NUREG/BR-0058
Revision 2

United States
Nuclear Regulatory Commission

Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission

Final Report

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ABSTRACT

The Regulatory Analysis Guidelines sets forth the policy for the Nuclear Regulatory Commission (NRC) for the preparation and the contents of regulatory analyses. The NRC performs regulatory analyses to support numerous NRC actions that affect nuclear power reactor and nonpower reactor licensees. This document contains a number of policy decisions that have broad implications for the NRC and its licensees. The more significant changes include the addition of a safety goal evaluation which is intended to eliminate some proposed requirements from further consideration because the residual risk is already acceptably low, and a revision in the dollar per person-rem conversion factor from $1000 to $2000 per person-rem.

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FOREWORD

For over 20 years the NRC has conducted regulatory value-impact analyses to determine whether there is an adequate basis for imposing new requirements on licensees. In January 1983, the NRC published its Regulatory Analysis Guidelines (NUREG/BR-0058) in order to clarify and formalize its existing value-impact guidance for the analysis of regulatory actions. Revision 1 to NUREG/BR-0058 was issued in May 1984 to include appropriate references to NUREG/CR-3568; a handbook that provided implementation guidance to the NRC staff for the policy set forth in the Guidelines.

In August 1993, the NRC published a draft version of the Guidelines, Revision 2, and invited public comment on the draft report. 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 Office of Management and Budget (OMB); and (5) procedural changes designed to enhance NRC's regulatory effectiveness.

In the draft report, the NRC indicated that a review and analysis of the dollar per person-rem conversion factor policy was ongoing and until its completion, the existing conversion factor policy would remain operative. The staff's reevaluation has now been completed, and the Commission has decided to implement a $2000 per person-rem conversion factor, subject it to present worth considerations, and limit its scope solely to health effects. This is in contrast to the existing policy and staff practice which entailed use of an undiscounted $1000 per person-rem conversion factor which served as a surrogate for all offsite consequences (health and offsite property).

The new conversion factor policy is based on a relatively simple and straight forward logic in which the dollar per person-rem conversion factor is defined as the product of the dollar value of the health detriment and a risk coefficient that establishes the probability of health effects as a result of low doses of radiation. In the NRC's formulation, the value of the latter term is on the order of 7×10^{-4} per rem and includes allowances for fatal cancers, nonfatal cancers, and severe genetic effects. The national and international bodies (NCRP, ICRP) directly responsible for evaluating and recommending a risk coefficient for the total health detriment are all in close agreement, and their recommendations have been adopted by the NRC. For the dollar valuation of the health detriment, the NRC has adopted $3 million as a representative value. This estimate is consistent with OMB's best estimate and an extensive literature review performed by the NRC. The resulting $2000 conversion factor was derived by multiplying these two factors (7×10^{-4} and $3 million), and expressing the result with one significant digit.

In addition, to provide meaningful summations of the costs and benefits that accrue over time, the dollar valuation of person-rem are to be expressed on a present-worth basis. Based on OMB guidance, present-worth calculations are to use the recommended discount rate specified in the latest version of OMB Circular A-94. This circular was most recently updated in late 1992 and specifies the use of a 7-percent real discount rate.

The final change in conversion factor policy concerns the treatment of offsite property consequences. The $2000 conversion factor is now clearly defined as the value of the health effects associated with a person-rem of dose. As such, it can no longer be used as a surrogate value for other consequences that could be attributable to offsite radiological releases or exposures. Thus, in those regulatory applications where offsite property consequences could result, these consequences would have to be calculated separately, and incorporated into the overall value-impact assessment.

The net effect of this revised conversion factor policy on the bottom-line value-impact results is mixed. In most regulatory applications the only consequence of radiological exposure is health

effects. As a result, the dollar valuation of a person rem would shift from an undiscounted $1000 to a $2000 conversion factor that would be subject to present worth calculations. In these circumstances, the doubling of the conversion factor and discounting tend to cancel each other. The differential in total dollar valuation is not of major significance and no improvement or change in regulatory decisions is expected. However, there are select circumstances where improvements in regulatory decisionmaking are possible. In regulatory applications involving certain severe power reactor accidents, offsite property consequences are an expected outcome. Under the new policy, an additional dollar allowance would need to be included and, in these instances, the change in total dollar value could be important to the regulatory decision.

The new conversion factor policy has been incorporated in this version of the Guidelines without the opportunity for public comment. This position was adopted because the NRC was interested in avoiding further delay in publication of the Guidelines so that analysts will have the benefit of other areas of improved guidance. Furthermore, in most regulatory applications this policy shift will have no meaningful effect on bottom-line cost-benefit results. In addition, given that this policy will be included in regulatory analyses for specific rulemakings, the opportunity to comment on it also exists within the context of individual regulatory initiatives. Finally, these Guidelines are not regulations and are not legally binding on anyone, and are merely intended to inform the analyst about expected staff practice.

A more complete discussion of the basis and implications of the new person-rem conversion factor are provided in NUREG 1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," (to be published in late 1995). Members of the public are encouraged to comment on this issue, and on the basis of these comments, the NRC holds open the possibility of revising this policy in the future.

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ABBREVIATIONS

ACRS	Advisory Committee on Reactor Safeguards
BWR	boiling water reactor
CDF	core damage frequency
CFR	Code of Federal Regulations
CPCFB	conditional probability of containment failure or bypass
CRGR	Committee To Review Generic Requirements
EA	environmental assessment
EDO	Executive Director for Operations
EIS	Environmental Impact Statement
EO	Executive Order
FR	Federal Register
Handbook	Regulatory Analysis Technical Evaluation Handbook
IRRAS	integrated reliability and risk analysis system
NRC	U.S. Nuclear Regulatory Commission
NEPA	National Environmental Policy Act
OMB	Office of Management and Budget
PRA	probabilistic risk assessment
PWR	pressurized water reactor
SARA	system analysis and risk assessment
SECY	staff papers before the Commission
SRM	staff requirements memorandum
staff	NRC staff members
U.S.C.	United States Code

1 INTRODUCTION

The Nuclear Regulatory Commission (NRC) will use these Regulatory Analysis Guidelines ("Guidelines") to evaluate proposed actions that may be needed to protect public health and safety. These evaluations are intended to aid the staff and the Commission to determine whether the proposed actions are needed, to provide adequate justification for the proposed action, and to provide a clear and well-documented explanation of why a particular action was recommended. The Guidelines establish a framework for (1) identifying the problem and associated objectives, (2) identifying alternatives for meeting the objectives, (3) analyzing the consequences of alternatives, (4) selecting a preferred alternative, and (5) 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 NRC's intent in preparing regulatory analyses is to ensure that its decisions that impose regulatory burdens on licensees are based on adequate information regarding reasonable alternatives and the extent of their burdens and the resulting values (benefits) and to follow a systematic and disciplined process that is also open and transparent in arriving at these decisions. The ultimate objective of this regulatory process is to ensure that all regulatory burdens are needed, are justified, and will achieve intended regulatory objectives with minimal impacts.

The regulatory analyses prepared by NRC 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 (EO) 12291 (Ref. 1) that directed all executive agencies to prepare a regulatory impact analysis for all major rules and stated that regulatory actions should be based on adequate information concerning the need for and consequences of proposed actions. Moreover, EO 12291 directed that actions were not to be undertaken unless they resulted in a positive net value to society. NRC, as an independent agency, was 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 EO 12291. The Commission determined that clarifying and formalizing the existing NRC value/impact procedures for the analysis of regulatory actions would enhance the effectiveness of NRC regulatory actions and further meet the spirit of EO 12291. The original version of these Guidelines (NUREG/BR-0058) was consequently issued in January 1983.

In December 1983, NRC issued "A Handbook for Value/Impact Assessment," NUREG/CR-3568[1] (Ref. 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 (Ref. 3) to include appropriate references to NUREG/CR-3568.

In September 1993, President Clinton issued EO 12866 (Ref. 1A). Section 1 of this Order, containing principles of regulation, and Section 6(a)(3), containing the elements of a regulatory analysis, are relevant to these Guidelines. EO 12866 also revokes EO 12291. Except for certain planning functions in Section 4 of the Order, NRC, as an independent agency, is not required to comply with EO 12866. Nevertheless, this version of the Guidelines reflects the content of EO 12866, in part, because of the Commission's previously expressed desire to meet the spirit of executive orders related to regulatory reform and decision making.

Revision 2 to the Guidelines is being issued to reflect (1) the NRC's accumulated experience with implementing Revision 1 to the Guidelines, (2) changes in NRC regulations and procedures since 1984, especially the backfit rule (10 CFR 50.109) and the Commission's 1986 "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants" (Ref. 4), (3) advances and

[1]This document is currently being revised and will tentatively be titled the *Regulatory Analysis Technical Evaluation Handbook*. The revised document is referred to herein as the "Handbook."

refinements in regulatory analysis techniques, (4) regulatory guidance for Federal agencies in EO 12866 and in issuances of the Administrative Conference of the United States (Ref. 5) and the Office of Management and Budget (OMB) (Ref. 6,11),[2] and (5) procedural changes designed to enhance NRC's regulatory effectiveness.[3]

The Commission's 1986 Policy Statement on Safety Goals for the Operation of Nuclear Power Plants 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 decisionmaking 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 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 whether any further backfits are warranted. Thus, the safety goal evaluation can truncate the need for further analysis. Therefore, the safety goal analysis discussed in Section 3 of this document is to be addressed as early as possible in the regulatory analysis process for safety enhancement initiatives.

In preparing a regulatory analysis, as in all activities relating to the protection of the public's health and safety, the NRC adheres to the Commission's Principles of Good Regulation.[4] These principles, which serve to guide the agency's decision making process, are independence, openness, efficiency, clarity, and reliability.

This document comprises five sections that are further subdivided. Section 2 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 a regulatory analysis in NRC decision making, and special requirements for proposed regulatory actions involving backfits of facilities subject to 10 CFR Part 50. Section 3 discusses the relationship of NRC's safety goals for nuclear power plant operations to regulatory analyses. Section 4 presents the format that should be followed in preparing a regulatory analysis document. It includes summary guidance on estimating and evaluating the values and impacts of alternative regulatory actions and selection of the proposed action. Information is also included in Section 4 on the required contents of regulatory analyses for proposed generic backfits to facilities regulated under 10 CFR Part 50 and for actions to be imposed on one or more classes of nuclear power reactors that are subject to review by the Committee To Review Generic Requirements (CRGR). Section 5 discusses certain procedural requirements that relate to the regulatory analysis process, including the impact of the Paperwork Reduction Act and the Regulatory Flexibility Act.

[2] OMB's Regulatory Impact Analysis Guidance (Ref. 6) was based on E.O. 12291. Both E.O. 12291 and the Guidance were revoked by E.O. 12866. However, OMB has advised Federal agencies that they should continue to follow the Regulatory Impact Analysis Guidance for estimating benefits and costs, pending OMB's review of what changes in the Guidance, if any, are needed because of E.O. 12866. Memorandum from Leon Panetta, Director OMB, to heads of Executive Departments and Agencies and Independent Regulatory Agencies concerning "Guidance for Implementing E.O. 12866," October 12, 1993.

[3] Certain regulatory actions are subject to the backfit rule at 10 CFR 50.109 and to the analysis and information requirements of the Committee To Review Generic Requirements (CRGR). NRC intends that, for these actions, the analysis performed in accordance with the Guidelines will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter (Ref. 7) without a need to prepare separate submissions. As part of the regulatory analysis, the "substantial increase in overall protection" test required under the backfit rule is assessed using the safety goal screening criteria.

[4] The principles are identified and described at p. 3 in the *1990 NRC Annual Report*, NUREG-1145, Vol. 7, July 1991.

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.
- No clearly preferable alternative is available 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[5] 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 process should begin when it becomes apparent that some type of action to address an identified problem may be needed. 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.

The regulatory analysis process is intended to be an integral part of NRC decision making that systematically provides complete disclosure of the relevant information supporting a regulatory decision. The process is neither to be used to produce after-the-fact rationalizations to justify decisions already made, nor to unnecessarily delay regulatory actions. The conclusions and recommendations included in a regulatory analysis document are neither final nor binding, but are intended to enhance the soundness of decision making by NRC managers and the Commission.

2.2 General Coverage

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. EO 12866 (Ref. 1A) requires that a regulatory analysis be prepared for all significant regulatory actions.[6] NRC policy requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in EO 12866. In general, each NRC office should ensure that all mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees, include an

[5]The Commission has stated (Ref. 20) that substantial means important or significant in a large amount, extent, or degree. Applying such a standard, the Commission would not ordinarily expect that safety applying improvements would be required as backfits that result in an insignificant or small benefit to the public health and safety, regardless of costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided. This approach is flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety. The approach is also flexible enough to allow for arguments that consistency with national and international standards, or the incorporation of widespread industry practices, contributes either directly or indirectly to a substantial increase in safety. Such arguments concerning consistency with other standards, or incorporation of industry practices, would have to rest on the particulars of a given proposed rule. The Commission also believes that this approach of "substantial increase" is consistent with the agency's policy of encouraging voluntary initiatives.

[6]Significant regulatory actions are defined in E.O. 12866 to include actions that "are likely to result in a rule that may (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. 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 or modified at the discretion of the Commission, the Executive Director for Operations (EDO) or a Deputy Executive Director, or the responsible NRC Office Director. A factor that could influence this decision 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 other regulatory applications, case-specific circumstances could justify the preparation of a more limited regulatory analysis. Such a regulatory analysis should be limited only in terms of depth of discussion and analysis, not in the reduction of the scope of the regulatory analysis and not in the need to justify the proposed action.

Generic actions[7] that may not need a regulatory analysis include notices, policy statements, and generic letters that only transmit 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) (discussed in Section 5.4) require a specific justification statement and are reviewed by the CRGR when directed to one or more classes of nuclear power reactors but do not require the type of regulatory analysis discussed in this document. New requirements affecting certified nuclear power plant designs will be justified through the notice and comment rulemaking process as specified at 10 CFR 52.63. Regulatory analyses are not required for requirements arising out of litigation, such as discovery in a licensing proceeding.

The analytical needs of regulatory analyses involving the relaxation of requirements can be markedly different. In these cases, the regulatory analysis should provide that level of assessment that will demonstrate with sufficient reasonableness that the two following conditions are satisfied:

1. 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.
2. The cost savings attributed to the action would be substantial enough to justify taking the action.

For proposed regulatory actions that would relax or reduce current requirements affecting nuclear power plants, the backfit rule at 10 CFR 50.109 and the safety goal evaluation process and screening criteria in Section 3 are not applicable. However, for all proposed relaxations (including those affecting nuclear power plants), supporting documentation should be prepared that contains the basis for concluding that the two conditions previously identified will be satisfied. Further, it is appropriate in justifying a proposed relaxation to cite the results or insights from risk analyses that support relaxation, as well as the NRC's original bases for having established the existing requirement to begin with.

In general, actions that would relax or reduce requirements should give licensees the option of whether to take advantage of the change and should not be mandatory. However, calculation of the cost savings should be based on the assumption that all licensees will take advantage of the change.

2.3 Proposed Actions Subject to the Backfit Rule and Review by The Committee To Review Generic Requirements

Regulatory actions that are subject to the backfit regulations at 10 CFR 50.109 (the "backfit rule") and CRGR review require that specific questions and issues be addressed. These Guidelines have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the backfit rule and provisions of the CRGR Charter (Ref. 7).

The CRGR has the responsibility to review and recommend to the EDO approval or disapproval of proposed NRC requirements or staff positions on one or more classes of nuclear power reactors. Section IV of the CRGR Charter specifies the

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

technical information to be submitted to the CRGR as part of its review process. This information is incorporated in Section 4 of these Guidelines. The CRGR Charter should be consulted for the administrative responsibilities to be included in a package, for example, an Office Director's finding and the General Counsel's concurrence.

The Handbook 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 document. Further, all backfit and findings required by the CRGR charter should be highlighted in the regulatory analysis.

When a regulatory analysis has been prepared in accordance with these Guidelines and the 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 the supplement or revision as an enclosure) rather than reprinting the regulatory analysis.

The backfit rule applies to proposed backfitting of production or utilization facilities. The term "backfitting" is defined at 10 CFR 50.109(a)(1). The terms "production facility" and "utilization facility" are defined at 10 CFR 50.2. 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 (NRC Manual Chapter 0514) (Ref. 8). This Directive contains plant-specific regulatory analysis requirements and thus, 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 discussion of the backfitting process is provided in "Backfitting Guidelines," NUREG-1409 (Ref. 9).[8]

Preparation of a regulatory analysis, including an evaluation of values and impacts, is necessary for all proposed plant-specific and generic backfits to facilities regulated under 10 CFR Part 50 except when one of the three conditions identified at 10 CFR 50.109(a)(4) applies. These conditions are—

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[9] 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 defense and security is regarded as necessary for adequate protection.

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

A regulatory analysis incorporating the documented evaluation may also be prepared in these instances as a management decisionmaking tool. In particular, if there is more than one way to achieve compliance or reach a level of adequate protection and the Commission finds it necessary

[8]NRC Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," is included as Appendix D to NUREG-1409.

[9]The level of protection constituting "adequate protection" is that level which must be assured without regard to cost. It 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.

or appropriate to specify the way, 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 EVALUATION FOR OPERATION OF NUCLEAR POWER PLANTS

Assessing the risk of 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,[10] and the single failure criterion. The frequency or probability of the hazard was not an explicit factor, primarily because the overall state-of-the-art of probabilistic risk assessment (PRA) technology was not sufficiently advanced and accepted. Because of the advancements made and an increased confidence in PRA, regulators have progressively relied more on the insights and results from risk assessment in managing regulatory activities. The safety goals for the operation of nuclear power plants, which are in an August 1986 Commission policy statement (Ref. 4), are a clear example of this change, and these goals established a guide for regulatory decisionmaking.

The safety goal evaluation is designed to answer when a regulatory requirement should not be generically imposed on nuclear power plants because the residual risk is already acceptably low. This evaluation is intended to eliminate some proposed requirements from further consideration independently of whether they could be justified by a regulatory analysis on their net value basis. The safety goal evaluation will also be used for determining whether the substantial added protection standard of 10 CFR 50.109(a)(3) is met.

Additionally, note that the Commission's safety goals reflect a mean value for a class or all U.S. nuclear power reactors as a whole. In this regard, the Commission specified in a Staff Requirements Memorandum (SRM) dated June 15, 1990, that "Safety goals are to be used in a more generic sense and not to make specific licensing decisions."

[10]Defense-in-depth is the process implemented by the Atomic Energy Commission (later NRC) to ensure that multiple levels of assurance and safety exist to minimize risk to the public from nuclear power plant operations.

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

3.1 When a Safety Goal Evaluation Is Needed

NRC's safety goal policy addresses a level of acceptable residual individual risk from operation of nuclear power reactors judged to be lower than that associated with adequate protection. The risk level associated with adequate protection is that level above which continued operation would not be allowed. The safety goal evaluation, as discussed in this section, is applicable only to regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). A safety goal evaluation is not needed for new requirements within the exceptions at 10 CFR 50.109(a)(4)(i)–(iii). If the proposed safety goal screening criteria are satisfied, the NRC considers that the substantial additional protection standard is met for the proposed new requirement.

As discussed in Section 2.2 of these Guidelines, relaxations of requirements affecting nuclear power plants are not backfits and thus do not fall within the scope of the backfit rule. Additionally, relaxations of requirements affecting nuclear power plants are not subject to the safety goal evaluation requirements. Nevertheless, a relaxation of requirements is subject to a regulatory analysis and specifically to the criteria listed on pages 2.3 and 2.4 of the Guidelines.

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 a safety goal evaluation is required, the results of the evaluation will establish whether a regulatory analysis should be prepared (Figure 3.1). If the proposed regulatory action meets the safety goal screening criteria, the regulatory analysis should include the results of the safety goal evaluation (see Section 4.4). Figure 3.1 depicts all steps performed in a regulatory analysis that is subject to a safety goal evaluation. References to appropriate sections of these Guidelines are included. Depending on the results of steps C and D, the regulatory analysis can be terminated. In performing steps C and D, a PRA should be relied upon to quantify the risk reduction and corresponding values of the proposed new requirement. However, the NRC recognizes that not all regulatory actions are amenable to a quantitative risk assessment and that certain evaluations may be based directly on engineering or regulatory judgment or qualitative analysis. Additional guidance is included in Section 3 of the Handbook beyond the implementation guidance in Section 3.3.

When performing a safety goal evaluation, the analyst should be aware of any previous or ongoing safety improvements that have the potential to impact the status quo risks associated with the issues being addressed. Because there is no formal process for accounting for the potential dependencies between issues, the analyst must resort to a "best effort" approach in accounting for preexisting or concurrent impacts. The analyst should make a thorough effort to identify any previous or ongoing safety improvements that may impact the issue being evaluated. For example, an analyst addressing proposed improvements in diesel generator performance at power reactors should be aware of any diesel generator improvements already addressed in station blackout considerations. To the extent possible, the analyst should modify the risk equations of the representative plant to reflect the upgraded status quo from these other safety improvements. The analyst can then proceed to evaluate the difference between this new status quo and the proposed improvements being addressed. Additional discussion of the cumulative accounting of past and ongoing safety improvements is in Appendix A to the Handbook.

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 practicable 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 the availability of PRAs that reflect both internally and externally initiated accidents and the current design of all U.S. nuclear power plants.

In summary, the safety goal evaluations are based upon the following broad guidelines:

- Safety goal screening criteria are to be applied only to safety enhancements and evaluated for the affected class of nuclear power plants. Safety goals are to be used as a reference point in ascertaining the need for safety enhancements. However, the safety goals are not requirements and, with the Commission's approval, safety enhancements may be implemented without strict adherence to the Commission's safety goal policy statement.

- Safety goal evaluations are to be performed in conjunction with the "substantial additional protection" criterion contained in the backfit rule [10 CFR 50.109(a)(3)] and applied to 10 CFR 50.109 analyses associated with substantial safety enhancements wherein the costs of the implementation are justified in view of the safety improvement to be realized.

- Evaluations of proposed regulatory initiatives for consistency with safety goals should identify and integrate related issues under study. Integration of related issues is essential to the efficient application of staff and industry resources. The overall objective is to avoid piecemeal evaluation of issues.

NRC's philosophy for safety goal evaluations involves the concept of defense-in-depth and a balance between prevention and mitigation. This

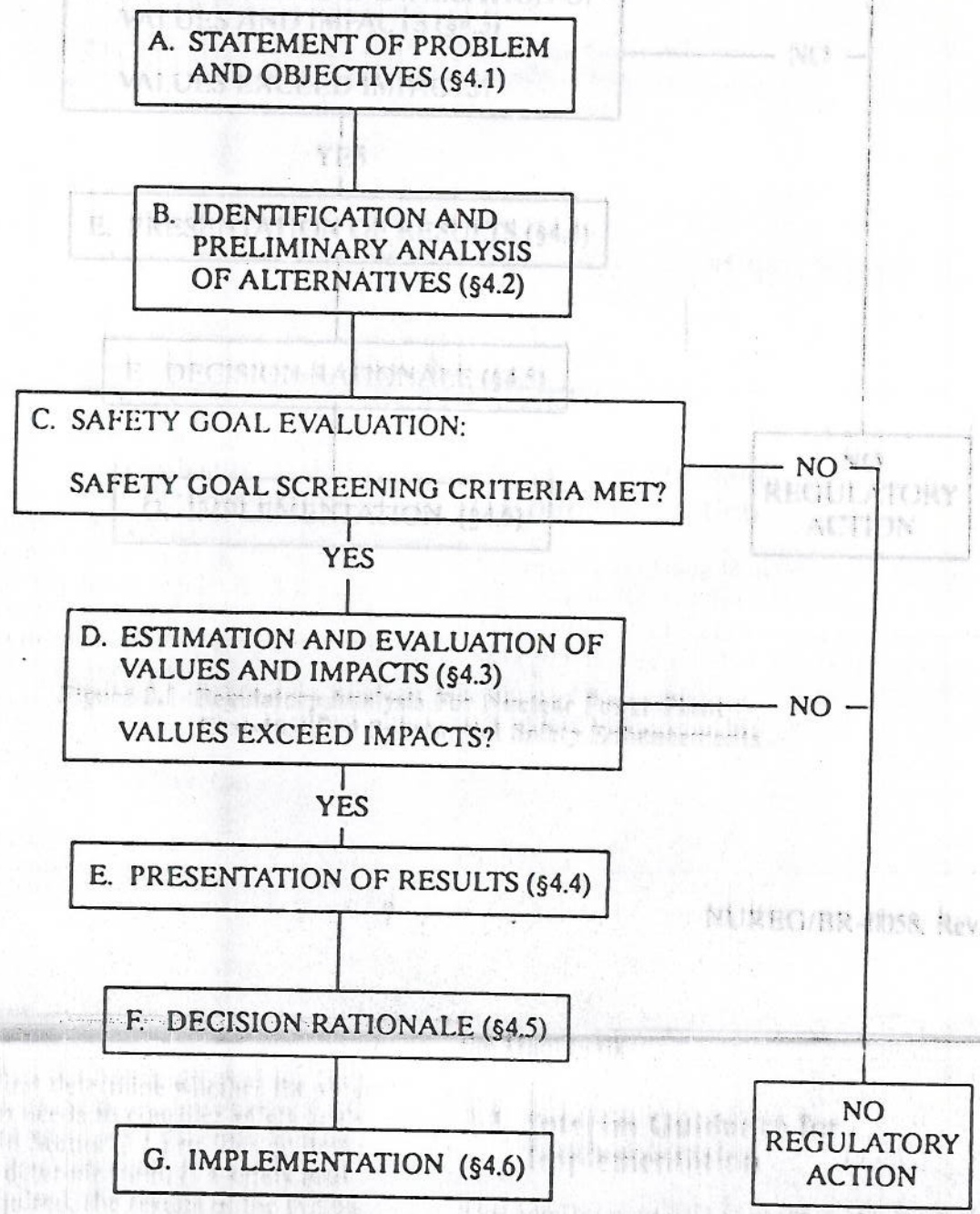

Figure 3.1 Regulatory Analysis For Nuclear Power Plant Cost-Justified Substantial Safety Enhancements

traditional defense-in-depth approach and the accident mitigation philosophy require reliable performance of containment systems. The safety goal evaluation focuses on accident prevention, that is, on issues intended to reduce core damage frequency. However, to achieve a measure of balance between prevention and mitigation, the safety goal screening criteria established for these evaluations include a mechanism for having greater consideration of issues, and associated accident sequences, with relatively poor containment performance.

3.3.1 Prevention of Core Damage Accidents—Comparison With Subsidiary Goal for Core Damage Mean Frequency of 10^{-4} per 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 ensure 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 boiling water reactors (BWRs)," one or more PRAs from individual plant examination submittals or that have otherwise been conducted for older BWRs should be selected. The Handbook that complements these Guidelines includes a table listing PRAs available for use with staff risk assessment codes [e.g., Integrated Reliability and Risk Analysis System (IRRAS) and Systems Analysis and Risk Assessment (SARA)] along with some basic attributes of each (e.g., plant type and year of initial commercial operation). As a minimum, the merit of the proposed new requirements should be explored and displayed using this PRA data from 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.

The risk assessments and analyses needed for safety goal evaluations should normally have the following characteristics:

- The analysis should explicitly define the class of affected plants and justify the use of specific PRAs to represent that class.
- The PRA should reflect the current state of PRA technology, and include an analysis of uncertainties.
- The product of the analyses should be mean values and uncertainty estimates.
- The analysis should receive an independent review by staff knowledgeable and experienced in PRA, plus reviews by the individual or group that identified the issue and the group that would be responsible for implementing the resolution.
- The analysis should be documented with sufficient detail to enable the analysis to be repeated. In addition, sufficient explanatory material should be provided to enable the reader to understand the significance of the calculations and to reconcile the various calculations with engineering judgment. Thus, the event or issue, its relationship to safety, the calculational approach, and all assumptions should be listed and justified, including choice of base PRA, choice of parameters, source of basic data, any mathematical approximations used, and so forth. The accident sequences affected should be described and explanations of why they are affected should be provided.
- The documentation should not present calculational results with more significant figures than are appropriate. More than one significant figure in the mantissa is not appropriate in most cases. Note, however, that if intermediate results are presented, a reader

[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.

attempting to use these intermediate results in duplicating the calculation may not calculate exactly the same final results due to round-off error.)

The Handbook provides a more complete and detailed discussion of the key characteristics of risk assessments available to be used for safety goal evaluations.

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 certain 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 goals, 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, considering the subsidiary safety goal[12] of 10^{-4} in mean core damage frequency per 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 clearly "substantial" if the reduction is equal to or greater than 10^{-4} per reactor year. If the reduction in CDF is 10 percent or more of the subsidiary safety goal of 10^{-4} in mean core damage frequency per reactor year but less than 10^{-4} consideration should be given to the probability of containment failure before a conclusion is reached on whether the reduction in CDF constitutes substantial additional protection. As illustrated in Figure 3.2, this means that, with certain exceptions as discussed later, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least 1×10^{-5} in the estimated mean value 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 safety goal 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. This does not mean that in all cases a proposed safety enhancement of at least 1×10^{-5} will subsequently prove to be justified for implementation after more detailed assessments are performed in accord with Section 4. In this regard, the effect of uncertainties should be considered and discussed.

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

Estimated Reduction In CDF	*Staff Action*
> 10^{-4}/reactor year	• Proceed with the regulatory analysis on a high priority basis.
10^{-4}–10^{-5}/reactor year	• The decision whether to proceed with the regulatory analysis is to be made by the responsible Division Director (see Figure 3.2).
< 10^{-5}/reactor year	• 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 new requirement can be formulated. A

[12]This goal has been determined by the staff to be a useful benchmark, but is not a Commission-approved safety goal.

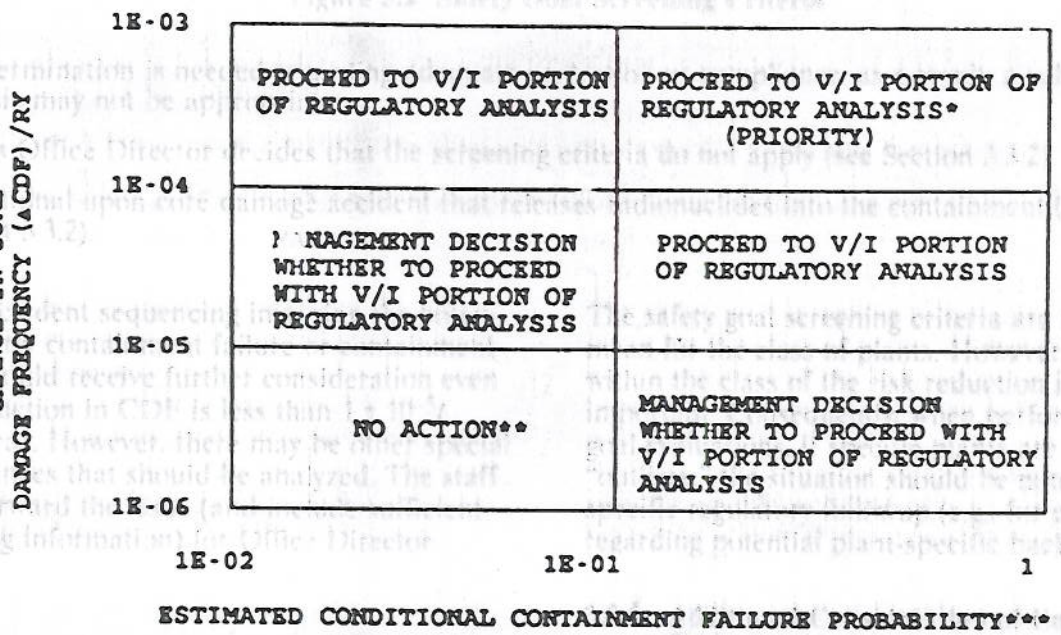

Figure 3.2 Safety Goal Screening Criteria

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

**Unless Office Director decides that the screening criteria do not apply (see Section 3.3.2).

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

class of accident sequencing involving the potential for early containment failure or containment bypass should receive further consideration even if the reduction in CDF is less than 1×10^{-5}/reactor year. However, there may be other special circumstances that 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 adequate quantitative supporting information for the proposed new requirement, a qualitative analysis and perspective should be provided. To the extent practical, these points and insights should be related to the safety goal screening criteria. For example, how does the proposed initiative affect the CDF and to what extent? How should the risk and the expected improvement be measured or estimated?

The safety goal screening criteria 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 evaluations, if specific plants are identified as "outliers," the situation should be noted for specific regulatory followup (e.g., for evaluations regarding potential plant-specific backfits).

3.3.2 Additional Consideration of Containment Performance

The previous section focuses on accident prevention, that is, on issues intended to reduce core damage frequency. To achieve a measure of balance between prevention and mitigation, the safety goal screening criteria established for safety goal evaluations include a mechanism for having greater consideration of issues, and associated accident sequences, with relatively poor containment performance. The measure of containment performance to be used in safety goal evaluations

is the conditional probability of early containment failure or bypass (CPCFB).[13] The safety goal screening criteria shown in Figure 3.2 are subdivided to require greater staff emphasis on the higher valued (i.e., >0.1) CPCFBs. A CPCFB value of 0.1 is consistent with Commission guidance on containment performance for evolutionary designs. In effect, the use of the CPCFB reduces the priority of or eliminates the additional study of issues with associated CPCFBs of less than 0.1.

The safety goal screening criteria provided here are based upon the recognition that the severe accident risk to the individual is dominated by the overall frequency of the following kinds of scenarios:

- Those involving core damage and release into an intact containment with early containment failure occurring.
- Those involving core damage and for which the containment system is breached as a result of accident phenomena either before or early in the core damage or melt progression.
- Those involving preexisting conditions that cause loss of containment integrity before core damage (e.g., large openings).
- Those for which containment is bypassed entirely and which have high probability of causing core damage to occur (e.g., intersystem loss-of-coolant accident).

The NRC recognizes that in certain instances, the screening criteria may not adequately address certain accident scenarios of unique safety or risk interest. An example is one in which certain challenges could lead to containment failure after the time period adopted in the safety goal screening criteria, yet early enough that the contribution of these challenges to total risk would be non-negligible, particularly if the failure occurs before effective implementation of accident management measures. In these circumstances, the analyst should make the case that the screening criteria do not apply and the decision to pursue the issue should be subject to further management decision.

Furthermore, note that the safety goal screening criteria described here do not address issues that deal only with containment performance. Consequently, issues that have no impact on core damage frequency (delta CDF of zero) cannot be addressed with the safety goal screening criteria. However, because mitigative initiatives have been relatively few and infrequent compared with accident preventive initiatives, mitigative initiatives will be assessed on a case-by-case basis with regard to the safety goals. Given the very few proposed regulatory initiatives that involve mitigation, this should have little overall impact from a practical perspective on the usefulness of the safety goal screening criteria.

3.3.3 Summary of Safety Goal Screening Criteria Guidance

The safety goal screening criteria discussed in Section 3 are summarized in Figure 3.2, which graphically illustrates the criteria and provides guidance as to when the staff should proceed to the estimation and evaluation of the values and impacts portion of the regulatory analysis and when a management decision is needed.

Management with responsibility for preparation of a safety goal evaluation should review the results of the evaluation and the overall uncertainty and sensitivity of associated estimates. A judgment should be made whether substantial additional protection would be achievable and whether continuation of the regulatory analysis process is therefore warranted.

3.3.4 Regulatory Analysis

If the safety goal evaluation of the proposed regulatory action results in a favorable determination (i.e., any decision except "no action"), the analyst may presume that the substantial additional protection standard of 10 CFR 50.109(a)(3) is achievable. The initiative should then be assessed in accordance with Section 4.3 of these Guidelines (see Figure 3.1). If the net value calculation

[13] CPCFB in this context is the conditional probability of early containment failure or bypass given a 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 pressurized water reactors (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." The definition recognizes the impacts of early failure and uses that as a baseline from which to assess containment performance, (e.g., CPCFB changes). In applying these screening criteria, the CPCFB definition may be extended, if appropriate, to up to four hours after vessel breach, to permit initiation of accident management and emergency preparedness actions. It is not a goal being sought since the staff recognizes the benefits of prolonging containment failure where such scenarios risk early failure.

required by Section 4.4 is not positive, further activities and analyses should be terminated unless there is a qualitative justification for proceeding further.

4. ELEMENTS OF A REGULATORY ANALYSIS

This section presents the specific elements to be included in a regulatory analysis document. The intent of these Guidelines is to ensure uniformity in the elements included in a regulatory analysis. These elements include the following:

- A statement of the problem and NRC objectives for the proposed regulatory action.
- Identification and preliminary analysis of alternative approaches to the problem.
- Estimation and evaluation of the values and impacts for selected alternatives, including consideration of the uncertainties affecting the estimates.
- The conclusions of the evaluation of values and impacts and, when appropriate, the safety goal evaluation.
- The decision rationale for selection of the proposed regulatory action.
- A tentative implementation schedule and implementation instrument for the proposed regulatory action.

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

Regulatory analyses are reviewed within the NRC and made publicly available. Reviewers include NRC technical staff and managers and formal groups such as the CRGR, the Advisory Committee on Reactor Safeguards (ACRS), 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, the 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 parties interested in a proposed regulatory action, may be used in the regulatory analysis after the staff has been assured of the reasonableness of the information.

The appropriate level of detail to be included in a regulatory analysis can vary, depending on the particular circumstances. The staff should consider the following five factors in determining the appropriate level of detail to include:

1. The complexity and policy significance of the particular problem being addressed;
2. The magnitude and likelihood of values and impacts;
3. The relative amount by which projected values exceed impacts;[14]
4. The immediacy of the need for a regulatory action and time constraints imposed by legislation or court decisions; and
5. Any supplemental direction provided by the Commission, the Office of the EDO, or an NRC Office Director.

The emphasis in implementing the Guidelines should be on simplicity, flexibility, and common sense, in terms of the type of information supplied and 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 detail to enable NRC decision makers and other interested parties to easily recognize—

- The problem within the context of the existing regulatory framework,

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

- 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 new requirement was appropriate and justified.
- The sources and magnitude of uncertainties that might affect the conclusions and the proposed new requirement, and
- 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 to demonstrate the implications of taking no action.

For certain regulatory issues there may be existing NRC or Agreement State regulatory requirements or guidance, industry programs, or voluntary efforts by licensees directed at the same or similar problem. These activities, and any variations in industry practice and commitments among licensees, should be identified and discussed to the extent practicable. The need for regulatory action must be justified within the context of what would prevail if regulatory action were not taken. This justification 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 discussion is included 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) should be noted, as well as any differences in facility type, age, design, or other relevant considerations.

4.1.1 Background of the Problem

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

- A brief history of the problem and the outcome of past efforts (if any) to alleviate it;
- Any legislation or litigation[15] that directly or indirectly addresses the problem;
- Whether existing requirements have created or contributed to the problem and whether these requirements can be modified to achieve the regulatory objective more effectively;
- The extent (if any) to which the immediate problem is part of a larger problem;
- The relationship of the problem to other ongoing studies or actions;[16]
- The objectives of the proposed new requirement and the relationship of the objectives to NRC's legislative mandates and authority, safety goals for the operation of nuclear power plants, and policy and planning guidance (e.g., NRC's Five-Year Plan);
- The relationship of the problem to formal positions adopted by national and international standards organizations;
- Identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness;

[15] Litigation records could come from court cases, decisions by an Atomic Safety and Licensing or Appeal Board, or Commission decisions in cases under litigation.

[16] Reviewing issues associated with the problem in the context of other issues that apply to the same problem is important. These other issues may be among NRC's prioritized generic safety issues (NUREG-0933) (Ref. 10) or other identified safety issues meriting NRC's attention.

- Constraints or other cumulative impacts that work against solutions to the problem; and
- Draft papers or other underlying staff documents supporting the requirements or staff positions.

4.1.2 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. Depending on whether the action is being initiated for adequate protection or compliance and not as a safety enhancement, a regulatory analysis may not be needed or its scope or focus could be markedly different (see Section 2.3). Thus, the analyst needs to address this issue early in the regulatory analysis process. For any single action, more than one type of backfit may be involved. Under these circumstances, plants should be assessed for each type of backfit on a case-by-case basis.

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 in Section 4.1.1. The initial list of alternatives should be identified and analyzed as early in the regulatory 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 that 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 calculated. If applicable, the list of alternatives should include alternatives to direct regulation such as providing economic incentives to encourage the desired behavior, for example, user fees or marketable permits or licenses, or providing information upon which choices can be made by the public or licensees.

Alternatives generally focus on or explore various ways to answer a series of hypothetical questions: what, who, how, and when. When applicable in defining alternatives, consider the following issues:

- What action should be taken?—It may be appropriate to identify alternative ways to resolve the problem. Viable alternatives could be based on variability in the physical and technical requirements needed to address the problem at hand. Alternatives could also include varying the scope of requirements and the number of licensees affected.
- Whose responsibility should it be to take action?—Different entities may be capable, and therefore, could assume responsibility for resolving the problem. For example, initiatives by licensees and industry support groups may constitute a viable alternative to some NRC initiatives.
- How should it be done?—The various mechanisms (e.g., generic letter, rule, policy statement) available to the NRC to accomplish the change should be considered.
- When should it become effective?—Alternative implementation schedules and compliance dates may be appropriate.

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 previously listed. For example, Congressional actions or court rulings could prescribe an NRC action with such specificity that the only alternatives open to the NRC are implementation mechanisms.

If 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

prescribe 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. In certain circumstances, this preliminary screening of alternatives may eliminate most of the alternatives being considered. In such cases, the regulatory analysis need only address the limited set of alternatives that remains.

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.

4.3 Estimation and Evaluation of Values and Impacts

The alternatives that survive the screening process of Section 4.2 should be analyzed in the section of the regulatory analysis document covering the estimation and evaluation of values and impacts. 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 definitions of values and impacts shown below are adopted. These definitions are largely derived from Section 6(a)(3)(C) of EO 12866.

Values The beneficial aspects anticipated from a proposed regulatory action such as, but not limited to, the (1) enhancement of health and safety, (2) protection of the natural environment, (3) promotion of the efficient functioning of the economy and private markets, and (4) elimination or reduction of discrimination or bias.

Impacts The costs anticipated from a proposed regulatory action such as, but not limited to, the (1) direct costs to NRC and Agreement States in administering the proposed action and to licensees and others in complying with the proposed action; (2) adverse effects on health, safety, and the natural environment; and (3) adverse effects on the efficient functioning of the economy or private markets.

The staff should consult the Handbook and any relevant NRC reports or documents issued subsequently to these Guidelines and the Handbook 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, Indian tribes, licensees of the NRC and/or Agreement States, employees of licensees, contractors and vendors, the NRC, and other Federal agencies. Within each affected group, further differentiation, for example, 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. Such estimates and evaluations should include transfer payments (see Section 4.3.2). 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 that have had safety features installed during construction and older facilities.

For each affected group, the attributes that characterize the consequences of the proposed action should be identified. The Guidelines (especially Sections 4.3.1 and 4.3.2) and the Handbook

should be reviewed before selecting appropriate attributes.

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, depending upon the level of detail available from the data sources employed in the regulatory analysis, acceptable estimates could include other point estimates such as the median. 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 have been implemented. Consequently the values and impacts associated with these requirements are not part of the 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 related to the subject action that are likely to be implemented.

The NRC encourages voluntary actions that enhance safety. When voluntary 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. However, when voluntary initiatives are in place over only a portion of the industry, or when they achieve only part of the safety objectives associated with a regulatory change under consideration, codifying the practice may be necessary. In these instances, voluntary actions, by demonstrating their practicality and effectiveness, will be important inputs in the staff's development of rules, particularly performance-based rules, and thus benefit those who have taken such action. For purposes of the regulatory analysis however, 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, the costs and benefits should not be reduced by the extent to which they may already be lessened by voluntary activities. Since the base case regulatory analysis takes no credit for voluntary actions, a sensitivity analysis should be performed and the regulatory analysis results displayed reflecting due consideration of voluntary actions.

Most voluntary actions are discretionary, and their impacts are primarily ongoing and future-oriented. Voluntary programs might be characterized as adopting vague requirements, lacking in NRC enforceability, and resulting in nonuniform programs across all licensees. The NRC intends 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 the NRC deems necessary. This would be the case, for example, when voluntary programs are nonuniform across all licensees. As a result, some licensees may not have a program, or established programs could easily dissipate by licensee action alone, perhaps without NRC's knowledge. Furthermore, if credit is provided for voluntary initiatives and 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, not subject to enforcement on the part of the NRC.

Uncertainties are important to consider in developing 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 analyses. Sensitivity analysis can be used in addition to or in lieu of formal uncertainty analysis; the former option should be exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporating uncertainties and sensitivities in a regulatory analysis is in the Handbook. The Handbook also discusses the distinction between them.

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

Values and impacts should be estimated by year for the entire period that groups will be affected by the proposed regulatory action. For licensed facilities, estimates should be made for the remainder of the operating license or projected useful life of the facility (i.e., extended into the license renewal period). For nuclear power reactors, 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, the basis for the judgment or conclusion that there would not be a significant effect should be stated for future reference.

Estimated values and impacts should 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, many regulatory actions, such as those affecting non-power reactor and materials licensees, may not be supported by available PRA analysis, and probabilistic analysis techniques may not be practical for some actions. However, the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective and useful trends concerning the value of the proposed action. Even inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered.

The 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, value attributes to be assessed include—

- Reductions in public and occupational radiation exposure,
- Enhancements to health, safety, or the natural environment,
- Averted onsite impacts,
- Averted offsite property[18] damage,
- Savings to licensees,
- Savings to the NRC,
- Savings to State, local, or tribal governments,
- Improved plant availability,
- Promotion of the efficient functioning of the economy, and
- Reductions in safeguards risks.

Particular care should be taken in estimating dollar savings deriving from averted onsite costs and improved plant availability because (1) values for these attributes are difficult to accurately estimate and (2) estimated values can potentially significantly outweigh other values and impacts associated with an alternative. In those instances where the exclusion of averted onsite costs and improved plant availability would be expected to result in a different or significantly altered conclusion, the staff should also display the results with these elements excluded for sensitivity analysis purposes and to help clarify the basis for the regulatory decision.

In the case of nuclear power plants, changes in public health and safety from radiation exposure and offsite property impacts should be examined over a 50-mile[19] distance from the plant site. The appropriate distance for other types of licensed facilities should be determined on a case-by-case basis. Care must be taken to ensure that changes in health risks associated with each alternative account for potential changes in plant or operational complexity. All changes in risk to the public and to workers should be estimated and discussed. When appropriate, health risks should be

[18]Offsite property refers to property that is not owned or leased by a licensee.

[19]While the NRC's metrication policy statement (57 FR 46202; October 7, 1992) calls for the use of dual units, it also states that "all event reporting and emergency response communications between licensees, the NRC, and State and local authorities will be in the English system of measurement." Hence, the use of the English unit, "miles", in this case.

estimated for both routine operations and accidents.

The analyst should be aware that alternatives may have both positive and negative components for a particular attribute. 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 ability to assess risks can vary dramatically, depending on the data and information available that is directly pertinent to the particular regulatory action being considered. Generally, the extent of any supporting detailed information will allow one of three types of regulatory analyses to be developed:

1. Detailed PRA or statistics-based analyses are available or can be developed to support the quantification of values.

2. Some factual information or data are available that can provide a quantitative perspective, but may involve considerable extrapolation of data. Thus, the resulting analysis may be quite uncertain and lack completeness or precision.

3. Extremely few data or accepted models exist to support a quantitative type analysis. As a result, the analysis must be qualitative. Once this situation is understood and the nature or type of the analysis is determined, the analyst should proceed as outlined below.

Typically, the most detailed and specific value assessment will involve regulatory initiatives impacting nuclear power reactors for which PRA 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-cSv (person-rem) averted. This value is then quantified in dollars based on a dollar per person-cSv (person-rem) conversion factor.

The next level of quantification supporting regulatory initiatives concerns situations in which PRAs are not available and other data and analyses 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 to provide some quantitative perspective or insight on the nature and absolute or relative magnitude of the risk, as well as 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. Typically, a sensitivity analysis that shows the variability in the derived risk as a function of key assumptions should be developed. The level of effort in terms of model development and data collection is dictated by the same factors that are utilized by the staff in determining the level of detail for the overall regulatory analysis.

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 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 regulatory analysis is subject to a higher level of scrutiny by the decision maker because of the degree of judgement involved. Reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have 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 the following six items:

1. Costs to licensees,
2. Costs to the NRC,
3. Costs to State, local, or tribal governments,
4. Adverse effects on health, safety, or the natural environment,

5. Adverse effects on regulatory efficiency or scientific knowledge needed for regulatory purposes, and

6. Adverse effects on the efficient functioning of the economy and private markets.

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 because they do not involve consumptive use of real resources (Ref. 6.11). However, if a proposed action being analyzed has as its major impact, a requirement that would produce additional costs for items generally considered transfer payments, the regulatory analysis needs to consider values and impacts from a sectoral perspective and, in this context, these costs should be identified and included in the regulatory analysis. (An example would be a regulatory action whose sole impact would be to require licensees to carry additional insurance.) Information on identifying transfer payments is included in the Handbook. In addition, depreciation is an accounting concept that should not be included as an impact.

In analyzing impacts, the staff 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 appropriate. Further, for new requirements that have extremely high implementation costs or that will greatly increase operating costs, the analyst needs to consider the possibility that the imposition of these impacts may result in some facilities no longer being economical to operate and, thus, having to terminate operations. The Handbook should be consulted for additional information related to potential premature facility closures.

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, for example, constant dollars from a reference year. Because the values and impacts need to be estimated for the entire period that members of society will be affected by the proposed regulatory action, a present-worth basis is normally used to allow meaningful summations and comparisons. Although this approach provides a rational basis for evaluating values and impacts, it has a number of complexities and controversies.

In order to place all values and impacts on a common basis, a conversion factor is needed that reflects the monetary worth of a unit of radiation exposure. The currently recommended value for this dollar conversion factor is $2000 per person-rem.[20] This dollar value only captures the health effects attributable to radiological exposure. In select regulatory applications, such as certain severe power reactor accident scenarios, a radiological release could also result in offsite property consequences whose monetary consequences would need to be addressed separately and treated as an additive factor in the overall value-impact assessment. The basis for the NRC's new conversion factor policy is provided in "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy", (to be published as NUREG-1530). Guidance on how the dollar per person-rem conversion factor is to be applied as well as guidance on valuing offsite property consequences will be included in the Handbook.

To provide meaningful summations, consistent with OMB guidance, all values and impacts, including public health and safety, are to be expressed on a present-worth basis. The principle for regulatory analysis is that future health effects should be valued the same as current effects and

[20] The $2000 per person-rem conversion factor will be subject to periodic review by the NRC based on changes to the underlying assumptions. The dollar per person-rem conversion factor will only be adjusted if changes in the underlying parameters cause the base conversion factor (when rounded to the nearest thousand dollars) to shift up or down by a thousand dollars or more. Any future change in the dollar per person-rem conversion factor will be noted in subsequent revisions to the Handbook.

present-worth techniques achieve this. For example, based on a given conversion factor, health and safety consequences are consistently valued at a fixed dollar value per person-cSv (person-rem). Thus, the monetary worth of a person-cSv (person-rem) averted is assigned a fixed value (in constant dollars) regardless of when the consequences occur in time. The present-worth calculation is simply determining how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future to avert a person-cSv (person-rem). By using present-worth, the health and safety effects, that is, person-cSv (person-rem), regardless of when averted in time, are valued equally.

Based on OMB guidance, present-worth calculations are to use the recommended discount rate specified in the latest version of OMB Circular A-94. This circular was most recently updated in October 1992, (Ref. 11) and specifies the use of a 7-percent real 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.

An alternative analysis, using a 3-percent real discount rate, should also be prepared for sensitivity analysis purposes. The base case, using for example OMB's currently recommended 7-percent rate, reflects recent economic conditions, yet NRC actions typically 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 (Ref. 12). A 3-percent rate is proposed for the alternative 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 or if the net value determination is significantly altered, this result should be discussed and placed in perspective for the decision maker.

For certain regulatory actions, such as those involving decommissioning and waste disposal issues, the regulatory analysis may have to consider consequences that can occur over hundreds or even thousands of years. For these reasons, and based on the technical literature, extended-time horizons make the appropriateness of using a relatively high interest rate for present-worth calculations questionable. When the timeframe exceeds 100 years, the analyst should avoid the use of a 7-percent real interest rate. In these instances, the 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 the latter case, no calculation of the resulting net value or value-impact ratio should be made. Further, the analyst may select another real rate as an additional option as long as sufficient justification is provided for use of that rate.

Finally, as a general principle, sensitivity or uncertainty analysis, or both, 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 typically would require computer simulations, while sensitivity analysis could be performed in an analytic manner. Should the sensitivity or 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 or uncertainty analyses are performed should reflect the magnitude and likelihood of values and impacts and their associated variability.

4.4 Presentation of Results

For each alternative considered, a net value calculation (summation of positive and negative attributes), as prescribed by OMB (Ref. 6,11), should be computed and displayed. The net value calculation requires, to the extent possible, that all values and impacts be quantified in present-worth monetary terms and added together (with the appropriate algebraic signs) to obtain the net value in dollars. In addition, the analyst may choose to display the results based on the ratio of values to impacts. This method of display is supplemental, however, and not a replacement for the net value method. Under the ratio method, the numerator reflects the sum of all quantifiable

present-worth estimates classified as values, while the denominator does likewise for impacts. Considerable care is required in calculating the ratio because statistical bias and differing results can occur, depending on the calculational approach employed. Although both presentation procedures may be used to clarify the results, the net value method is generally preferred because it provides an absolute measure of the aggregate net effect of the proposed action. Selecting the alternative with the largest net value is consistent with obtaining the largest societal gain from among the alternatives analyzed. The ratio, on the other hand, is a relative measure, particularly useful for prioritizing a large collection of proposed actions in the presence of a cost constraint. Under a cost constraint, independent actions are optimally selected by the largest ratios, continuing to add actions in descending order, until the cost constraint is obtained. The ACRS endorsed the view that the net value and ratio measures should both be a part of the decision process (Ref. 13).

OMB maintains that the regulatory analysis should select the regulatory alternative that achieves the greatest present value—the discounted monetized value of expected net benefits (i.e., benefits minus costs). (See Ref. 11.) OMB also notes that the ratio has characteristics that make its results potentially misleading.

> 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 (See Ref. 6).

Tabular and 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 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 regulatory 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 NRC may require compliance or adequate protection actions. 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 with important values that cannot be assigned monetary values or with uncertainties that are substantial. If the alternatives yield 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 State, local, or tribal governments 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), the results of that analysis should appear in this section of the regulatory analysis. A satisfactory finding relative to the proposed safety goal screening criteria is considered a prerequisite for achieving the substantial additional protection criteria of the backfit standard in 10 CFR 50.109(a)(3). 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 required by 10 CFR 50.109(a)(3) to show that there is a substantial increase in the overall protection of the public health and safety and that the costs of implementation are justified in view of this increased protection. A clearly positive finding with respect to the net value or value-impact ratio would normally satisfy this standard.

4.5 Decision Rationale for Selection of the Proposed Action

This section of the regulatory analysis should explain why the proposed action is recommended over the other alternatives considered. Taking no action should be considered an alternative except when the 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 following:

- The net value and 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 alternatives with the NRC's legislative mandates, safety goals, and policy and planning guidance that are in effect at the time the proposed alternative is recommended, and
- 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 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, and
- A statement on whether the proposed action is interim or final, and if interim, the justification for imposing the proposed requirement 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) 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 and their safety significance. If possible, a summary of the current backlog of existing related requirements awaiting implementation should be included. Regulatory actions should generally be scheduled in the order of their safety significance even if this means deferring the implementation of regulatory actions approved at an earlier date. An explanatory section should be included in the implementation section of the regulatory analysis document when the analysis recommends that the proposed action receive a higher implementation priority than actions previously approved. Any other information that may be considered appropriate with regard to priority, schedule, or cumulative impact should also be included.

The proposed implementation 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 should 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 burden 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 regulatory analyses to certain statutory procedural requirements applicable to the NRC and to information requests directed to licensees. The Paperwork Reduction Act (Section 5.1) and Regulatory Flexibility Act (Section 5.2) documentation are typically included as appendices to the regulatory analysis and they are discussed here for completeness. The other information requests and procedural requests (Sections 5.3 – 5.5) typically consider issues similar to those examined in regulatory analyses, and consequently, these Guidelines can prove useful in their development.

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 in NRC Management Directive 3.54, "Collections of Information and Reports Management" (Ref. 14) and in the Regulations Handbook (Ref. 17).

Whenever a proposed regulatory action identified under Section 4.5 of these Guidelines will probably involve information collections subject to OMB approval, a draft OMB clearance package is to 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,s)]: (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, or (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 the OMB disapproves an information collection, independent regulatory agencies such as the 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 3.54, "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, the NRC issued size standards to determine whether an NRC licensee would be considered a small entity for purposes of the Regulatory Flexibility Act (Ref. 15). On November 6, 1991, the NRC restated its size standards to clearly identify the different classes of licensees affected and the standard that is applied to each class of licensee (Ref. 16). Specifically, the NRC added the Regulatory Flexibility Act's definition of "small governmental jurisdiction" that was adopted by the NRC

but was 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 that 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 (1) is supported by a qualifying small governmental jurisdiction or (2) is not State or publicly supported and has 500 or fewer employees.

The NRC Regulations Handbook (Ref. 17) sets out procedural requirements for preparation of regulatory flexibility analyses. If a proposed rule would probably have a significant economic impact on a substantial number of small entities, a draft regulatory flexibility analysis must be prepared consistent with the NRC procedural requirements. 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, a certification to this effect must be included 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 in 10 CFR Part 51. The NRC Regulations Handbook (Ref. 17) contains additional information. When a generic or programmatic EIS has been prepared that forms the basis for a 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 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 NRC Office Director or Regional Administrator before issuance of the information request.

Section IV(B)(xi) of the CRGR Charter (Ref. 7) contains additional guidance for information requests affecting multiple nuclear power 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; and
- A statement affirming that the request does not impose new requirements on the licensee.

Section 0514-041 of NRC Manual Chapter 0514 (Appendix D in Ref. 9) discusses plant-specific information requests directed at individual nuclear power plants.

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 discussed in Section 2.3, a proposed backfit to one or more facilities regulated under 10 CFR Part 50 does not require a regulatory analysis if the resulting safety benefit is required for purposes of compliance or adequate protection under 10 CFR 50.109(a)(4). In these cases a documented evaluation must be prepared, including a statement of the objectives of and the reasons for the action along with the basis for invoking the exception. These requirements are stated at 10 CFR 50.109(a)(6). Additional guidance is in the Supplementary Information portions of the *Federal Register* notices for the final backfit rule (Refs. 18 and 19). As noted in Section 2.3, the concept of what constitutes adequate protection is determined case by case. Such determinations may change over time to reflect new information pertinent to whether improvements are needed to ensure adequate protection.

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

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Copies are available for inspection or copying for a fee from the NRC Public Document Room (PDR) at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; phone 202–634–3273; facsimile 202–634–3343.