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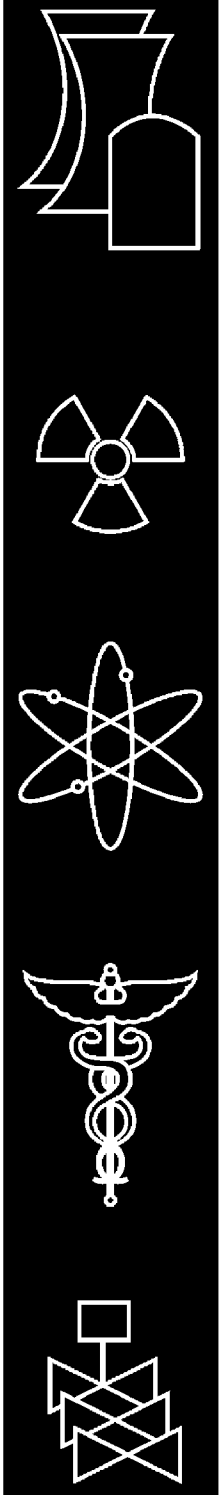

Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission

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

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ABSTRACT

The Regulatory Analysis Guidelines set forth the U.S. Nuclear Regulatory Commission's (NRC) policy 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. These include the use of a safety goal evaluation, which is intended to eliminate some proposed requirements from further consideration because the residual risk is already acceptably low, the use of a $2000 per person-rem conversion factor, and the use of criteria for the treatment of individual requirements.

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FOREWORD

The staff of the U.S. Nuclear Regulatory Commission (NRC) performs regulatory analyses to ensure that the agency makes sound decisions regarding actions needed to protect the health and safety of the public or the common defense and security. Toward that end, these highly structured and reasoned analyses ensure that the agency bases its decisions on adequate information, and that the staff arrives at its decisions by following a systematic and disciplined process that is also open and transparent, as follows:

- Identify the problem and associated objectives.
- Determine whether a proposed action is needed.
- Identify alternative courses of action to meet the stated objectives.
- Analyze the consequences of each identified alternative.
- Select a preferred alternative, and provide adequate justification for that action.
- Present a clear and well-documented explanation of why the NRC staff recommended the particular action.

The NRC staff performs regulatory analyses to support numerous regulatory actions that affect the agency's reactor and materials licensees:

- Regulatory analyses typically accompany rules, orders, bulletins, generic letters, regulatory guides, standard review plans, and standard technical specifications.
- Regulatory analyses are required for all regulatory actions that involve backfitting licensed facilities [subject to the backfit rule found in Title 10, Section 50.109, of the *Code of Federal Regulations* (10 CFR 50.109)].
- Regulatory analyses are required for all regulatory actions that impose generic requirements (subject to review by the Committee To Review Generic Requirements).

This document sets forth the NRC's policies for the development of regulatory analyses. This revision of the NRC's Regulatory Analysis Guidelines incorporates a new Commission policy concerning the treatment of individual requirements in regulatory analyses. This policy provides for a disciplined process to justify new requirements that are added in the course of developing risk-informed regulations. As such, this policy addresses concerns that bundling requirements into a single action could mask an individual requirement that is either unnecessary or unjustified (for example, when the net benefit from one requirement supports another requirement that is not cost-justified).

This revision of the Guidelines also includes changes to reflect the latest regulatory analysis guidance from the Office of Management and Budget. In addition, it discusses the NRC's treatment of uncertainty, in order to conform to the agency's Information Quality Guidelines.

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ABBREVIATIONS

ACRS	Advisory Committee on Reactor Safeguards
ASME	American Society of Mechanical Engineers
BPV	Boiler and Pressure Vessel Code (ASME)
BWR	boiling-water reactor
cSv	centisievert
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
E.O.	Executive Order
FR	*Federal Register*
Handbook	Regulatory Analysis Technical Evaluation Handbook
IRRAS	integrated reliability and risk analysis system
ISI	inservice inspection
IST	inservice testing
NEPA	National Environmental Policy Act
NRC	U.S. Nuclear Regulatory Commission
NUREG	NRC technical report designation
NUREG/BR	NUREG brochure
NUREG/CR	NUREG contractor report
OM	Operations and Maintenance Code (ASME)
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
U.S.C.	United States Code
UT	ultrasonic testing

1 INTRODUCTION

The U.S. 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 will aid the staff and the Commission in determining whether the proposed actions are needed, in providing adequate justification for the proposed action, and in documenting a clear 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 them in 1976. In preparing regulatory analyses, the NRC intends to ensure that its decisions that impose regulatory burdens on licensees are based on adequate information regarding the values and impacts associated with a reasonable set of alternatives, 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 the NRC before 1983 were termed value-impact analyses and followed the value-impact guidelines issued in SECY-77-388A, "Value-Impact Guidelines," on December 19, 1977 (Ref. 1). In February 1981, President Reagan issued Executive Order (E.O.) 12291 (Ref. 2) that directed executive agencies to prepare a regulatory impact analysis for all major rules and stated that regulatory actions should be based on adequate information concerning the need for and consequences of proposed actions. Moreover, E.O. 12291 directed that actions were not to be undertaken unless they resulted in a positive net value to society. As an independent agency, the NRC was not required to comply with E.O. 12291. However, the Commission noted that its established regulatory review procedures included an evaluation of proposed and existing rules in a manner consistent with the regulatory impact analysis provisions of E.O. 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 E.O. 12291. The NRC issued the original version of these Guidelines as NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," in January 1983 (Ref. 3).

In December 1983, the NRC issued "A Handbook for Value-Impact Assessment," NUREG/CR-3568 (Ref. 4). The 1983 handbook outlined systematic procedures for performing value-impact assessments. The NRC issued Revision 1 to NUREG/BR-0058 in May 1984 (Ref. 5) to include appropriate references to NUREG/CR-3568.

In September 1993, President Clinton issued E.O. 12866 (Ref. 6). 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. This Executive Order also revokes E.O. 12291. Except for certain planning functions in Section 4 of E.O. 12866, the NRC, as an independent agency, is not required to comply with E.O. 12866. Nevertheless, this fourth revision of the Guidelines reflects the intent of E.O. 12866, in part, because of the Commission's previously expressed desire to meet the spirit of Executive Orders related to regulatory reform and decisionmaking.

In November 1995, the NRC issued Revision 2 to the Guidelines (Ref. 7) 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, found in Title 10, Section 50.109, of the *Code of Federal Regulations* (10 CFR 50.109) (Ref. 8) and the "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," published in the *Federal Register* (51 FR 30028) on August 21, 1986 (Ref. 9), (3) advances and refinements in regulatory analysis techniques, (4) regulatory guidance for Federal agencies in E.O. 12866 (Ref. 6) and in issuances of the Administrative Conference of the United States (Ref. 10) and the Office of Management and Budget (OMB) (Refs. 11–13),[1] and (5) procedural changes designed to enhance the NRC's regulatory effectiveness.[2]

In January 1997, the NRC issued a "Regulatory Analysis Technical Evaluation Handbook," NUREG/BR-0184 (Ref. 16). This document, herein referred to as the "Handbook," expands upon policy concepts included in the Guidelines and provides data and methods to support the development of regulatory analyses.

In July 2000, the NRC issued Revision 3 to the Guidelines to address the NRC's policy concerning the treatment of industry initiatives in regulatory analyses (Ref. 17). This discussion appears in Section 4.3.1 of the Guidelines.

The NRC is issuing this fourth revision of the Guidelines to incorporate final criteria for the treatment of individual requirements in regulatory analyses, conforming changes based on OMB's Circular A-4 (Ref. 11), and additional discussion on the treatment of uncertainties in regulatory analyses.

The Commission's "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," issued in 1986 (Ref. 9), presents a risk-based philosophy for the NRC staff to use as part of its regulatory analysis process for proposed actions that may have an impact on commercial nuclear power reactors. The Commission's 1986 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 that 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, as part of 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 regulatory analysis process

[1]The OMB's Regulatory Impact Analysis Guidance (Ref. 12) 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 (Ref. 14).

[2]Certain regulatory actions are subject to the backfit rule (10 CFR 50.109) and to the analysis and information requirements of the Committee To Review Generic Requirements (CRGR). The 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. 15) 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.

for safety enhancement issues should address the safety goal analysis, discussed in Section 3 of this document, as early as possible.

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" (Ref. 18). These principles, which serve to guide the Agency's decisionmaking process, are independence, openness, efficiency, clarity, and reliability.

This document consists of five sections. Section 2 discusses the purpose and applicability of the Guidelines. The discussion includes information on when a proposed regulatory action must include a regulatory analysis, the role of a regulatory analysis in the NRC's decisionmaking process, and special requirements for proposed regulatory actions involving backfits of facilities subject to 10 CFR Part 50 (Ref. 8). Section 3 discusses the relationship of the NRC's safety goals for nuclear power plant operations to regulatory analyses. Section 4 presents the format of a regulatory analysis document, which includes summary guidance on estimating and evaluating the values and impacts of alternative regulatory actions, as well as selecting the proposed action. Section 4 also includes information 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 (Ref. 19) and the Regulatory Flexibility Act (Ref. 20).

2 DISCUSSION

2.1 Purpose of a 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 the following:

- The 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[3] 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 the NRC's decisionmaking that systematically provides complete disclosure of the relevant information supporting a regulatory decision. The process is to be used neither 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 decisionmaking by NRC managers and the Commission.

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[3]The Commission has stated that "substantial" means important or significant in a large amount, extent, or degree (Ref. 21). 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.

2.2 General Coverage

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. Executive Order 12866 (Ref. 6) requires that a regulatory analysis be prepared for all significant regulatory actions.[4] The NRC requires regulatory analyses for a broader range of regulatory actions than for significant rulemakings as defined in E.O. 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 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[5] 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) (Ref. 8) (discussed in Section 5.4 of this report) 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 (Ref. 8). Regulatory analyses are not necessary 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 the level of assessment that will demonstrate with sufficient reasonableness, that the two following conditions are satisfied:

[4]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."

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

(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 of this report 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.

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 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. 15).

The CRGR has the responsibility to review and recommend to the EDO approval or disapproval of proposed NRC requirements or staff positions that will impact more than one facility. The CRGR Charter specifies the 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 (e.g., an office director's finding and the General Counsel's concurrence).

Tables 2.2 and 2.3 of the Handbook identify backfit and CRGR information requirements, and show where those items should normally be discussed in the regulatory analysis. Further, all backfit and CRGR reporting requirements 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 Manual Chapter 0514, "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," issued August 1988 (Ref. 22). 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 NUREG-1409, "Backfitting Guidelines," issued July 1990 (Ref. 23).[6]

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 following three conditions, identified at 10 CFR 50.109(a)(4), applies:

(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

(ii) that regulatory action is necessary to ensure that the facility provides adequate protection[7] to the health and safety of the public and is in accord with the common defense and security

(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 these exception criteria, costs are not to be considered in 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 Manual Chapter 0514 (Ref. 22) for plant-specific backfits and in Section IV(B)(ix) of the CRGR Charter for generic backfits (Ref. 15).

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 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 decisionmaker.

[6]NRC Manual Chapter 0514 is included as Appendix D to NUREG-1409.

[7]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 the NRC's regulatory requirements.

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 decisionmaking. 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,[8] 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 the "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," published in August 1986 by the NRC (Ref. 9), 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 imposed generically 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 can also be used for determining whether the substantial added protection standard of 10 CFR 50.109(a)(3) is met (Ref. 8).

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 dated June 15, 1990, that "safety goals are to be used in a more generic sense and not to make specific licensing decisions" (Ref. 24).

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

The NRC 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.

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

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 appearing in Section 2.2 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 (see 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 of these Guidelines). Figure 3.1 depicts the 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 in Figure 3.1, 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 beyond the implementation guidance in Section 3.3 of these guidelines is included in Section 3 of the Handbook.

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 Implementation Guidance

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.

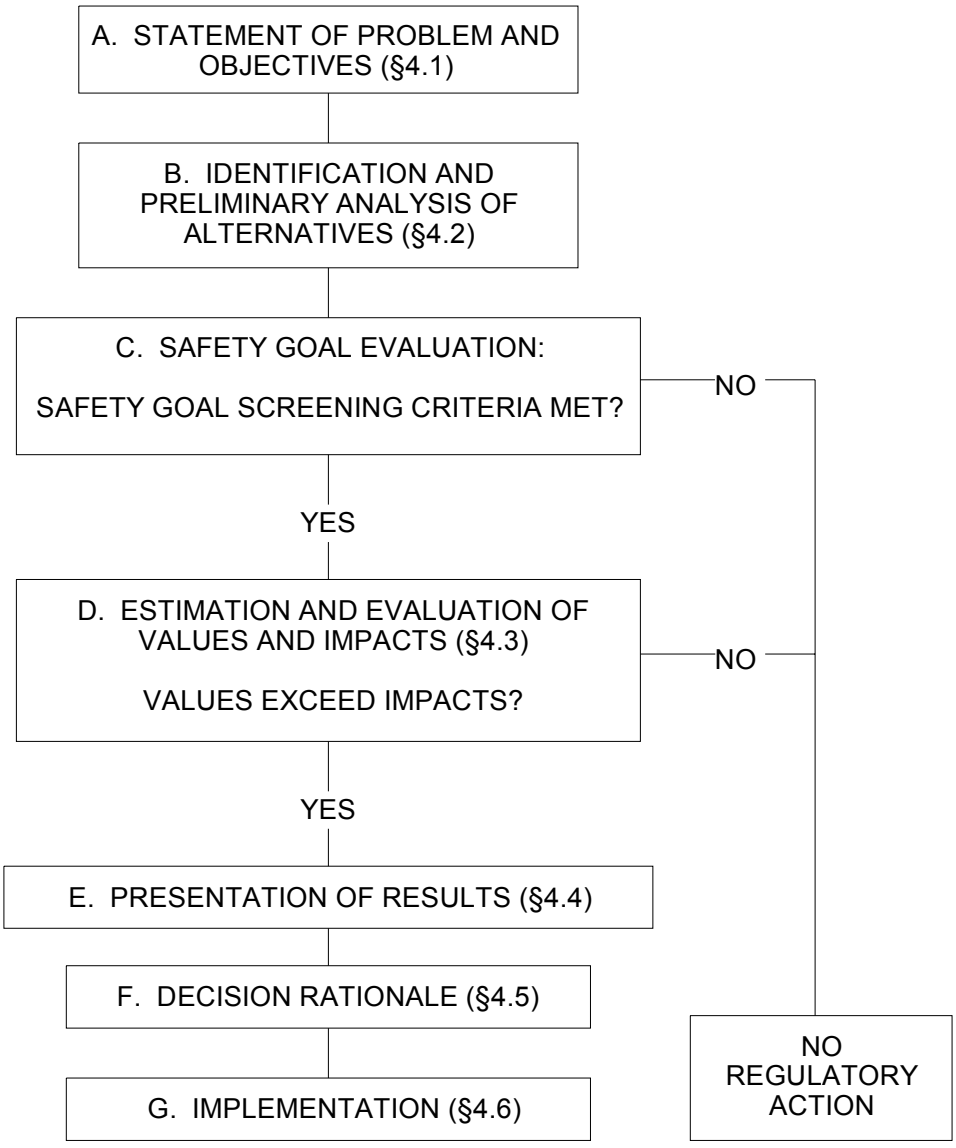

Figure 3.1 Regulatory Analysis for Nuclear Power Plant Cost-Justified Substantial Safety Enhancements

The NRC philosophy for safety goal evaluations involves the concept of defense-in-depth and a balance between prevention and mitigation. This traditional defense-in-depth approach and the accident mitigation philosophy require reliable performance of containment systems. The safety goal evaluation focuses on accident prevention, that is, on issues intended to reduce core damage frequency (CDF). 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 CDF[9] 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.

[9]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.

- The analysis should receive an independent review by staff knowledgeable and experienced in PRA, as well as 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, etc. 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 attempting to use these intermediate results in duplicating the calculation may not calculate exactly the same final results due to rounding errors.

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 (Ref. 8) and (2) is appropriate, considering the subsidiary safety goal[10] of 10^{-4} in mean CDF per reactor year.

In light of the inherent uncertainties of current PRA analysis, 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 CDF 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 in this document, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least $1x10^{-5}$ in the estimated mean value CDF (i.e., the CDF before the proposed regulatory change should exceed the CDF after the change by at least $1x10^{-5}$) 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

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

warranting regulatory attention. This does not mean that in all cases a proposed safety enhancement of at least $1x10^{-5}$ will subsequently prove to be justified for implementation after more detailed assessments are performed in accord with Section 4 of the Guidelines. 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 decides otherwise based upon strong engineering or qualitative justification (see Figure 3.2).

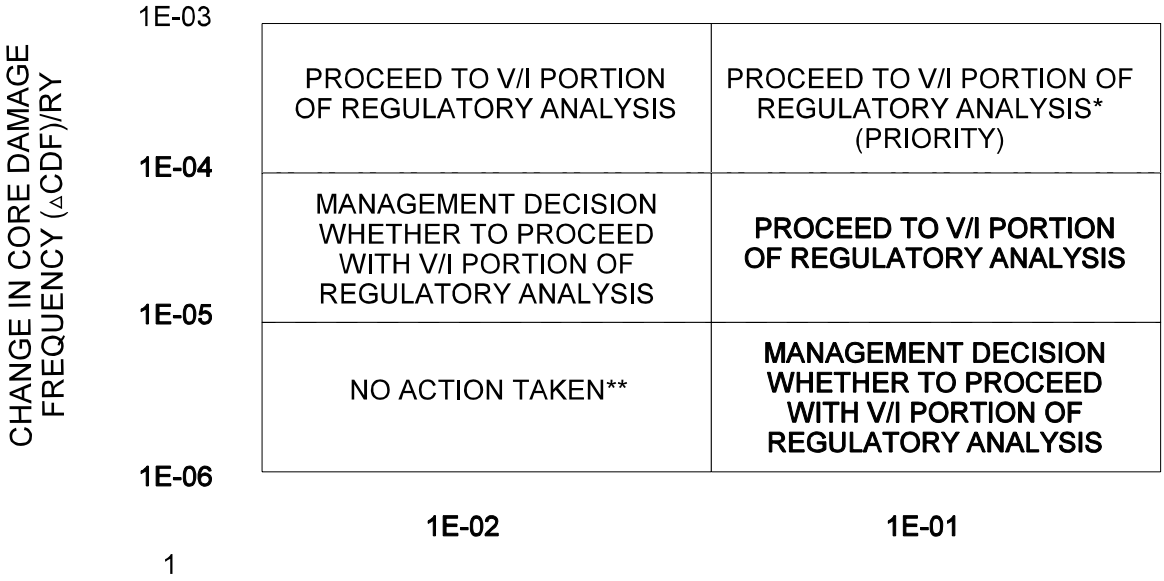

Figure 3.2 Safety Goal Screening Criteria

* 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).

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 $1x10^{-5}$/reactor year), the regulatory analysis should in general proceed only if an alternative justification for the proposed new requirement can be formulated. A 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 $1x10^{-5}$/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 CDF. 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).[11] The safety goal screening criteria shown in Figure 3.2 are subdivided to require greater staff emphasis on the higher valued (i.e., greater than 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 associated with those CPCFBs of less than 0.1.

The safety goal screening criteria provided in these Guidelines 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

[11]CPCFB in this context is the conditional probability of early containment failure or bypass given a core melt. In NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," issued 1991, 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" (Ref. 25). 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 4 hours after vessel breach, to permit initiation of accident management and emergency preparedness actions. It is not a goal being sought because the staff recognizes the benefits of prolonging containment failure in those scenarios that risk early failure.

- 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 nonnegligible, 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 in these Guidelines do not address issues that deal only with containment performance. Consequently, issues that have no impact on core damage frequency (ΔCDF 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 (Ref. 8). The initiative should then be assessed in accordance with Section 4.3 of these Guidelines (see Figure 3.1). If the net value calculation 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 the NRC Regulatory Analysis 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 (Ref. 16). 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 review by those outside the NRC, the staff should generally post the analysis, with all the supporting documents, on the Internet so the public can review the findings. A good analysis should be transparent and results must be reproducible. One should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. 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.

Because of its influential nature and its specific role in the rulemaking process, it is appropriate to set minimum quality standards for a regulatory analysis. The staff should provide documentation that the analysis is based on the best reasonably attainable scientific, technical, and economic information available. To achieve this, the staff should rely on peer-reviewed literature, when available, and provide the source for all original information. The staff is encouraged to have the regulatory analysis peer reviewed, and be able to attest that the regulatory analysis satisfies the NRC's Information Quality Guidelines (Ref. 26).

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[12]

(4) the immediacy of the need for a regulatory action and time constraints imposed by legislation or court decisions

(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 the NRC decisionmakers and other interested parties to easily recognize the following:

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

In theory, there may be instances when it would be beneficial for a regulatory analysis to include supplemental information (e.g., analyses and results that go beyond the guidance provided in these Guidelines). This might be the case, when, for example, the regulatory initiative is a “significant regulatory action” as defined in E.O. 12866 (see footnote 4) (Ref. 6), or of such policy import that a major controversy is likely to ensue. In OMB Circular A-4 (Ref. 11), additional regulatory analysis guidance is provided for such initiatives. Among other things, this additional guidance includes the use of a standardized accounting statement, cost-effectiveness analysis, incremental analyses of values and impacts, and the calculation of internal rates of return. In addition, it calls for both a more expansive treatment of monetized health and safety benefits and the characterization of key attributes that are not readily

[12]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.

quantified. This includes the use of shadow prices and willingness-to-pay measures to monetize attributes where no markets or imperfect markets prevail, and alternative health and safety measures that consider quality adjusted life years, equivalent lives, and non-fatal risks.[13] In reality, NRC initiatives rarely meet the high economic and policy thresholds of Circular A-4, and therefore, for most NRC regulatory analyses this level of analysis would not be required nor justified given the increased level of effort involved. Thus, rather than provide this more detailed guidance in this document, analysts are referred to Circular A-4 when a specific regulatory action satisfies OMB's high threshold standards.

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.

Many NRC initiatives are pursued because existing regulations are deemed insufficient to protect the public health and safety or the common defense and security. Therefore, relating the action to these concerns is important when defining the problem and objectives. However, from OMB's perspective, for many such regulatory initiatives, the underlying causative factor for governmental action is market failure, and OMB encourages acknowledging such a relationship when it is relevant. For the NRC, requirements that focus on health and safety improvements, including environmental improvements, can typically be attributed to a failure of private markets to account for externalities, which are uncompensated values or impacts that one party's actions impose on another party. For example, a licensee's operations may impose uncompensated residual risks and/or environmental damages on the public.

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 practical. 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 serves as the baseline and is central to the estimation of incremental values and impacts. Additional discussion is included in Section 4.3 of these Guidelines.

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., the 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:

[13] It is worth noting that the NRC's $2000 per person-rem conversion factor does account for nonfatal risks.

- a brief history of the problem and the outcome of past efforts (if any) to alleviate it
- any legislation or litigation[14] 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[15]
- 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., the NRC's Strategic Plan (Ref. 28))
- 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
- constraints or other cumulative impacts that work against solutions to the problem
- 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 of these Guidelines). 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

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

[15]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. 27) or other identified safety issues meriting NRC's attention.

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 are 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 (e.g., 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. In addition, if alternatives have been defined in terms of their inclusion or exclusion of individual requirements, the alternatives' elimination should be based on criteria for the treatment of individual requirements as discussed in Section 4.3.2. 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. Further guidance on implementation of performance-based requirements is available in NUREG/BR-0303, "Guidance for Performance-Based Regulation," issued December 2002 (Ref. 29).

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 E.O. 12866 (Ref. 6):

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 the 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 (e.g., children as a subset of the general population) may be necessary if the health and safety implications of the proposed action affect that segment of the general population differently or disproportionately. Under these circumstances and to the extent practical, separate estimates and evaluations of values and impacts and their associated

uncertainties, should be made for each distinct category. Such estimates and evaluations should include transfer payments (see Section 4.3.3). 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 4.3.2 and 4.3.3) 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.[16] The baseline is not to be confused necessarily with the status quo, as the baseline should reflect how the world would look absent the proposed action. Thus, if it is reasonable to assume a maturation of existing programs or other regulatory changes, the baseline should reflect the effects of these changes. As this can raise uncertainty when more than one baseline is reasonable and the choice of baseline will significantly affect estimated values and impacts, measuring consequences against alternative baselines should be considered. This approach is specifically recommended in treating industry initiatives and is discussed in detail in Section 4.3.1.

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.

Uncertainties are important to consider and need to be presented in a regulatory analysis. However, common sense needs to be applied in determining the level of effort to be given to the consideration and discussion of uncertainty. In general, the detail and breadth of the uncertainty analysis should be commensurate with the overall policy significance, complexity, and level of controversy, as well as the perceived importance of the uncertainties to the bottom line conclusion. Thus, to the extent practical, the sources and magnitudes of uncertainties in value and impact estimates should be discussed in the regulatory analyses. In addition, best available peer-reviewed studies, and data collected by accepted or best available methods, should be utilized and discussed. Specifically, expected values, expressions of uncertainty that can be presented in terms of upper- and lower-bounds, and studies, data, and methodologies that support or fail to support the value and impact estimates must, to the extent practical, be reported in the regulatory analysis. Hypothetical best- and worst-case values and impacts can also be estimated from sensitivity analyses. Sensitivity analysis can be used in addition to, or in

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

lieu of, formal uncertainty analysis. It 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.

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 nonpower 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 Treatment of Industry Initiatives in Estimation of Values and Impacts

Industry initiatives are typically actions performed by licensees that form the bases for either continued compliance with the regulations or obviate the need for new regulations. It must be clear to the public that substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, will in no way compromise plant safety, and does not represent a reduction in the NRC's commitment to safety and sound regulation. The NRC and the industry are jointly responsible for the long-term success of using industry initiatives as substitutes for NRC regulatory action. Licensees must effectively manage and implement their commitments associated with these industry initiatives and the NRC must provide a credible and predictable regulatory response if licensees fail to satisfy these commitments.

Industry initiatives can generally be put into one of the following categories—(1) those put in place in lieu of, or to complement, a regulatory action to ensure that existing requirements are met, (2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and (3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern. Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives.

The presence of industry initiatives is potentially very important in the estimation of values and impacts and, as such, its treatment in the regulatory analysis must be explicitly considered. All consequences of a proposed regulatory change are measured relative to the baseline, which is how things would be if the proposed regulation were not imposed. If industry initiatives which complement or substitute for a proposed regulatory action exist, the future role of these industry initiatives must be determined. This determination would affect the baseline, which in turn would affect the calculation of incremental values and impacts. For example, if "full credit" is given to industry initiatives (i.e., it is assumed that complementary industry initiatives will continue in the future), the incremental values attributable to the proposed regulation are diminished. Alternatively, if "no credit" is given, the incremental values assigned to the proposed rule are increased.

For the purposes of the regulatory analysis, value-impact results are to be calculated based, to the extent practical, on varied assumptions concerning the future role of industry initiatives. Initially, two sets of value-impact estimates are to be derived: one based on no credit and the other based on full credit for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes. If the overall value-impact result does not tilt from an overall net cost to an overall net benefit (or vice versa), there is no need to proceed further and the final results would be reported as a range of values that reflect the sensitivity of these results to this assumption. However, if the results are highly sensitive to that level of variation, such that the overall value-impact conclusion shifts or the final recommendation changes, the analyst would proceed to develop a "best-estimate" base case.

Under this best-estimate base case, the staff will evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. The NRC is currently developing guidelines designed to increase the NRC's assurance that industry initiatives will be effective long-term alternatives to regulatory actions. Clearly, the more an industry initiative satisfies these guidelines, the more credit one should give to the industry initiative. Before these guidelines are formally approved, the staff should rely on relevant features and characteristics of the industry initiatives to assess the weight or amount of credit to attach to any given industry initiative. Relevant characteristics would include the following:

- costs associated with the industry initiative (if the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal it is more likely the industry initiative will continue in the future)

- the extent to which written commitments exist (if written commitments exist it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative)

- the degree to which the industry initiative is noncontroversial and standard industry practice (if the industry initiative is noncontroversial and standard industry practice, as a function of consistency with provisions of industry codes and standards, the participation rate among relevant licensees, how long the program has been operating, or its effectiveness, the more likely it will continue without the rule change)

- the scope and schedule for industry initiatives that are still pending (for industry initiatives that are still works in progress, the more well defined the scope and the sooner the initiative is expected to be in place, the more likely it will be available in the future)

Based on such an assessment, the regulatory analysis would contain, to the extent practical, a best estimate of the values and impacts of the regulation under consideration. These results would serve as the basis for the staff's recommendations to the Commission. Careful attention is needed when PRA techniques are used to give partial or no credit to industry initiatives, because risk estimates from PRAs are based on existing conditions which typically include credit for any industry initiative that may be in place. When the PRA is modified to eliminate or reduce credit for industry initiatives, the reviewer needs to assure that these changes are properly reflected in the details of the PRA model.

4.3.2 Criteria for the Treatment of Individual Requirements

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is cost justified. However, aggregating or bundling different requirements in a single analysis could potentially mask the inclusion of an unnecessary individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second unnecessary requirement that is not cost justified. Similarly, in the case of other types of rules, including those subject to backfit analysis,[17] the net benefit from one requirement could potentially support another requirement that is not cost justified.[18]

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine if it is appropriate to include each individual requirement. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives[19] that are the focus of the regulatory initiative. Even though inclusion of individual requirements is necessary in this case, the analyst should obtain separate cost estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements.

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should adhere to the following guideline:

> If the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and

[17]"The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (NUREG/BR-0058) have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the Backfit Rule (10 CFR 50.109) (Ref. 8) and the provision of the CRGR Charter (Ref. 15).

[18]This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

[19]The stated objectives of the rule are those stated in the preamble (also known as the Statement of Consideration) of the rule.

benefits of the regulatory initiative with and without the individual requirement included, and a direct comparison of those results.[20]

In applying this guideline, the NRC will need to separate out the discrete requirements in order to evaluate their effect on the cost-benefit results. In theory, each regulatory initiative could include several discretionary individual requirements and each of those discretionary requirements could be comprised of many discrete steps, in which each discrete step could be viewed as a distinct individual requirement. This raises the potential for a large number of iterative cost-benefit comparisons, with attendant analytical complexities. Thus, considerable care needs to be given to the level of disaggregation that one attaches to a discretionary requirement.

In general, a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality. For example, more detailed disaggregation is only appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public comment stage.[21]

In some cases, an individual requirement that is being considered for inclusion in a voluntary alternative to current regulations may be justifiable under the backfit criteria. In these cases the individual requirement is both cost justified and provides a substantial increase in the overall protection of the public health and safety or the common defense and security. If so, the NRC should consider imposing the individual requirement as a backfit affecting all plants to which it applies, rather than merely including it in a voluntary alternative rule affecting only those plants where the voluntary alternative is adopted.

A special case involves the NRC's periodic review and endorsement of consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. These NRC endorsements can typically involve hundreds, if not thousands, of individual provisions. Thus, evaluating the benefits and costs of each individual provision in a regulatory analysis can be a monumental task. Further, the value gained by performing such an exercise appears limited. These consensus standards tend to be noncontroversial and have already undergone extensive external review and been endorsed by industry. Although regulatory actions endorsing these consensus standards must be addressed in a regulatory analysis, it is usually not necessary for the regulatory analysis to address the individual provisions of the consensus standards.

The NRC believes this is appropriate for several reasons:

[20]There may be circumstances in which the analyst considers including an individual requirement that is unrelated to the overall regulatory initiative. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory initiative more cost-beneficial. In those instances in which the individual requirement is a backfit, the requirement must be addressed and justified as a backfit separately. These backfits are not to be included in the overall regulatory analysis of the remainder of the regulatory initiative.

[21]See NUREG/BR-0053, Revision 5, "U.S. Nuclear Regulatory Commission Regulations Handbook" (Ref. 30), Section 7.9, for discussion of how to treat comments.

- It has been longstanding NRC policy to incorporate later versions of the ASME Code into its regulations; thus, licensees know when receiving their operating licenses that updating the ASME Code is part of the regulatory process.

- Endorsement of the ASME Code is consistent with the National Technology Transfer and Advancement Act (Ref. 31), inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking.

- These consensus standards undergo significant external review and discussion before being endorsed by the NRC.

Some aspects of these regulatory actions endorsing consensus standards are backfits which must be addressed and justified individually. For example, the NRC endorsement (incorporation by reference) of the ASME Boiler and Pressure Vessel (BPV) Code provisions on inservice inspection and inservice testing, and the ASME Operation and Maintenance (OM) Code, are not ordinarily considered backfits because of the NRC's longstanding policy to incorporate later versions of the ASME codes into its regulations. However, under some circumstances the NRC's endorsement of a later ASME BPV or OM Code is treated as a backfit. The application of the backfit rule to ASME Code endorsements is discussed in the appendix to these Guidelines. Aside from these backfits, these regulatory analyses should include consideration of the major features (e.g., process changes, recordkeeping requirements) of the regulatory action which should then be aggregated to produce qualitative or quantitative estimates of the overall burdens and benefits in order to determine if the remainder of the action is justified.

4.3.3 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 the following:

- reductions in public and occupational radiation exposure

- enhancements to health, safety, or the natural environment

- averted onsite impacts

- averted offsite property[22] 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

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

- 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 in which 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[23] 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 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.

[23]While the NRC's metrication policy statement (Ref. 32) 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.

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 decisionmaker 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.

4.3.4 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

(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 (Refs. 12, 13). 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 (e.g., a regulatory action with the sole impact of requiring 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.

4.3.5 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.[24] 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 with monetary consequences that 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 NUREG-1530, "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy," (Ref. 33). Guidance on how the dollar per person-rem conversion factor is to be applied as well as guidance on valuing offsite property consequences is 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

[24]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.

and 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 (i.e., person-cSv (person-rem)), regardless of when averted in time, are valued equally.

Based on OMB guidance, present-worth calculations should be presented using both 3 percent and 7 percent real discount rates (Ref. 11). The 3 percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7 percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. As the distribution of regulatory impacts on capital and consumption are not always well known, two sets of base case estimates should be developed and presented—one at 3 percent and one at 7 percent. The use of alternative discount rates as a further sensitivity analysis is appropriate as long as sufficient justification is provided for use of that rate.

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. The OMB recognizes that special considerations arise when comparing benefits and costs across generations. Under these circumstances, OMB continues to see value in applying discount rates of 3 and 7 percent. However, ethical and technical arguments can also support the use of lower discount rates. Thus, if a rule will have important intergenerational consequences, one should consider supplementing the analysis with an explicit discussion of the intergenerational concerns such as how future generations will be affected by the regulatory decision. Additionally, supplemental information could include a presentation of the values and impacts at the time in which they are incurred with no present-worth conversion. In this case, no calculation of the resulting net value or value-impact ratio should be made. Also, one should consider a sensitivity analysis using a lower, but positive discount 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 (Refs. 12, 13), 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. 34).

The OMB maintains that the regulatory analysis should select the regulatory alternative that achieves the greatest present value in terms of the discounted monetized value of expected net benefits (i.e., benefits minus costs) (Ref. 13). The 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 [Ref. 12].

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.

Further, in those instances in which nonquantified values or impacts are a dominant consideration (e.g., an enhancement to safeguards requirements), the analyst should consider conducting a threshold analysis to help decisionmakers understand the significance of these factors to the overall analysis. The threshold analysis answers the question, how small could the value of the nonquantified benefit be (or how large would the nonquantified costs need to be) before the proposed action would yield zero net benefits?

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 the 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 of these Guidelines), 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 at 10 CFR 50.109(a)(3) (Ref. 8). 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
- the impact of the proposed action on existing or planned NRC programs and requirements

This section of the regulatory analysis document should also include the following:

- 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

- 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 burdens imposed on licensees by multiple regulatory requirements. When appropriate, alternative schedules should be prepared.

The 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. The documentation required by the Regulatory Flexibility Act (Ref. 20) (Section 5.2) is typically included as an appendix to the regulatory analysis; documentation required by the Paperwork Reduction Act (Ref. 19) (Section 5.1), though not appended to the regulatory analysis, must be developed and approved in tandem with it. The remaining procedural requirements discussed here (Sections 5.3–5.5) typically involve issues closely related to those examined in the regulatory analysis.

5.1 Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 et seq.) (Ref. 19) 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 Manual Chapter 0230, "Collections of Information and Reports Management," issued July 1989 (Ref. 35), and in the NRC Regulations Handbook (Ref. 30).

Whenever a proposed regulatory action identified under Section 4.5 of these Guidelines will probably involve information collections subject to OMB approval, an OMB clearance package must be prepared for the rulemaking. While the OMB clearance package need not be included as part of the rulemaking package that is submitted to the EDO or Commission for approval, the clearance package must be approved by the OCIO for its submittal to OMB before the rule can be submitted to the Office of the Federal Register for publication. (See NRC Manual Chapter 0230 for guidance in preparing the OMB clearance package).

Agencies are required to obtain OMB approval for collections of information under any of the following conditions—(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 (5 CFR 1320.3(c) and 1320.5) (Ref. 36)).

OMB's criteria for approval of information collections are contained in 5 CFR 1320.5(d)(1). 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 1320.9(c) (Ref. 36)).

In the event that 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 1320.15). Procedures

for Commission override of an OMB disapproval are contained in NRC Manual Chapter 0230 (Ref. 35).

5.2 Regulatory Flexibility Act

The Regulatory Flexibility Act (Ref. 20) 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) (Ref. 37). The size standards used by the NRC to qualify a licensee as a small entity, codified at 10 CFR 2.810 (Ref. 38), are as follows:

- A small business is a for-profit concern providing a service with average gross receipts of $5 million or less over its last 3 completed fiscal years, or a manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

- A small organization is a not-for-profit organization that is independently owned and operated and has annual gross receipts of $5 million or less.

- A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district 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. 30) sets out procedural requirements for preparation of regulatory flexibility analyses. The NRC public Web site provides a summary of these procedures (Ref. 39). If a proposed rule would likely 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 and repeated in the final 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) (Ref. 40) 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)). The NRC procedures for implementing NEPA are in 10 CFR Part 51 (Ref. 8). The NRC Regulations Handbook (Ref. 30) 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. 15) 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 the following:

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

Section 0514-041 of NRC Manual Chapter 0514 (Appendix D to NUREG-1409 (Ref. 23)) 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 of these Guidelines 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 of these Guidelines, 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. 41, 42). 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.

6 REFERENCES

1. Nuclear Regulatory Commission (U.S.), "Value-Impact Guidelines," Commission Paper SECY-77-388A, December 19,1977.

2. Executive Office of the President, "Federal Regulation," Executive Order 12291, *Federal Register*, Vol. 46, No. 32, pp. 13193–13198, February 19, 1981. http://www.archives.gov/federal_register/codification/executive_order/12291.html

3. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 0, January 1983.

4. Nuclear Regulatory Commission (U.S.), "A Handbook for Value-Impact Assessment," NUREG/CR-3568, December 1983.

5. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 1, May 1984.

6. Executive Office of the President, "Regulatory Planning and Review," Executive Order 12866, *Federal Register*, Vol. 58, No. 190, pp. 51735–51744, October 4, 1993. http://www.archives.gov/federal_register/executive_orders/pdf/12866.pdf

7. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 2, November 1995.

8. Code of Federal Regulations, *Title 10*, *Energy*, Part 50, "Domestic Licensing of Production and Utilization Facilities," Sections 50.54, "Conditions of Licenses," 50.109, "Backfitting," 50.2, "Definitions"; Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"; Section 52.63, "Finality of Standard Design Certifications."

9. Nuclear Regulatory Commission (U.S.), "Policy Statement on Safety Goals for the Operation of Nuclear Power Plants," August 4, 1986. Corrected and reprinted at *Federal Register*, Vol. 51, No. 162, pp. 30028–30035, August 21, 1986. http://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf

10. Administrative Conference of the United States, "Agency Procedures for Performing Regulatory Analysis of Rules," (Recommendation No. 85-2, 1 CFR 305.85-2) and "Valuation of Human Life in Regulatory Decisionmaking" (Recommendation No. 88-7, 1 CFR 305.88-7). http://www.law.fsu.edu/library/admin/acus/305852.html, http://www.law.fsu.edu/library/admin/acus/305887.html

11. Office of Management and Budget, "Regulatory Analysis," Circular No. A-4, September 17, 2003. http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf

12. Office of Management and Budget, "Regulatory Impact Analysis Guidance," Appendix V to "Regulatory Program of the United States Government: April 1, 1992–March 31, 1993."

13. Office of Management and Budget, "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs: Guidelines and Discounts," Circular No. A-94, *Federal Register*, Vol. 57, No. 218, pp. 53519–53528, November 10, 1992. http://www.whitehouse.gov/omb/circulars/a094/a094.pdf

14. L. Panetta, Director, Office of Management and Budget, memorandum to heads of Executive Departments and Agencies and Independent Regulatory Agencies, "Guidance for Implementing E.O. 12866," October 12, 1993.

15. W. D. Travers, Executive Director for Operations, U. S. Nuclear Regulatory Commission, memorandum to the Commissioners, "Notification of the Revised Charter of the Committee to Review Generic Requirements," November 8, 1999.

16. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Technical Evaluation Handbook," NUREG/BR-0184, January 1997.

17. Nuclear Regulatory Commission (U.S.), "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 3, July 2000.

18. Nuclear Regulatory Commission (U.S.), "1990 NRC Annual Report," Volume 7, NUREG-1145, July 1991, p. 3.

19. *Paperwork Reduction Act of 1995*, 5 U.S.C. 3501 et seq. http://www.archives.gov/federal_register/public_laws/paperwork_reduction_act/3501.html

20. *Regulatory Flexibility Act of 1980*, as amended, 5 U.S.C. 601 et seq. http://www.sba.gov/advo/laws/regflex.html

21. S. Chilk, Staff Requirements Memorandum to J.M. Taylor and W.C. Parler, "SECY-93-086—Backfit Considerations," June 30, 1993.

22. Nuclear Regulatory Commission (U.S.), "NRC Program for Management of Plant-Specific Backfitting of Nuclear Power Plants," NRC Manual Chapter 0514, August 1988.

23. Nuclear Regulatory Commission (U.S.), "Backfitting Guidelines," NUREG-1409, July 1990.

24. Staff Requirements Memorandum to the EDO, "SECY-89-102-Implementation of the Safety Goals," June 15, 1990.

25. Nuclear Regulatory Commission (U.S.), "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," NUREG-1150, 1991.

26. Nuclear Regulatory Commission (U.S.), "NRC Information Quality Guidelines," *Federal Register*, Vol. 67, No. 190, pp. 61695–61699, October 1, 2002. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-24944-filed.pdf

27. Nuclear Regulatory Commission (U.S.), "A Prioritization of Generic Safety Issues," NUREG-0933 and supplements, August 1992. http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/

28. Nuclear Regulatory Commission (U.S.), "Strategic Plan: FY2004–FY 2009," NUREG-1614, Vol. 3, August 2004. http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v3/

29. Nuclear Regulatory Commission (U.S.), "Guidance for Performance-Based Regulations," NUREG/BR-0303, December 2002.

30. Nuclear Regulatory Commission (U.S.), "U.S. Nuclear Regulatory Commission Regulations Handbook," NUREG/BR-0053, Rev. 5, March 2001. http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0303/index.html

31. National Technology Transfer and Advancement Act, Pub. L. 104-113, 110 Stat. 775, 1995. http://ts.nist.gov/ts/htdocs/210/nttaa/113.htm

32. Nuclear Regulatory Commission (U.S.), "Policy Statement on Conversion to the Metric System," *Federal Register*, Vol. 57, No. 195, pp. 46202-46204, October 7, 1992. http://www.nrc.gov/reading-rm/doc-collections/commission/policy/61fr31169.pdf

33. Nuclear Regulatory Commission (U.S.), "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," NUREG-1530, December 1995.

34. P. Shewman, Advisory Committee on Reactor Safeguards, letter to J.M. Taylor, U.S. Nuclear Regulatory Commission, "Revised Regulatory Analysis Guidelines, November 12, 1992.

35. Nuclear Regulatory Commission (U.S.), "Collections of Information and Reports Management," NRC Manual Chapter 0230, July 1989.

36. Code of Federal Regulations, *Title 5*, *Administration*, Part 1320, "Controlling Paperwork Burdens on the Public," Sections 1320.4, "Coverage"; 1320.5, "General Requirements"; 1320.9, "Agency Certifications for Proposed Collections of Information"; 1320.11, "Clearance of Collections of Information in Proposed Rules"; and 1320.15, "Independent Regulatory Agency Override Authority."

37. Public access to budget data, 5 U.S.C. 603, (1974).

38. Code of Federal Regulations, *Title 10*, *Energy*, Section 2.810, "NRC Size Standards." http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/part002-0810.html

39. "Regulatory Flexibility Act Procedures," June 2003. http://www.nrc.gov/what-we-do/regulatory/rulemaking/flexibility-act.html

40. *National Environmental Policy Act of 1989*, as amended, 42 U.S.C. 4332 et seq. http://ceq.eh.doe.gov/nepa/regs/nepa/nepaeqia.htm

41. Nuclear Regulatory Commission (U.S.), “Revision of Backfitting Process for Power Reactors,” *Federal Register*, Vol. 50, No. 183, pp. 38097–38113, September 20, 1985.

42. U. S. Nuclear Regulatory Commission, “Revision of Backfitting Process for Power Reactors—Final Rule,” *Federal Register*, Vol. 53, No. 08, pp. 20603–20611, June 6, 1988.

For information on the availability of NRC documents in hard copy, contact the NRC Public Document Room (PDR) reference staff by emailing PDR@nrc.gov, or by calling 1-800-397-4209 or 301-415-4737 (TDD 1-800-635-4512, facsimile 301-415-3548). The PDR is located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland; the PDR’s mailing address is U.S. NRC, PDR, Mail Stop O1F13, Washington, DC 20555.

APPENDIX

GUIDANCE ON BACKFITTING RELATED TO ASME CODES

Title 10, Section 50.55a, of the *Code of Federal Regulations* (10 CFR 50.55a) requires nuclear power plant licensees to construct American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) Code Class 1, 2, and 3 components under the rules provided in Section III, Division 1, of the ASME BPV Code; inspect Class 1, 2, 3, Class MC, and Class CC components under the rules provided in Section XI, Division 1, of the ASME BPV Code; and test Class 1, 2, and 3 pumps and valves under the rules provided in the ASME Code for Operation and Maintenance of Nuclear Power Plants (OM) Code. From time to time, the NRC: amends 10 CFR 50.55a to incorporate by reference later editions and addenda of Section III, Division 1, of the ASME BPV Code; Section XI, Division 1, of the ASME BPV Code; and the ASME OM Code.

Section A. Incorporation by Reference of Later Editions and Addenda of Section III, Division 1 of ASME BPV Code

Incorporation by reference of later editions and addenda of Section III, Division 1, of the ASME BPV Code is prospective in nature. The later editions and addenda do not affect a plant that has received a construction permit or an operating license, or a design that has been approved because the edition and addenda to be used in constructing a plant are, by rule, determined on the basis of the date of the construction permit and are not changed, except voluntarily by the licensee. Thus, incorporation by reference of a later edition and addenda of Section III, Division 1, does not constitute a “backfitting” as defined in 10 CFR 50.109(a)(1).

Section B. Incorporation by Reference of Later Editions and Addenda of Section XI, Division 1, of the ASME BPV and OM Codes

Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV Code and the ASME OM Code affect the inservice inspection (ISI) and inservice testing (IST) programs of operating reactors. However, the backfit rule generally does not apply to incorporation by reference of later editions and addenda of the ASME BPV Code (Section XI) and OM Code for the following reasons:

- The NRC’s longstanding policy has been to incorporate later versions of the ASME codes into its regulations; thus, licensees know when receiving their operating licenses that such updating is part of the regulatory process. This is reflected in 10 CFR 50.55a, which requires licensees to revise their ISI and IST programs every 120 months to the latest edition and addenda of Section XI of the ASME BPV Code and the ASME OM Code incorporated by reference into 10 CFR 50.55a, that is in effect 12 months before the start of a new 120-month ISI and IST interval. Thus, when the NRC endorses a later version of a code, it is implementing this longstanding policy.

- ASME BPV and OM codes are national consensus standards developed by participants with broad and varied interests, in which all interested parties (including the NRC and utilities) participate. This consideration is consistent with both the intent and spirit of the backfit rule (i.e., the NRC provides for the protection of the public health and safety, and does not unilaterally impose undue burden on applicants or licensees).

- Endorsement of these ASME codes is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, ISI and IST by rulemaking.

Section C. Other Circumstances In Which the NRC Does Not Apply the Backfit Rule to the Endorsement of a Later Code

Other circumstances in which the NRC does not apply the backfit rule to the endorsement of a later code are as follows:

- When the NRC takes exception to a later ASME BPV or OM code provision, and merely retains the current existing requirement, prohibits the use of the later code provision, or limits the use of the later code provision, the backfit rule does not apply because the NRC is not imposing new requirements. However, the NRC provides the technical and/or policy bases for taking exceptions to the code in the Statement of Consideration for the rule.

- When an NRC exception relaxes an existing ASME BPV or OM code provision but does not prohibit a licensee from using the existing code provision, the backfit rule does not apply.

Section D. Endorsement of Later ASME BPV or OM Codes That Are Considered Backfits

There are some circumstances when the NRC considers it appropriate to treat as a backfit the endorsement of a later ASME BPV or OM code:

- When the NRC endorses a later provision of the ASME BPV or OM code that takes a substantially different direction from the currently existing requirements, the action is treated as a backfit. An example was the NRC's initial endorsement of Subsections IWE and IWL of Section XI, which imposed containment inspection requirements on operating reactors for the first time. The final rule dated August 8, 1996 (Volume 61 of the *Federal Register*, p. 41303 (61 FR 41303)), incorporated by reference in 10 CFR 50.55a the 1992 Edition with the 1992 Addenda of IWE and IWL of Section XI to require that containments be routinely inspected to detect defects that could compromise a containment's structural integrity. This action expanded the scope of 10 CFR 50.55a to include components that were not considered by the existing regulations to be within the scope of ISI. Because those requirements involved a substantially different direction, they were treated as backfits and justified under the standards of 10 CFR 50.109.

- When the NRC requires implementation of later ASME BPV or OM code provisions on an expedited basis, the action is treated as a backfit. This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expedited language. An example was the final rule dated September 22, 1999 (64 FR 51370), which incorporated by reference the 1989 Addenda through the 1996 Addenda of Section III and Section XI of the ASME BPV Code, and the 1995 Edition with the 1996 Addenda of the ASME OM Code. The final rule expedited the implementation of the 1995 Edition with the 1996 Addenda of Appendix VIII of Section XI of the ASME BPV Code for qualification of personnel and procedures for performing

ultrasonic testing (UT) examinations. The expedited implementation of Appendix VIII was considered a backfit because licensees were required to implement the new requirements in Appendix VIII before the next 120-month ISI program inspection interval update. Another example was the final rule dated August 6, 1992 (57 FR 34666), which incorporated by reference in 10 CFR 50.55a the 1986 Addenda through the 1989 Edition of Section III and Section XI of the ASME BPV Code. The final rule added a requirement to expedite the implementation of the revised reactor vessel shell weld examinations in the 1989 Edition of Section XI. Imposing these examinations was considered a backfit because licensees were required to implement the examinations before the next 120-month ISI program inspection interval update.

- When the NRC takes an exception to an ASME BPV or OM code provision and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code, it is treated as a backfit. An example of this is presented in the portion of the final rule dated September 26, 2002 (67 FR 60520), in which the NRC adopted dissimilar metal piping weld UT examination coverage requirements from those in the ASME Code.