the regulatory analysis. For example, in evaluating a new requirement for existing plants, the staff should assume that all existing NRC and Agreement State requirements and written licensee commitments have been implemented, and consequently, the values and impacts associated with these requirements and commitments are not part of the

---

[16]Both value and impact attributes may have positive or negative aspects (e.g., occupational exposure may increase due to implementation of a new requirement, and at the same time risk of occupational and public exposure may decrease due to a reduced risk of an accident).

[17]Procedures for making best estimates are discussed in the Handbook.

incremental values or impacts associated with the regulatory action under consideration. Similarly, insofar as new regulatory requirements may affect future plants, the reference point for these plants should also be the existing regulatory requirements. To ensure against double counting of either the values or impacts in the regulatory analysis, the staff should be aware of values and impacts associated with other formally proposed regulatory actions that are likely to be implemented in close proximity to the subject action.

The NRC encourages voluntary actions which enhance safety, and when such actions are being implemented on an industry-wide basis with no evident safety problem, great weight and due consideration should be given to these initiatives before imposing requirements to codify them in the regulations. In those situations however, when voluntary initiatives are in-place over only a portion of the industry, or which achieve only part of the safety objectives associated with a regulatory change under consideration, it may be necessary to codify the practice. The handling of these voluntary practices has important implications on the baseline case and consequently on the quantification of incremental values and impacts. For the purpose of the regulatory analysis, with certain exceptions noted below, no credit should be given for the voluntary actions taken by licensees. This means that when calculating the values and impacts of a proposed regulatory requirement and its alternatives, those consequences should not be reduced by the extent to which they may already be realized due to voluntary activities. Impacts already incurred by licensees or applicants in conjunction with these voluntary actions can be excluded from the incremental impact estimates if they are irreversible, i.e., cost recovery is not possible.

Most voluntary actions are discretionary in nature, and their impacts are primarily on-going and future-oriented. Such programs might typically be characterized as adopting very vague requirements, lacking in NRC enforceability, and resulting in a non-uniformity of programs across all licensees. It is the NRC's intent to be able to impose regulatory requirements in lieu of voluntary programs that, for any number of reasons, are not providing the level of safety assurance deemed necessary by the NRC. This would be the case, for example, when voluntary programs are non-uniform

across all licensees and as a result some licensees may not have such programs, or established programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and thus values and impacts associated with the proposed regulatory action are reduced, meaningful health and safety improvements could not be assumed in the future because they would remain uncodified and voluntary in nature, and not subject to enforcement on the part of the NRC. When the base case value-impact results take no credit for voluntary actions, a sensitivity analysis is to be performed and the value-impact results also displayed with credit for voluntary actions.

In general, if the NRC could ensure, with some high or reasonable assurance, that the voluntary program would continue and effectively accomplish its objectives, then the values and impacts attributable to the regulatory initiative should be reduced accordingly. Thus, for example, voluntary actions that are a part of an overall industry commitment with appropriate follow-up evaluations, would be subject to special treatment on a case by case basis. In addition, credit should typically be given to a voluntary action whose dominant impacts have already been incurred, such as the addition of a capital intensive safety system, because there is little financial incentive to eliminate it. Similarly, a voluntary program that involves a written commitment or one that affords the NRC some degree of enforceability is not easily abandoned.

Uncertainties are an important element to consider explicitly in the development of a regulatory analysis. The sources and magnitudes of uncertainties in value and impact estimates and the methods used to quantify uncertainty estimates should be discussed in all regulatory analyses. Hypothetical best and worst case values and impacts can be estimated for sensitivity analysis purposes. Sensitivity analysis can be used in addition to or in lieu of formal uncertainty analysis, the latter option being exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporation of uncertainties and/or

sensitivities in a regulatory analysis is in the Handbook. The Handbook also discusses the distinction between them.

Values and impacts should be estimated by year and for the entire time period that groups will be affected by the proposed regulatory action. For licensed facilities, estimates typically should be made for the remainder of the operating license or projected useful life of the facility. For power reactor requirements, separate estimates for a license renewal term should be made if the analyst judges that the results of the regulatory analysis could be significantly affected by the inclusion of such a renewal term. If not, for future reference, state the basis for the judgement or conclusion that there would not be a significant effect.

Estimated values and impacts will generally be expressed in monetary terms whenever possible, and expressed in constant dollars from the most recent year for which price adjustment data are available. Consequences that cannot be expressed in monetary terms should be described and quantified in appropriate units to the extent possible. In this regard, it is recognized that many regulatory actions, such as those affecting non-power reactor and materials licensees, may not be supported by available PRA analysis and that for some actions, probabilistic analysis techniques may not be practical. However, the staff needs to make every effort to apply alternative tools that can provide a qua itative perspective and useful trends concerning the value of the proposed action. Even inexact quantification with large uncertainties is often preferable to no quantification provided the uncertainties are appropriately considered.

Staff should use care to verify that neither values nor impacts are double counted. Values and impacts that are determined to be unquantifiable, should be identified and discussed qualitatively. An attribute should not be omitted from a regulatory analysis document simply because it is determined to be unquantifiable.

4.3.1 Estimation of Values

Relevant value attributes should be identified and assessed for each alternative. These assessments should reflect best estimates, preferably mean values, which would account for differences in the likelihood and effectiveness of each alternative's ability to solve the problem. To the extent applicable, possible value attributes to be assessed include changes in: (1) public radiation exposure health risk, (2) projected offsite damage to property or the environment, (3) occupational radiation exposure health risk, (4) antitrust practices, (5) safeguards risks, and (6) mitigation of environmental damage. Changes in public health and safety due to radiation exposure and offsite property impacts should be examined over a 50-mile distance from the plant site. Care must be taken to insure that the change in risk accounts for potential changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements. All changes in risk to the public and to workers should be estimated and discussed. When appropriate, health risks should be estimated for both routine operations and accidents.

Changes to any of these value attributes may be either positive or negative. Any individual attribute may have both positive and negative components. For example, a requirement for new equipment within areas where radiation is present will result in increased occupational exposure during installation of the equipment. However, this requirement may reduce occupational exposure during routine operation and in the event of an accident. The net change in occupational exposure must consider all these positive and negative components in exposure in deriving a net value for occupational exposure.

The ability to assess the risk can vary dramatically depending on the data and information available which is directly pertinent to the particular regulatory action under consideration. Generally, the extent of any supporting detailed information will allow one of three types of regulatory analyses to be developed:

(1) Detailed PRA or statistically based analyses are available or can be developed to support the quantification of values (benefits).

(2) Some factual information or data is available which can provide a quantitative perspective, but may involve considerable extrapolation of data and thus, the resulting analysis may be quite uncertain and lack completeness and/or precision.

(3) Extremely little data or accepted models exist to support a quantitative type analysis, and as a result, the analysis must be qualitative. Once this situation is understood, and the nature or type of the analysis is determined, then the analyst should proceed as outlined below. For a more detailed discussion, including examples of actual assessments, the analyst is referred to the Handbook.

Typically, the most detailed and specific value assessment will involve regulatory initiatives impacting nuclear power reactors for which PRA type analyses can be applied. The PRA can be used to generate a fairly detailed and comprehensive quantification of the expected risk reduction expressed in changes in core melt frequency or in person-rem averted. This value is then quantified in dollars based on a dollar per person-rem conversion factor.

The next level of quantification supporting regulatory initiatives concerns situations where PRAs are not available and other data and analysis must be used to justify the anticipated regulatory burden. Although no unique formula or algorithm can be postulated, the generally recommended approach is to utilize whatever data may be available within a simplified model in order to provide some quantitative perspective or insight on the nature and absolute or relative magnitude of the risk, and any discernable trends in the data. Typically, this approach will generate results that are subject to significant levels of uncertainty. The uncertainties will, in turn, require explicit disclosure of the simplifying assumptions embedded in the model as well as the data limitations. A sensitivity analysis that shows the variability in the derived risk as a function of key assumptions should typically be developed. The level of effort in terms of model development and data collection is dictated by the same factors utilized by the staff in determining the level of detail for the overall regulatory analysis (see Section 4.0).

The third level or type of regulatory analysis involves regulatory initiatives that for one reason or another cannot be quantified with meaningful limits on uncertainty. Certain power reactor issues, such as those involving emergency preparedness, security, and personnel requirements tend to fall into this category. In these instances, the analyst must provide a qualitative basis and a clear description of how the regulatory action is justified. The analyst is cautioned that this type of value-impact assessment is subject to a higher level of scrutiny by the decision maker because of the need to ensure that additional burdens on licensees are justified. Reliance on the qualitative approach should be a last resort to be used only after intensive efforts to develop pertinent data or factual information has proven unsuccessful.

4.3.2 Estimation of Impacts

The number of potential impact attributes is very large. What constitutes an appropriate impact is highly dependent on the specific circumstances of the alternative under consideration. To the extent applicable, impacts to be assessed include:

- Direct costs/savings to licensees
- Costs/savings to the NRC
- Costs/savings to state and local government agencies
- Non-radiation risk related costs/savings to the general public
- Averted onsite impacts[18]
- Changes in regulatory efficiency and/or scientific knowledge needed for regulatory purposes
- Conformance with formal positions adopted by national and international standards organizations.

---

[18]The Commission has previously directed the staff to treat averted on-site costs as an offset against other licensee costs and not as a value (benefit) in regulatory analyses. Staff Requirements Memorandum to the EDO on "SECY-89-102 - Implementation of the Safety Goals," June 15, 1990. The basis for this direction is in a memorandum from William Parler, NRC General Counsel, to Commissioner Frederick Bernthal, June 4, 1987.

Impact estimates should be included for incremental impacts associated with each alternative. When applicable, the estimation of impacts should include information on both installation and continuing costs, including the cost of facility downtime or the cost of construction delay. Sunk costs may be identified, but should not be included in the evaluation of impacts or the presentation of the results of the evaluation. Impacts should be estimated from society's perspective. Transfer payments such as insurance payments and taxes should not be included as impacts. In addition, depreciation is an accounting concept that should not be included as an impact.

The analysis of impacts also has to be sensitive to the true impact (cost) to licensees. For example, the practice of allocating no replacement energy costs by claiming that the requirement can be accomplished during a regularly scheduled outage is not always practical or reasonable. In reality the cumulative effect of all new requirements can add incremental downtime, and therefore analysts should attribute appropriate replacement energy cost penalties to their respective regulatory actions if practical. Further, for new requirements having extremely high implementation costs or which will greatly increase operating costs, the analyst needs to consider the possibility that the imposition of such impacts may result in some facilities no longer being economic and thus may have to terminate operations.

4.3.3 Evaluation of Values and Impacts

The evaluation of quantified estimates of the values and impacts associated with a proposed regulatory action involving NRC licensees generally involves expressing values and impacts on a common basis, i.e., constant dollars from a reference year.

Since the values and impacts need to be estimated for the entire time period that members of society will be effected by the proposed regulatory action, a present worth basis is normally used in order to allow meaningful summations and comparisons. This approach provides a rational basis for evaluating health and safety effects as well as the associated impacts, yet this approach has a number of complexities and controversies.

In order to provide for placing all values and impacts on a common basis, it is necessary to have a conversion or coefficient reflecting the monetary worth of a unit of radiation exposure. In this regard, in accordance with past NRC practice, unless otherwise justified, $1000/person-rem in 1993 dollars is to serve as the dollar conversion factor for all offsite consequences (health related impacts and dollar values for offsite cleanup, contamination, and property damage values) of severe power reactor accidents, and as a reference point or baseline where offsite consequences are not involved such as for occupational exposure, non-power reactor accidents, and ALARA determinations associated with cleanup of contaminated sites. It should be noted that the dollar evaluation of radiation exposure is a highly sensitive issue because it indirectly attaches a value on human life. Various methodological approaches provide varying degrees of justification for a wide range of $/person-rem values. A review and analysis of this issue is ongoing, and the $1000 value is to be used pending completion of the current reassessment. This reassessment may also address a periodic inflationary adjustment for the $/person-rem value.

In other than severe power reactor applications, alternative values to the $1000/person-rem may be considered and evaluated. In this regard, there may be a range of applicable values based on willingness-to-pay analyses, occupational exposure surveys, health consequence models such as (HECOM), adjustments for inflation and alternative fatality coefficients, and other case-specific data, as available. The Handbook contains a discussion of these estimating methodologies as well as representative values. If alternative values are explored, dollar values applicable to the situation should be discussed and the value-impact results clearly displayed for the decision maker in order to show the sensitivities of the proposed action to this consideration.

As noted previously, in order to provide meaningful summations, a present worth basis is normally used for evaluating all values and impacts. Applying present worth techniques to health and safety consequences has been controversial because it suggests a "discounting of benefits" and the implication that a lower value is being placed on future lives and illnesses.

However, the principle for regulatory analysis is that future health effects should be valued the same as current effects and present worth techniques achieve this. For example, based on the current conversion factor, health and safety consequences are to be consistently valued at $1000 per person-rem. Thus, for example, a person-rem averted in the year 1995 or 2010 or 2050 will be assigned a value of $1000 (in constant dollars). The present worth calculation is simply determining how much society would need to invest today to assure that $1000 is available in a given year in the future to avert a person-rem. By using present worth, health and safety effects, i.e., person-rem, regardless of when averted in time, are valued equally.

Based on OMB guidance, all values and impacts should be expressed on a present worth basis using the recommended discount rate specified in the latest version of OMB Circular A-94. This circular was most recently updated on November 10, 1992 and specifies the use of a 7 percent real (i.e., inflation adjusted) discount rate. OMB's 7 percent rate approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years.

The NRC also recommends that an alternative analysis using a 3 percent real discount rate be prepared for sensitivity analysis purposes. The base case, using for example OMB's currently recommended 7 percent rate, reflects recent economic conditions, yet typically NRC actions involve a 30 to 60 year time horizon. Given that uncertainties expand as one attempts to project further into the future it is considered prudent to examine the result of assuming a lower rate as part of a sensitivity analysis. There are also theoretical arguments in the economics literature that support the use of lower rates.[19] A 3 percent rate is recommended for the alternate case because it approximates the long-term risk-free real rate of return on investment based on historical data. If the alternative rate does not alter the bottom-line result, simply indicating this conclusion is sufficient. If there is a different conclusion

---

[19] See for example, Paananen, O.H., Hendrickson, P.L., Selection of a Discount Rate for Use in Regulatory Analyses Prepared by the U.S. Nuclear Regulatory Commission and Application of Discount Rates to Future Averted Health Affects Pacific Northwest Laboratory, January 1993.

or if the value-impact determination is significantly altered, this result should be discussed and placed in perspective for the decision maker.

Further, for certain regulatory actions, such as those involving decommissioning and waste disposal issues, the value-impact analysis may have to consider consequences that can occur over hundreds or even thousands of years. For the reasons listed above, and based on the technical literature[20], extended time horizons bring into question the appropriateness of using a relatively high interest rate for present worth calculations. Under those unique circumstances where the timeframe exceeds 100 years, the analyst should avoid the use of a 7 percent real interest rate. In these instances, the NRC regulatory analysis should display results to the decision maker in two ways. First, on a present worth basis using a 3 percent real rate, and second, by displaying the values and impacts at the time in which they are incurred with no present worth conversion. In this latter case, no calculation of the resulting net value or value-impact ratio should be made.

Finally, as a general principle, sensitivity and/or uncertainty analysis should be performed whenever the values of key attributes can range widely. A sensitivity analysis would consider the effect of varying the values of the attributes one at a time to measure each attribute's effect upon the overall result. Uncertainty analysis would typically require computer simulations while sensitivity analysis could be performed in an analytic manner. Should the sensitivity/uncertainty analysis indicate that the preference among alternatives depends significantly on the variation in one or more key attributes, additional investigation to reduce this dependence may be appropriate. The extent to which sensitivity/uncertainty analysis is performed should reflect the magnitude and likelihood of values and impacts and their associated variability.

---

[20] Ibid.

4.4 Presentation of Results

For each alternative considered, a net value calculation (values/benefits minus impacts/costs), as prescribed by OMB,[21] should be computed and displayed. In addition, the analyst may choose to display the results based on the ratio of values to impacts. Both presentation procedures may be used to clarify the results, and a comparison of the two presentation methods is included in the Handbook. Tabular and/or graphic displays of results and associated uncertainties should be included if their use will facilitate comparison of alternatives. The values and impacts of attributes that are quantified in other than monetary terms should be displayed in a manner that facilitates comparison of alternatives. Values and impacts not quantified in the regulatory analysis should be discussed and compared among alternatives.

For alternatives projected to result in significantly different values and impacts for different categories of licensees, separate evaluations of values and impacts should be made for each such distinct category. In addition, if significant differences exist between recipients of values and those who incur impacts, the distribution of values and impacts on various groups should be presented and discussed.

For certain proposed regulatory actions, the value-impact analysis may consist of only a cost effectiveness analysis. For example, the NRC may be required to initiate a requirement and achieve a certain level of value based on court or Congressional mandates, or to achieve compliance or adequate protection. Under these circumstances, the issue is not to determine whether the impacts of the new requirement are justified but rather to ensure that the requirement achieves the necessary level of value in an efficient and cost effective manner given the other implementing mechanisms available. Similarly, there may be proposed actions where important values cannot be assigned monetary values or where uncertainties are substantial. If the alternatives yield

---

[21] Office of Management and Budget, "Regulatory Impact Analysis Guidance," Regulatory Program of the United States Government April 1, 1990 - March 31, 1991, Appendix V.

similar values, cost effectiveness analysis can be used to choose the most efficient alternative.

The effect of each alternative on other NRC programs and requirements should be discussed. Effects on programs of other Federal agencies or agencies of state and local government should also be discussed. The extent to which the effects are discussed should be in proportion to their significance.

For those proposed regulatory actions subject to a safety goal evaluation (see Section 3.0), this section of the regulatory analysis should include the results of that analysis. A satisfactory finding relative to the proposed safety goal criteria is judged as a prerequisite for achieving the substantial additional protection criteria of the backfit standard in 10 CFR 50.109. Proposed actions subject to the backfit rule (except for backfits falling within the three exception categories of 10 CFR 50.109(a)(4) (see Section 2.3)), are also required to show that the direct and indirect costs of implementation are commensurate with the substantial increase in safety. A clearly positive finding with respect to the net value or value-impact ratio would normally satisfy this standard.

For proposed regulatory actions that would relax or reduce current requirements, the backfit rule and the safety goal analysis process and criteria contained in Section 3 are not applicable. However, for relaxations, supporting documentation should be prepared which contains the basis for concluding that the following conditions will be satisfied.

- The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented
- The cost savings attributed to the action would be substantial enough to justify taking the action, and clearly out-weight any reduction in benefits.

In general, actions which would relax or reduce requirements should leave it up to licensees whether to take advantage of the change and should not be mandatory. However the cost savings should be based upon the assumption that all licensees will take advantage of the change. This is consistent with the NRC's position on voluntary practices as described in Section 4.3.

4.5 Decision Rationale for Selection of the Proposed Action

This section of the regulatory analysis document should explain why the proposed action is recommended over the other alternatives considered. Taking no action should be considered as an alternative except in cases where action has been mandated by legislation or a court decision. The decision criteria for the selection of the proposed action should be identified. The criteria should include (but are not necessarily limited to):

- The net value and/or value-impact computations
- The relative importance of attributes that are quantified in other than monetary terms
- The relative importance of nonquantifiable attributes
- The relationship and consistency of the proposed alternative with the NRC's legislative mandates, safety goals, and policy and planning guidance which are in effect at the time the proposed alternative is recommended
- The impact of the proposed action on existing or planned NRC programs and requirements.

This section of the regulatory analysis document should also include:

- A statement of the proposed generic requirement or staff position as it is proposed to be sent out to licensees
- A statement of the sponsoring office's position as to whether the proposed action would increase or relax (or reduce) existing requirements or staff positions

- A statement on whether the proposed action is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

4.6 Implementation

The regulatory analysis should identify how and when the proposed action is to be implemented. The proposed NRC instrument for implementing the proposed action should be identified (e.g., rule, regulatory guide, etc.) and the reasons for selecting the proposed instrument discussed. A specific date for implementation should also be identified and discussed.

A schedule should be prepared showing the steps needed to implement the proposed action. The action should be prioritized and scheduled in view of other ongoing regulatory activities affecting the facilities. If possible, a summary of the current backlog of existing related requirements awaiting implementation should be included. An assessment of whether implementation of existing requirements should be deferred as a result and any other information that may be considered appropriate with regard to priority, schedule, or cumulative impact should be included. The schedule should be realistic and allow sufficient time for such factors as needed analyses, approvals, procurement, installation and testing, training, and resources needed by licensees to implement other NRC and Agreement State requirements. Regulatory analyses are required to identify related regulatory and industry actions, even though it may be very difficult to properly characterize and account for all actions. Although regulatory actions generally are to be implemented in a timely manner, implementation schedules should be sufficiently flexible to minimize the cumulative burdens imposed on licensees by multiple regulatory requirements. When appropriate, alternative schedules should be prepared.

NRC staff actions as well as actions that will be needed by others (e.g., Agreement States and licensees) should be identified. In this regard, this section should describe the magnitude and availability of NRC resources to facilitate implementation of the proposed action.

5. RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

This section discusses the relationship of the development of a regulatory analysis to certain statutory procedural requirements applicable to the NRC and to information requests directed to licensees. The Paperwork Reduction (5.1) and Regulatory Flexibility (5.2) Statements, are typically included as appendices to the Regulatory Analysis, and are documented here for completeness. The other information requests and procedural requests (5.3 thru 5.5) typically consider similar issues to the Regulatory Analysis, and consequently, the Guidelines can provide useful guidance in their development as well.

5.1 Paperwork Reduction Act

The Paperwork Reduction Act (Public Law 96-511) contains procedural requirements designed to minimize and control the burdens associated with collections of information by Federal agencies from individuals, businesses and other private entities, and state and local governments. The NRC's internal procedures for complying with the Paperwork Reduction Act and preparing justifications for OMB approval of information collections are contained in NRC Management Directive 3.19, "Collections of Information and Reports Management".

Whenever a proposed regulatory action identified under Section 4.5 of these Guidelines will likely involve information collection(s) subject to OMB approval, a draft OMB clearance package shall be included as a stand-alone appendix to the regulatory analysis.

Agencies are required to obtain OMB approval for collections of information under any of the following conditions (5 CFR 1320.4(a), 1320.7(c)): (1) the information collection involves 10 or more persons by means of identical questions or reporting or recordkeeping requirements, (2) the information collection is contained in a rule of general applicability, (3) the collection is addressed to all or a substantial majority of an industry, even if that majority involves fewer than 10 persons.

OMB's criteria for approval of information collections are contained in 5 CFR 1320.4(b) and (c). To obtain OMB approval for information collections, an agency must demonstrate that the collection of information: (1) is the least burdensome necessary for the proper performance of the agency's functions, (2) is not duplicative of information otherwise available to the agency, and (3) has practical utility. The agency should minimize its cost of collecting, processing and using the information, but not by shifting disproportionate costs or burdens onto the public. Agencies should consult with interested agencies and members of the public in an effort to minimize the burden of the information collection to the public. OMB clearance packages are to identify any significant burdens placed on a substantial number of small businesses or entities (5 CFR 1320.11(a)).

In the event that OMB disapproves an information collection, independent regulatory agencies such as NRC may override the disapproval or stay of effectiveness of approval of a collection of information by a majority vote of the Commissioners (5 CFR 1320.20). Procedures for Commission override of an OMB disapproval are contained in NRC Management Directive 3.19, "Collections of Information and Reports Management" (formerly NRC Manual Chapter 0230).

5.2 Regulatory Flexibility Act

The Regulatory Flexibility Act (Public Law 96-354) requires Federal agencies to prepare a regulatory flexibility analysis if a proposed rule will have a significant economic impact on a substantial number of small entities. The analysis is to describe the impact of the proposed rule on small entities (5 U.S.C. 603). On December 9, 1985 (50 FR 50241), the NRC adopted size standards it would use to determine whether an NRC licensee would be considered a small entity for the purpose of implementing requirements of the Regulatory Flexibility Act. On November 6, 1991 (56 FR 56671), the NRC published a general notice that restated its size standards to clearly identify the different classes of licensees affected and the standard that is applied to each class of licensee. Specifically, the NRC added the Regulatory Flexibility Act's definition of small governmental jurisdiction adopted by the NRC but not included in the 1985 notice announcing the adoption of the size

standards. The size standards used by the NRC to qualify a licensee as a small entity are as follows:

- A small business is a business with annual receipts of $3.5 million or less except private practice physicians for which the standard is annual receipts of $1 million or less.

- A small organization is a not-for-profit organization which is independently owned and operated and has annual receipts of $3.5 million or less.

- Small governmental jurisdictions are governments of cities, counties, towns, townships, villages, school districts, or special districts with a population of less than 50,000.

- A small educational institution is one that is (1) supported by a qualifying small governmental jurisdiction, or (2) one that is not state or publicly supported and has 500 or fewer employees.

NRC has established procedural requirements for preparation of regulatory flexibility analyses. These requirements are presented in the NRC Regulations Handbook, NUREG/BR-0053. If a proposed rule is likely to have a significant economic impact on a substantial number of small entities, a draft regulatory flexibility analysis, consistent with the NRC procedural requirements, must be prepared. The regulatory flexibility analysis is normally included as an appendix to the regulatory analysis document and as an insert to the proposed rule. The regulatory flexibility analysis need not repeat information discussed in the body of the regulatory analysis; such information may be referenced. If the NRC determines that the proposed rule would not have a significant economic impact on a substantial number of small entities, the NRC is required to include a certification to this effect in the proposed rule. The regulatory analysis must contain sufficient information concerning the potential impact of the proposed rule on small entities to support this certification.

5.3 National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires Federal agencies to prepare an environmental impact statement (EIS) for major Federal actions significantly affecting the quality of the human environment [42 U.S.C. 4332(2)(C)]. NRC's procedures for implementing NEPA are at 10 CFR Part 51 and the NRC Regulations Handbook, NUREG/BR-0053, contains preparatory information. When a generic or programmatic EIS has been prepared which forms the basis for the proposed regulatory action, a brief summary of the EIS will be an acceptable substitute for the information and analysis requirements identified in Sections 4.1-4.3 of these Guidelines. The EIS may be referenced at other appropriate points in the regulatory analysis document to avoid duplicating existing written material.

When a regulatory analysis and an EIS or environmental assessment (EA) are being prepared for a proposed regulatory action, preparation of the two documents should be coordinated as much as possible. For example, the alternatives examined in the regulatory analysis should correspond as much as possible to the alternatives examined in the EIS or EA.

5.4 Information Requests Under 10 CFR 50.54(f)

Procedures for NRC information requests directed to production and utilization facility licensees appear at 10 CFR 50.54(f). The regulation requires NRC to prepare a written statement justifying the reasons for the information request except when the information is needed to verify licensee compliance with the current licensing basis for the facility. The written statement is to establish that the burden imposed on the licensee is justified in view of the potential safety significance of the issue. All justification statements must be approved by the cognizant Office Director or Regional Administrator before issuance of the information request.

Section IV(B)(xi) of the CRGR Charter contains additional guidance for information requests affecting multiple plants. The CRGR Charter specifies

that when a written justification is required, the written statement is to include:

- A problem statement that describes the need for the information in terms of the potential safety benefit
- The licensee actions required and the estimated cost to develop a response to the information request
- An anticipated schedule for NRC use of the information
- A statement affirming that the request does not impose new requirements on the licensee.

Written statements prepared according to the preceding requirements to justify information requests are not regulatory analyses within the scope of these Guidelines. Nevertheless, the written justification will have many of the elements of a regulatory analysis. The elements of a regulatory analysis discussed in Section 4 can appropriately be included in an information request justification. An information request justification will normally be a more concise document than a regulatory analysis.

5.5 Supporting Analysis for Compliance and Adequate Protection

As documented in 10 CFR 50.109 and in NUREG-1409, a regulatory action does not require a backfit analysis if the resulting safety benefit is required for purposes of compliance or adequate protection under Section 50.109(a)(4). In these cases of exceptions to the backfit standard and analysis, a documented evaluation should be prepared, including a statement of the objectives of and the reasons for the action along with the basis for invoking the exception. Guidance is provided in 10 CFR 50.109(a)(6) and the Supplementary Information portions of the Federal Register Notices for the final backfit rule (see 53 F.R. 20603 (June 6, 1988) and 50 F.R. 38097 (September 20, 1985)). In this connection, the concept of what constitutes adequate protection is determined case by case. It is expected that this determination may change to reflect new information pertinent to whether improvements are needed to ensure adequate protection.

For either the compliance case or the adequate protection case, if immediately effective regulatory action is needed, the required documented evaluation may follow the issuance of the regulatory action.

BIBLIOGRAPHY

Administrative Conference of the United States, "Agency Procedures for Performing Regulatory Analysis of Rules" (Recommendation No. 85-2, 1 CFR 305.85-2) and "Valuation of Human Life in Regulatory Decisionmaking" (Recommendation No. 88-7, 1 CFR 305.88-7).

Allison, D.P., J.M. Conran, and C.A. Trottier, Backfitting Guidelines, NUREG-1409, July 1990.

Finkel, A.M., Confronting Uncertainty in Risk Management: A Guide for Decision-Makers, Resources for the Future, Washington, D.C., 1990.

Gillette, C.P., and T.D. Hopkins, Federal Agency Valuations of Human Life, prepared for the Administrative Conference of the United States, July 1988.

Hammond, P.B., and R. Coppock, eds., National Research Council, Valuing Health Risks, Costs, and Benefits for Environmental Decision Making, National Academy Press, Washington, D.C., 1990.

McGarity, T.O., "Regulatory Analysis and Regulatory Reform," Texas Law Review, 65:1243-1333, June 1987.

National Research Council, Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C., March 1983.

Office of Management and Budget, "Regulatory Impact Analysis Guidance," Appendix V in Regulatory Program of the United States Government: April 1, 1990 - March 31, 1991.

Taylor, J.M., Executive Director for Operations, NRC, Memorandum to Office Directors, "Revised Charter - Committee to Review Generic Requirements," April 18, 1991.

W. Reuland and H. Wyckoff, Nuclear Safety Analysis Center, Electric Power Research Institute, Questionable Techniques Used in Cost-Benefit Analyses of Nuclear Safety Enhancements, NSAC-143, November 1989.

U.S. Code of Federal Regulations, Title 10, Part 50.109, 1991.

U.S. Department of Transportation, Guidance for Regulatory Evaluations: A Handbook for DOT Benefit-Cost Analysis, April 1984.

U.S. Environmental Protection Agency, Guidelines for Performing Regulatory Impact Analysis, EPA-230-01-84-003, December 1983.

U.S. General Accounting Office, "Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations," GAO/RCED-84-62, April 1984.

USNRC, "Regulatory Analysis Guidelines," Rev. 1, NUREG/BR-0058, May 1984.

Enclosure 3

Averted Onsite Costs

AVERTED ONSITE COSTS:

As follow-up to SECY-91-172 (Regulatory Impact Survey Report - Final), the Commission, by memorandum of December 20, 1991, directed that the staff pursue the following action:

> "In view of the staff's ongoing effort to modify the Regulatory Analysis Guidelines and the recent commentary on the issue of averted on-site costs (see EPRI/NSAC Report NSAC-143, transmitted to the Commission on March 27, 1991), the staff should evaluate the various arguments for how averted on-site costs should be treated in cost-benefit analyses. The proposed revisions to the Regulatory Analysis Guidelines, including a thorough discussion of the issue of averted on-site costs, should then be submitted to the Commission for review and approval."

In section 4.3.2 (Estimation of Impacts) of the proposed Regulatory Analysis Guidelines, the staff's proposed policy concerning onsite averted costs is identified. This paper provides the underpinnings for that position. Included here is relevant background, the basis for the staff's position, alternative treatments, and the concerns raised by industry.

AVERTED ONSITE COSTS (AOSC)

BACKGROUND

Averted onsite costs (AOSC) are meant to capture accident-related consequences that are viewed as the financial responsibility of the licensee. Typical cost elements include the cost of replacement output and or capacity; plant cleanup, decontamination, and repairs; early decommissioning; and potential onsite litigation and other financial-based licensee/industry impacts. The appropriateness or relative importance of these individual elements to the overall AOSC estimate is ultimately a function of the severity of the accident under consideration, and guidance in quantifying onsite averted costs, including representative dollar estimates of AOSC for power reactors, is available in NUREG/CR-3568, "A Handbook for Value Impact Analysis."

The inclusion of AOSC in NRC value-impact analyses has been the subject of considerable controversy since it originally surfaced in the early 1980s. The issue was first raised by the ACRS in commenting on the Commission's proposed safety goals. In its 1982 safety goal deliberations, the Commission considered whether the averted reactor damage should be counted as a benefit. Industry commenters strongly opposed any inclusion of averted plant damage because they believed that the NRC should restrict itself to public health and safety matters and not take into consideration the financial investment of the utility and its shareholders. The Commission agreed with the utilities and decided not to include onsite property damage factors.

In the subsequent evaluation of its safety goals, the Commission instructed the staff to develop any revisions which were shown to be necessary as a result of the evaluation. With respect to AOSC, the Safety Goals Steering Group concluded that the definition of benefits should be comprehensive and should include AOSC. Several arguments were offered in support of this position.

First, as the TMI experience demonstrates, in the event of a core melt accident even one that involves minimal offsite exposure, the financial risk is not borne exclusively by the utility. A substantial fraction of such funding for TMI 2 cleanup has come from the public, either via customer revenues or State and Federal government contributions. In addition, the loss of a reactor can result in decreased electric utility system reliability, higher customer rates, and replacement energy by fossil fuels with negative impact on the environment and ultimately, on public health. This implies that AOSC has very clear implications for the general public. Second, even if a core melt accident resulted in minimal offsite exposure, not only would its consequences include significant onsite economic impacts, but also could result in significant onsite radiological exposures. In fact, for various core melt accident scenarios, the Steering Group concluded that onsite consequences are larger than the estimated offsite consequences for all but the largest and least probable releases. Third, there is too much uncertainty in the risk analyses to permit making a distinction between accidents which threaten only the utilities' investment as opposed to public, or offsite, risks. Fourth, as with all NEPA-type assessments, value-impact evaluations by their very nature should include all relevant impacts from a societal perspective so that decision makers have a complete picture of the consequences of their actions.

In May, 1987, Commissioner Bernthal requested the views of the Office of the General Counsel on whether excluding averted onsite costs in backfit analyses is legally defensible. The response from William Parler, General Counsel concluded that...

> "under no defensible view of cost-benefit analysis can the agency exclude outright any consideration of averted on-site costs. However, given the agency's mission to protect the health, safety, and property of the public, averted on-site costs should be considered...not as benefits but rather as reductions in the costs associated with the proposed backfits."

Section 161 b. of the Atomic Energy Act gives the Commission authority to take actions to minimize danger to "property" and does not on its face distinguish between licensee's property and other property. However the reason for considering averted on-site costs is not protection of the licensee's property, but rather full and accurate accounting of the real net cost of the action to the utility so that the public is not deprived of additional safety because utility savings were not contained in the value-impact analysis.

In a Staff Requirements Memorandum to the EDO on "SECY-89-102, "Implementation of the Safety Goals," June 15, 1990, the Commission supported the use of AOSC as an offset against other licensee costs (and not as a benefit) in cost-benefit analyses. This constituted a full endorsement of the OGC position as expressed in 1987.

INCLUSION OF AOSC IN VALUE-IMPACT ANALYSIS

In NSAC/143,"Questionable Techniques Used in Cost-Benefit Analyses of Nuclear Safety Enhancements," industry continues to argue that AOSC should not be considered in NRC's regulatory supported value-impact analyses. Their view is that the NRC's sole responsibility is for public health and safety, and that safety enhancements should not be influenced by financial benefits to utilities. However, industry supports the backfit rule which provides for consideration of financial costs to utilities. It seems inconsistent to say that NRC can consider financial costs which would tend against imposing a backfit but not financial benefits which would tend in favor of the backfit. Industry offers no reason to draw this distinction. In either case, NRC is "influenced" by utility financial or economic considerations.

In what appears to be a compromising mode, industry suggests that the analyst consider separately the benefit to public health and safety, and the financial benefit to the utility. This would require the development of two value-impact ratios in order to provide the decision-maker with all pertinent information.

For the reasons enumerated by the Safety Goal Steering Group, the staff believes that a comprehensive value-impact framework that includes AOSC is appropriate for NRC regulatory decisions. In the staff's view, the key determinant is the NRC's need to display ALL meaningful consequences from a societal perspective. Ultimately, the NRC is deciding whether to commit scarce societal resources, and that decision must be weighed against the values that accrue to all segments of society. From a societal perspective, values that accrue to any specific segment of society should be given equal weight to the general public.

The utilities would prefer for the NRC to perform two partial analyses. First, justify the burden based on the public health and safety benefit, and second, based on the utilities' financial benefit. The implications of this are troublesome because it effectively results in double-counting the costs, i.e., in each instance, total cost would be compared to only a portion of the benefit. In addition, the decision-maker would also now be faced with two decision criteria which could likely conflict. This would require the NRC to attach weights and consider tradeoffs between the two which effectively would involve making interpersonal comparisons between different segments of society. Furthermore, based on its views concerning AOSC, industry argues that other cost savings to the industry, in addition to AOSC, are not to be included in the regulatory supported value-impact analysis. For example, if a new regulatory requirement results in an absolute reduction in overall burden, or produces partial savings in other areas of the plant, industry argues that these should be totally ignored in the regulatory based analysis. In practice, the NRC has consistently taken into account all cost savings to the

industry in order to derive a net impact. Thus, adopting the same industry logic that would justify denial of AOSC would also necessitate a reevaluation in this area.

In one respect, the staff is sensitive to the industry's position. The staff acknowledges that it is appropriate and customary for a firm such as a utility to base its decisions solely on the financial benefits it derives, and thus, from the utilities' perspective it seems logical that the NRC should be subject to a similar standard. However, this position misses one of the most fundamental principles underlying value-impact methodology, i.e., the private vs. social perspective. Whereas the industry's proper decision criterion and perspective is private and consequently, narrowly focused, the NRC's is more broadly based and can reasonably include societal considerations.

TREATING AOSC AS A COST OFFSET

In NSAC/143, industry identifies two fundamental weaknesses associated with the treatment of AOSC as a cost offset. Industry argues that it is poor value-impact practice to co-mingle values and impacts and that it does not yield internally consistent economic results.

1. Averted costs such as AOSC are values (benefits) and as such cannot be netted with positive costs and entered in the denominator. An important distinction between values and impacts is that the impacts tend to be near term and are relatively certain, whereas values are probabilistic in nature, much more uncertain, and tend to occur over a span of future decades. In their view, these distinctions are worth preserving in the value-impact analysis in order to give it greater clarity and meaning. Further, if AOSC equals or exceeds the direct industry cost, the denominator becomes zero or negative, producing, in industry's eyes, illogical results.

2. The choice as to where to place an attribute should not produce internally inconsistent results. However, this is exactly the case. For example, if the person-rem averted is $400, AOSC is $200, and the impacts are $300, the value-impact ratio is 2.0 when AOSC is included in the numerator as a value (benefit), and 4.0 when AOSC is treated as cost offset.

With respect to industry's first concern, the co-mingling of values and impacts, the staff acknowledges that inclusion of AOSC as a cost offset is less than optimum because of many of the issues raised by industry. However, in the staff's view, industry tends to overstate the case. Although it would be desirable to contrast highly certain near term impacts against highly uncertain probabilistic values that are future oriented, there is no definition of values and impacts, including the one proposed by industry, that would always produce such a desired result. The reality is that values and impacts will frequently contain shadings that cloud such absolute characteristics. For example, impacts can be probabilistic, highly uncertain, and continue to weigh heavily in the future, whereas health and safety values can also be important in the near term.

Furthermore, rather than accept industry's contention that a negative or zero denominator produces illogical results, the staff's view is that it is simply subject to a different interpretation (i.e., health and safety values can be achieved with either no impact or cost savings to industry).

With respect to industry's second concern, internally inconsistent results, the staff has proposed to revise its Guidelines. The proposed NRC Guidelines now recommend that all value-impact results be displayed on a net value basis (all consequences are assigned positive and negative values and arithmetically summed). This effectively leaves moot the question of whether AOSC appears in the denominator or numerator, and constitutes a complete co-mingling of values and impacts. Nevertheless, the staff does not see anything inherently incorrect in such an approach. It has been adopted here because it is the preferred and recommended display in OMB's latest regulatory analysis guidance and, its use effectively eliminates the inconsistencies noted by industry in the ratio formulation. However, the proposed Guidelines still permit the NRC analyst to also display ratio results in recognition that they also provide an important perspective to the decision maker. In the staff's view, the use of the ratio and the extent to which internally inconsistent results might mislead the decision maker is significantly mitigated by the fact that all alternatives and all regulatory actions are being assessed on the same basis.

RELATED ISSUES

Onsite Property Insurance:

In a prior evaluation of AOSC, four arguments were identified against the cost offset approach. None of them were considered persuasive, although the conclusion was made that estimates of AOSC should take into account the property insurance the agency requires of licensees. This position says that since the NRC requires licensees to take out insurance against onsite property damage, consideration of AOSC in regulatory analyses amounts to a kind of double-counting, because costs which would be covered by insurers in the event of an accident would nonetheless be treated as licensee costs in regulatory analyses. It was therefore recommended that AOSC estimates used in regulatory analyses need to exclude costs that would be borne by insurers.

Clearly, it is correct that only a portion of the total estimated AOSC is borne by the licensee. However, a technically correct rigorous value-impact framework should include the respective portions of the total AOSC that are borne by the licensee and the insurer and should not be limited to only those impacts that are actually incurred by the licensee. The regulatory analysis is ultimately concerned with the societal burden that accrues as a result of the accident, and from a societal perspective, it makes little difference who ultimately bears the cost as long as the total cost is accurately reflected.

The concern that this would constitute double-counting because the licensee already paid for that coverage ignores the fact that, from a societal perspective, insurance represents a redistribution of resources with no real loss for society. Insurance premiums, like taxes, are a transfer payment

between different segments of society and, in and of themself, constitute no real consumptive use of resources. (The only exception is relatively minor transaction costs and costs of managing and administering the insurance fund).

The staff recognizes that insurance is a real cost to the licensee and a real benefit to the insurance companies, but from a societal perspective they are a wash with no real resource implications and should in no way diminish the AOSC estimate that is to be included in the regulatory analysis.

Other Onsite Costs:

Another aspect of AOSC relates to other site costs that could be averted as a direct result of regulatory actions. A recent notable example in this regard was the maintenance rulemaking (50.65) where a cost offset was included in the regulatory analysis for the expected increased plant availability. Similarly, regulatory action associated with the operability of motor operated valves was justified in part on expected increased plant availability reflected as a cost offset in the regulatory analysis.

STAFF'S CURRENT POSITION

In the NRC's proposed Regulatory Analysis Guidelines, the staff views AOSC as an integral part of the value-impact analysis and, in deference to OGC's legal interpretations, supports its use as a cost offset when value-impact results are presented as a ratio. However, the Guidelines recommend that value-impact results be displayed on a net value basis in order to eliminate certain criticisms raised by industry.

Enclosure 4

Present Worth of Future Health and Safety Effects

PRESENT WORTH VALUATION OF FUTURE HEALTH AND SAFETY EFFECTS

In the past, the Agency has been criticized[1] for inconsistency because of its practice of applying a "discount rate"[2] only to future costs when performing value-impact (benefit-cost) analyses. Hence, the staff tasked Pacific Northwest Laboratories (PNL) to prepare a report addressing this issue. Specifically, PNL was asked to prepare a paper which examines: current literature on the subject of present worth valuation, current guidance on the part of the Office of Management and Budget (OMB), and related practices on the part of other Federal regulatory agencies.

In general, the findings presented in the PNL report[3] have been incorporated in the proposed Guidelines. Perhaps the most significant change in NRC policy prompted by the findings in the report is that health and safety effects should be subject to present worth valuation. Previous staff practice was to present worth all monetized values and impacts with the exception of health and safety effects. Health and safety remained "undiscounted" to avoid even the appearance that NRC would value future lives less then present lives. Further, NRC regulatory analyses typically evaluated consequences over relatively short time periods (e.g on the order of 30 years in power reactor applications), and hence, the results were tolerable given the large uncertainties and error bands already inherent in the estimates of both accident probabilities and the dollar valuation of health effects. However, upon further reflection the staff now believes that the more sophisticated and realistic approach of a uniform present worth treatment of all values and impacts is appropriate to ensure a proper and consistent analysis of the merits and costs of a proposed regulatory action. Given that this is a significant departure from earlier staff practice, the reasoning for this new staff position is elaborated below.

The ultimate objective of a value-impact assessment is to determine whether the proposed resource commitment is justified based on the expected values (benefits) to be derived. Ideally, to best accomplish this, all consequences of the action should be put on the same basis and at the same point in time so that a meaningful comparison between values and impacts can be made.

---

[1]Nuclear Safety Analysis Center, Questionable Techniques Used in Cost-Benefit Analyses of Nuclear Safety Enhancements, NSAC-143, Electric Power Research Institute, November 1989.

[2]The application of present worth techniques to effects of one period so they may be compared with those of another period is commonly referred to as "discounting." While this word is widely used by economists and throughout the government, such as in OMB guidance, its use has been subject to misinterpretation.

[3]Paananen, O.H., and Hendrickson, P.L., Selection of a Discount Rate for Use in Regulatory Analyses Prepared by the U.S. Nuclear Regulatory Commission and Application of Discount Rates to Future Averted Heath Effects, Pacific Northwest Laboratory, January 1993.

Consequently, the presentation of all effects of the action (both values and impacts) in monetary terms, relative to the time the decision is to be made, is a key element in such analyses. Creating this common base is the process of "present worth valuation." The interest rate used in present worth calculations reflects the fact that dollars invested in regulation could have been invested elsewhere in productive ventures with a positive rate of return. It also reflects the fact that because of the earning power of money, a benefit which may be worth x dollars today, can be obtained in the future by investing a sum less than x dollars today. Many argue that failure to present-worth any individual attribute in the overall equation distorts the utility and meaning of the overall value-impact result.

In NSAC/143,[4] industry sets forth a number of arguments for applying present worth techniques to health effects. Their first argument is as follows:

> At first glance it might seem that present valuing health effects treats a person-rem that occurs in the future as being less important than a person-rem that occurs today. This incorrect impression can occur because arithmetically, present valuing results in smaller numbers. However, the fact is that time valuing is needed to make a person-rem equally important regardless of when it occurs. When one equates a person-rem to some dollar value, such as $1000, there is a tacit underlying assumption that the person-rem will in some manner result in a $1000 cost. This cost can occur no sooner than when the person-rem is incurred. Time valuing determines how many dollars must be set aside in the present value base year, so that with interest, the person-rem equivalent cost (for example, $1000) can be paid in the year the person-rem is incurred.

Industry also argues that consequences need not be expressed in monetary units to apply present worth principles (OMB regulatory analysis guidance adopts the same position.)

> All costs and benefits, including health effects, whether or not monetized, must be time valued to the chosen base year. While it can aid insight to monetize items such as person-rem before time valuing them, the conversion is not necessary. Person-rem can be time valued directly. This step is essential for assuring that a person-rem is equally important regardless of when it occurs.

Lastly, industry argues that the non-discounting of health effects distorts the value-impact result and effectively produces an internally inconsistent economic analysis. The objective of converting to a present worth value is to ensure consistent value-impact comparisons by evaluating each value and impact, regardless of when it occurs, in terms of its value at a selected base year. When all attributes are present worthed, the methodology is internally consistent, and any base year can be selected for making financial comparisons

---

[4]Nuclear Safety Analysis Center, op. cit.

without effecting the value-impact result. A policy of not discounting health and safety effects makes the value-impact result sensitive to the selection of a base year. In industry's view:

> Quantities such as costs alone, benefits alone, and the net benefit (benefit minus cost) will differ by a factor that accounts for the value of money for the period between differing base years. For example, for a 10 percent discount rate, a cost, or benefit, or net benefit for a certain base year would be a factor of $(1.+ 0.10)^5 = 1.61$ larger than at an assumed financial time base 5 years earlier.

Additional arguments in support of this position include:

a) The Office of Management and Budget (OMB) guidance is explicit that all values and impacts associated with proposed regulatory actions are to be present worthed.[5]

b) A recent court case involving the Environmental Protection Agency (EPA) indicated that the EPA should discount benefits as well as costs when performing a benefit cost analysis of a proposed regulatory action.

c) Applying present worth techniques to all values and impacts occurring over time allows an analyst to evaluate a regulatory action on a common basis, in spite of its temporal disparity.

---

[5]It should be noted, however, that because the NRC is an independent agency, it is not required to follow OMB guidance.

Enclosure 5

ACRS Letter of November 12, 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

November 12, 1992

Mr. James M. Taylor
Executive Director for Operations
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Taylor:

SUBJECT: REVISED REGULATORY ANALYSIS GUIDELINES

During the 391st meeting of the Advisory Committee on Reactor Safeguards, November 5-7, 1992, we reviewed a draft of NUREG/BR-0058, Revision 2, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." Our Subcommittee on Safety Philosophy, Technology, and Criteria considered this matter during a meeting on October 28, 1992. During these meetings, we had the benefit of discussions with representatives of the NRC staff, and of the document referenced.

This brochure will be NRC's policy-setting document with respect to regulatory analyses. As such, it deals with a number of very important issues that bear directly on the overall NRC regulatory philosophy and approach. Some of the positions taken in the proposed guidelines represent departures from current practice, have never been formalized before, or differ from the industry and the Office of Management and Budget (OMB) positions.

We believe this to be such an important document that even a draft version to be issued for public comment should reflect high levels of intellectual and technical content, coherence, and clarity of thought and presentation. Although the draft document does have much to commend it, we believe the subject deserves better. We recommend that substantial additional effort be put into rethinking and redeveloping some of the regulatory positions and into developing a "showcase" document with respect to content, style, and quality of prose. We do not see any urgent need for, and recommend against, issuing the draft document at this time. We expect to review the revised document before it is issued for public comment.

In its presentations to us, the staff identified some specific issues for particular attention. Although we agree with some of the positions taken on these in the document, we have fundamental differences with several of them. We provide you with our comments below.

Safety Goal Implementation

This document suffers from the absence of a clear statement of the means by which the Commission's overall regulatory philosophy will be implemented through the concepts of adequate protection, safety goals, the backfit rule, ALARA principles, etc. Whether here or elsewhere, such a statement is urgently needed.

The safety goal decision chart only deals with issues that result in changing the core-damage frequency. We believe it should also consider issues that could change the conditional containment failure probability.

Quantification of Benefits

Figure 3.1 of the proposed guidelines should include a step in which a determination is made on whether the proposed enhancement is something that can be evaluated by quantitative risk estimates. If so, we believe that PRAs must be used to quantify the benefits. If not, the analysis would go to a different decisionmaking scheme (e.g., expert opinion, engineering/regulatory judgment).

Treatment of Voluntary Actions

We agree with the position taken on voluntary actions in the proposed guidelines. However, we are concerned that this will tend to discourage voluntary actions. Some means, outside the regulatory analysis process, should be sought to promote and encourage such actions.

Discount Rate

While the OMB directive of 1981 (which has never been rescinded) applied specifically to executive agencies, NRC ought to have good reasons for ignoring it. The fact that others do so is not a good reason. We were told that efforts had not been made to better understand OMB's rationale. We recommend that this be done.

Simultaneously Satisfying the Requirements of the Backfit Rule and/or the Committee to Review Generic Requirements

We agree that regulatory analyses should be made in such a manner that they also meet these other needs.

Treatment of Averted Onsite Costs

The staff intends to treat averted onsite costs (AOSC) as an offset to the costs incurred by the utilities in implementing the associated requirement. We believe AOSC should be included in the benefits column and not the costs column. We are concerned, however, that the methods and assumptions used for computing AOSC

are highly uncertain and can dominate the final answer. Accordingly, we recommend that further effort be given to establishing definitive guidance for AOSC evaluations.

In the draft document, the staff recommends that the results be presented in terms of net value (value minus impact) rather than as a ratio (value/impact). This should not be an issue because these are entirely different measures and both should be part of the decision process.

Discounting of Health and Safety Effects

We are unconvinced by the arguments presented for the staff's position that health and safety effects not be discounted in the value/impact analyses. Appropriate balancing of costs and benefits require discounting of each.

Monetary Value of a Person-Rem Averted

There is, in principle, no problem with the staff's proposed interim position, "continuing to use the value of $1000/person-rem until a final recommendation can be made after further review and analysis," except that such a position has existed for about 15 years, and can persist indefinitely. We recommend that an appropriate treatment of the monetary values to be associated with onsite and offsite health effects (both early and latent) and land contamination be developed promptly.

Sincerely,

Paul Shewmon

Paul Shewmon
Chairman

Reference:
Letter dated September 11, 1992, from C. J. Heltemes, Jr., Office of Nuclear Regulatory Research, to Raymond F. Fraley, Advisory Committee on Reactor Safeguards, transmitting:

(a) Draft SECY paper (undated) for the Commissioners from James M. Taylor, Executive Director for Operations, NRC, Subject: Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (Predecisional)

(b) Draft NUREG/BR-0058, Revision 2 (undated), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (Predecisional)

(c) Separate Enclosures (undated) on Averted Onsite Costs and Discounting of Health and Safety (Predecisional)

Enclosure 6

Public Announcement

Public Announcement

NRC Issues Draft Regulatory Analysis
Guidelines for Public Comment

The Nuclear Regulatory Commission (NRC) is publishing for comment a proposed revision of the Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (Guidelines). This is the NRC's policy-setting document with respect to regulatory analyses, and it includes a number of policy positions that have broad implications for decisions which impose new requirements on NRC licensees. To assure a full airing of these policy issues, the NRC is inviting comment on its proposed Guidelines from all interested parties.

The original version of the Guidelines was issued in January 1983. In December 1983, the NRC issued A Handbook for Value-Impact Assessment, NUREG/CR-3568, which set out systematic procedures for performing value-impact assessments. Revision 1 to NUREG/BR-0058 was issued in May 1984 to include appropriate references to NUREG/CR-3568.

This proposed revision of the Guidelines (Revision 2) is being issued to reflect: (1) the NRC's accumulated experience with implementing the previous Guidelines; (2) changes in NRC regulations and procedures since 1984, especially the backfit rule (10 CFR 50.109) and the Policy Statement on Safety Goals for the Operation of Nuclear Power Plants (51 FR 30028, August 21, 1986); (3) advances and refinements in regulatory analysis techniques; (4) regulatory guidance for federal agencies issued by the Administrative Conference of the United States and the Office of Management and Budget; and (5) procedural changes designed to enhance NRC's regulatory effectiveness.

January 4, 1993

MEMORANDUM FOR: The Chairman
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
Commissioner de Planque

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: COMIS-92-025 - REGULATORY REVIEW

As requested by the December 24, 1992 memorandum from the Secretary, enclosed for Commission review is the Charter for the Regulatory Review Group. The Review Group is comprised of several SES managers and representatives from NRR, RES, the Regions, and OGC. The staff selected for this review is well versed in the policy, technical, and legal aspects of the task and represents the spectrum of the rule setting, licensing, inspection, and risk technology processes. Mr. Frank Gillespie, Director, Program Management, Policy Development & Analysis Staff, NRR, is the Review Group Leader.

As one of the early activities of the review, Mr. Sniezek, Mr. Gillespie and selected members of the Review Group will meet with each Commissioner individually to receive the Commissioner's insights regarding the review. Additionally, the Review Group will brief the Commission in a public meeting regarding the progress of the review about 2 months after the Commission approves the Charter of the Review Group. Interim findings during the review may dictate revisions to the initial Charter. The Commission will be informed if revisions become necessary.

Regarding resources, as currently envisioned, approximately 5 FTE of Review Group effort will be required for this review. An additional 2-3 FTE will be expended by the staff in interfacing with the Review Group and responding to specific questions raised during the review. Because of the talent being devoted to the Review Group effort, there will be some negative impact on other activities; however, with the exception of the diversion of management attention from the managers' normal areas of responsibility, the impact in any one area should be slight. Upon completion of the Review Group efforts, I intend to discuss the recommendations with senior staff management. We will then develop a schedule for implementation of the recommendations and define the resource requirements in a paper to the Commission.

Original Signed By:
James M. Taylor

James M. Taylor
Executive Director
for Operations

Enclosure:
Charter
cc: SECY
OGC

document name:CM92025.sam

DISTRIBUTION:
EDO rf
DEDR rf (2)
JTaylor
JSniezek
PNorry, ADM
EJordan, AEOD
RScroggins, OC
JLieberman, OE
GCranford, IRM
BHayes, OI
ACRS
OIG

PBird, OP
RVollmer, OPP
CKammerer, OSP
RBernero, NMSS
TMurley, NRR
EBeckjord, RES
TMartin, RI
SEbneter, RII
ABDavis, RIII
JMilhoan, RIV
JMartin, RV
NRC PDR

Reg Review Group
FGillespie CThomas
JJaudon BSiegel
ACerne ~~JMurphy~~ NCN
CCraig MDrouin
JCutchin NOlsan

DEDR JHSniezek 01/ /93
EDO JMTaylor 01/ /93

9301130178

REGULATORY REVIEW GROUP
CHARTER

Purpose:

Conduct a comprehensive and disciplined review of power reactor regulations and related NRC processes, programs, and practices for their implementation. The analysis will be a fundamental examination of the regulations and staff implementation strategies with focus on the essential safety principles that significantly contribute to public health and safety. A detailed review should be conducted specifically for those regulations or implementation practices which appear to go beyond that which is required for "adequate protection."[1] In conducting this detailed review special attention will be placed on the feasibility of substituting unnecessarily prescriptive requirements and guidance with performance based requirements and guidance founded on risk insights. Revision of appropriate requirements and guidance in this manner should result in increased overall industry flexibility in plant operations without impacting reactor operational safety and may in fact contribute to operational safety.

Regulatory Review Group Composition and Interfaces:

Review Group Leader - Frank Gillespie, Director, Program Management Policy Development & Analysis Staff, Office of Nuclear Reactor Regulation

Secretary - Nancy Olson, Program Management Policy Development & Analysis Staff, Office of Nuclear Reactor Regulation

Members - Tony Cerne, Resident Inspector, Pilgrim Station, RI
Johns P. Jaudon, Deputy Director, Division of Radiation Safety and Safeguards, RIV
Cecil Thomas, Deputy Director, Division of Reactor Controls and Human Factors, NRR
Claudia Craig, Inspection and Licensing Policy Branch, NRR
Joe Murphy, Deputy Director, Division of Systems Research, RES
James M. Cutchin, Special Counsel, Office of the General Counsel
Byron Siegel, Project Manager, Division of Reactor Projects III/IV/V, NRR
Mary Drouin, Senior Risk & Reliability Engineer, Division of Safety Issue Resolution, RES

---

[1]There is not a precise regulatory definition for the term "adequate protection." Rather, it is the aggregate judgment by the NRC of those actions necessary for the licensee to maintain safe operations. Refer to 53 FR 20603, Statements of Consideration pertaining to 10 CFR 50.109 for a more detailed discussion.

Three sub groups will address the review group activities described below. The review group includes representation from headquarters and regional technical staffs and OGC. This assignment takes precedence over all other assignments and is to be conducted on a full-time basis. Guidance and overall direction for the Review Group will be provided by the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research. A Steering Committee comprised of the Directors of NRR, NMSS, RES, and AEOD, and Mr. Scinto, OGC will provide timely feedback to the Regulatory Review Group and ensure key program managers' experiences are factored into the review. Periodic (4-6 weeks) status briefings are to be given to the Executive Director for Operations and the Steering Committee.

An essential element of this Review Group is to develop a consensus, to the extent possible, on the approach and the key intermediate findings developed by the group. To this end, meetings and briefings with licensees, industry representatives (such as NUMARC), NRC staff, the Commissioners, ACRS, and the public will be held to solicit comments.

Background:

The staff previously instituted a number of reviews with the objective of improving the regulatory framework within which the NRC operates. One such recent program, described in SECY-92-263, seeks to identify, assess and eliminate regulatory requirements that have marginal importance to safety and yet impose a regulatory burden on licensees. Additionally, in response to a Presidential request, the Committee to Review Generic Requirements performed a special review of existing regulations that resulted in some regulation changes and refers to the marginal-to-safety program (SECY-91-141). However, these programs and other related activities need to be considered as part of a broader and more complete examination of the current regulatory framework. The mission of the Regulatory Review Group is to provide this integrated, more complete examination.

Task Group Activities:

The Regulatory Review Group will perform the following major tasks:

1. Conduct a series of meetings or utilize other methods, where appropriate, that elicit candid views on: areas of redundant regulation, overly burdensome regulation, areas where regulatory guidance and implementation verification processes may be overly prescriptive, areas where the regulations or regulatory guidance may be ambiguous, and suggested simplification and clarification of existing requirements and processes. Seek the candid views of the Commissioners, NRC staff, industry representatives, licensees, ACRS, NARUC and the public regarding priority areas to be examined, issues of particular concern, and recommendations for improvement. Incorporate the results into the review effort.

2. Assessment of Regulations

   a. Conduct a review of the current body of power reactor regulations to identify whether or not the regulation appears to go beyond that required for continued safe operation, is prescriptive or performance based, or is in need of clarification, and provide a brief evaluation of each major section of the regulations.

   b. Conduct a review of the statements of considerations for the rules, and selected SECY papers to identify the underlying principles and bases for the rules and, if possible, aggregate the rules that address the same overall issues (e.g., security, emergency preparedness, Reactor Coolant Pressure Boundary, etc.) so that an integral evaluation can be performed.

   c. Based on a. and b. above, evaluate the extent to which each major section of the regulations should be revised or examined further by the staff for potential revision. Revision of appropriate requirements in this manner should result in increased overall flexibility in plant operations without impacting safety and may contribute to operational safety.

3. Assessment of NRC Implementing Guidance

   Conduct a review of the implementing guidance for a broad sample of regulations to determine how the regulation is applied in the licensing and inspection process. Explore the industry view of the guidance and what role the implementation plays in making the regulations more restrictive than envisioned by the rule itself or the Statement of Considerations. The task group will examine the implementing guidance for coherence and consistency with the intent of the regulation and identify areas where interpretations of the rule should be relaxed, eliminated, or clarified.

4. Assessment of Operating Licenses

   Select several operating licenses issued at various times. Determine how the regulations and regulatory guidance were incorporated into the operating license. Determine how much inherent flexibility licensees have in making changes to their plant or operations and what in the licensing process inhibits this flexibility and makes the rule or implementation of the rule more restrictive once incorporated into the license. This will include identifying such things as what license condi'ions were imposed, what actions require preapproval by the NRC, what actions require post implementation NRC review, and requirements in the license that cause actions which may not be needed for the protection of public health and safety.

5. Assessment of Risk Technology

Examine how an integral analysis (probabilistic risk assessment [PRA]) can be used to provide more flexibility in the regulations and the implementation of the regulations. Determine what types of general ground rules or restrictions would be necessary to confidently sustain broad PRA usage as an accepted, credible tool for optimizing operations while maintaining the current level of safety. This will include addressing uncertainties and limitations of analytical tools and restrictions that should be placed on their use, identifying ways of accommodating limitations and specify conditions under which NRC could support broad application of risk technology to optimize licensee flexibility. Identify areas where existing regulatory processes can be revised in favor of performance-based approaches. Consider the policy, legal, and technical issues which need to be addressed to do so.

6. Current Programs

Examine the status of current staff efforts under the marginal-to-safety program, CRGR Special Review, and examination of requirements resulting from the "insider" threat to determine if there are areas where redirection may be appropriate or changes can be made in a short period of time. Refer to SECY 91-141, SECY 92-263, and SECY 92-272 and related Staff Requirements Memoranda.

7. Report of Findings

Submit a report to the EDO describing the findings of the review group. The report should specifically include:

a. Identification of existing reactor requirements which should be eliminated, revised, or further evaluated by the staff. The scope and extent of revisions should be described and justification for the revision, elimination, or further evaluation briefly discussed.

b. Identification of regulatory guidance which should be eliminated or revised. The scope and extent of revisions should be described and justification for the revision or elimination briefly discussed.

c. Identification of staff licensing/inspection processes which should be eliminated or revised. The scope and extent of revisions should be described and justification for the revision or elimination briefly discussed.

d. Recommendations for follow up efforts by the staff to implement the results of the review. The recommendations should include a prioritization of follow-up efforts taking into account the potential impact on operational safety, the overall reduction in burden which is achievable, the timeliness of relief achievable, and the staff resources required to implement the recommendation.

REGULATORY REVIEW GROUP

FRANK GILLESPIE
Secretary - NANCY OLSON

RULES/IMPLEMENTING GUIDANCE

JOHNS JAUDON, RIV
TONY CERNE, RI
CLAUDIA CRAIG, NRR
JAMES M. CUTCHIN, OGC

LICENSE ANALYSIS

CECIL THOMAS, NRR
BYRON SIEGEL, NRR

PRA TECHNOLOGY

JOE MURPHY, RES
MARY DROUIN, RES