UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 26, 2019

COMMISSION VOTING RECORD

DECISION ITEM: SECY-18-0042

TITLE: DRAFT FINAL NUREG/BR-0058, REVISION 5, "REGULATORY ANALYSIS GUIDELINES OF THE U.S. NUCLEAR REGULATORY COMMISSION"

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of July 26, 2019.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Russell E. Chazell
Acting Secretary of the Commission

Enclosures:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Svinicki
Commissioner Baran
Commissioner Caputo
Commissioner Wright
OGC
EDO
PDR

VOTING SUMMARY – SECY-18-0042

RECORDED VOTES

	APPROVED	DISAPPROVED	ABSTAIN	NOT PARTICIPATING	COMMENTS	DATE
Chrm. Svinicki		X			X	06/05/19
Cmr. Baran	X				X	05/07/19
Cmr. Caputo		X			X	06/05/19
Cmr. Wright		X			X	06/03/19

Notation Vote

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN SVINICKI

SUBJECT: SECY-18-0042: Draft Final NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission"

Approved ____ **Disapproved** XX **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** XX **Attached** _____ **None** _____

I appreciate the staff's diligent work in producing NUREG/BR-0058, Revision 5 and its enclosed appendices. The development of this revision was a significant undertaking. In light of the Commission's recently concluded action on SECY-18-0049 and the resultant revisions to Management Directive (MD) 8.4, however, I conclude that the Commission should return NUREG/BR-0058, Revision 5 and its appendices to the staff without prejudice and direct the staff to conform the NUREG to MD 8.4, as it now stands. The staff should return the NUREG, as further revised, to the Commission for its review and approval no later than six month from the date of the staff requirements memorandum arising from SECY-18-0042.

SIGNATURE

06/ 5 /19
DATE

Entered on "STARS" Yes ✓ **No** ___

Notation Vote

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Baran

SUBJECT: SECY-18-0042: Draft Final NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission"

Approved X **Disapproved** ____ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** X **Attached** X **None** ____

I approve publication of the revised guidance and accompanying *Federal Register* notice, subject to the attached edits.

Entered in "STARS"
Yes X
No ____

SIGNATURE

5/7/19
DATE

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

JMB edits

NUREG/BR-0058, Revision 5

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

Final Report

Office of Nuclear Material Safety and Safeguards

1 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) uses this guidance to evaluate, when appropriate, the costs and benefits of proposed regulatory actions to protect public health and safety, promote the common defense and security, and protect the environment. Before following this guidance, the NRC staff should determine as a threshold matter whether applying a new requirement to an already licensed facility is necessary for adequate protection of public health and safety. This will ensure that the staff does not impermissibly consider costs.

Cost-benefit ~~These~~ evaluations help the staff provide an adequate ~~justification~~ basis for the proposed action and document a clear explanation of why the proposed action was recommended. This guidance contains the 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 analysis is referred to as a cost-benefit analysis.[1]

The NRC staff has revised NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to accomplish three objectives. First, this revision consolidates the NRC cost-benefit analysis guidance of NUREG/BR-0058, Revision 4, issued September 2004, and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," issued January 1997, into one document. It also references the applicable portions of NUREG-1409, "Backfitting Guidelines." NUREG/BR-0058 provides cost-benefit guidance for NRC's regulatory analyses, backfit analyses, and National Environmental Policy Act (NEPA) reviews across NRC program offices. Second, this revision incorporates improvements in methods for assessing factors that are difficult to quantify and includes relevant best practices identified in Government Accountability Office (GAO)-09-3SP, "GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs," and recommendations from GAO-15-98, "NRC Needs To Improve Its Cost Estimates by Incorporating More Best Practices." Third, this revision incorporates NRC experience and improvements in uncertainty analysis, as well as Commission direction on cost-benefit analysis since the last revision to these documents.

Although the NRC is not required to conduct cost-benefit analyses, it voluntarily began performing them in 1976. In preparing cost-benefit analyses, the NRC ensures that decisions ~~imposing burdens on~~resulting in costs for licensees are based on adequate information about the costs and benefits associated with a reasonable set of alternatives. The NRC also follows a systematic and disciplined process that is open and transparent. The ultimate objective of this process is to ensure that all new requirements ~~burdens~~ are ~~justified~~ appropriate from a cost-benefit perspective and will achieve intended regulatory objectives. The NRC conducts a type of cost-benefit analysis as part of the regulatory review of ~~cost-justified substantial safety enhancements, as well as~~ safety, regulatory, and environmental analyses.

The cost-benefit analyses prepared by the NRC before 1983 were termed "value-impact" analyses and followed the value-impact guidelines in SECY-77-388A, "Value-Impact Guidelines," dated December 19, 1977. In February 1981, ~~President Ronald Reagan issued~~ Executive Order (EO) 12291, "Federal Regulation," ~~that~~ directed executive agencies to prepare

[1] In this NUREG, the term "problem" is intended to include not only identified safety or security problems, but also the potential for achieving a cost-beneficial substantial safety enhancement.

a cost-benefit impact analysis for all major rules and stated that cost-benefit actions should be based on adequate information about the need for and consequences of proposed actions. Moreover, EO 12291 directed that actions were not to be undertaken unless they resulted in a positive net value to society. As an independent agency, the NRC was not required to comply with EO 12291. However, the Commission noted that its established cost-benefit review procedures included an evaluation of proposed and existing rules consistent with the cost-benefit impact analysis provisions of EO 12291. The Commission determined that clarifying and formalizing its existing cost-benefit procedures for the analysis of cost-benefit actions would enhance the effectiveness of such actions and further meet the spirit of EO 12291. The result was ~~NRC issued~~ the original version of these guidelines as NUREG/BR-0058, issued in January 1983.

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

The Commission's policy statement on "Safety Goals for the Operations of Nuclear Power Plants," issued in 1986 (Volume 51 of the *Federal Register* [FR], page 30028 [51 FR 30028]; August 21, 1986), presents a risk-informed~~based~~ philosophy for the NRC staff to use in its regulatory analysis process for proposed actions that may affect 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~~ appropriate ~~as~~ safety enhancements applicable to more than one nuclear power reactor.

Specifically, application of this philosophy minimizes the number of occasions that resources are spent on conducting extensive regulatory analyses that ~~later~~ ultimately 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 regulatory changes ~~(i.e., backfits)~~ are warranted. Thus, the safety goal evaluation can reduce ~~truncate~~ the need for further analysis or consideration of proposed regulatory actions. Therefore, the regulatory analysis process for safety enhancement issues should address the safety goal analysis, discussed in Section 2.2 of this document, as early as possible.

In September 1993, ~~President Bill Clinton issued~~ EO 12866, "Regulatory Planning and Review~~.~~" was issued, revoking EO 12291. Section 1 of EO 12866 contained principles of regulation, and Section 6(a)(3) contained the elements of a cost-benefit analysis that are relevant to this guidance. ~~EO 12866 revokes EO 12291.~~ Except for certain planning functions in Section 4 ~~of EO 12866~~, the NRC, as an independent agency, is not required to comply with EO 12866, but~~.~~ ~~Nevertheless,~~ this guidance reflects the intent of the EO ~~12866~~, in part, because of the Commission's previously expressed desire to meet the spirit of Executive Orders related to cost-benefit reform and decisionmaking, when appropriate.

In November 1995, the NRC issued Revision 2 to NUREG/BR-0058 to reflect the following:

- the NRC's accumulated experience with implementing Revision 1 to NUREG/BR-0058

- changes in NRC regulations and procedures since 1984, particularly the promulgation of the backfit rule in Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting," and the publication of the Commission policy statement on safety goals for the operations of nuclear power plants in the *Federal Register* (51 FR 30028) on August 21, 1986

- advances and refinements in cost-benefit analysis techniques

- cost-benefit guidance for Federal agencies in EO 12866 and in issuances of the Administrative Conference of the United States and the Office of Management and Budget (OMB).[2]

- procedural changes designed to enhance the effectiveness of the NRC's cost-benefit analysis

In January 1997, the NRC issued NUREG/BR-0184. This guidance expands upon policy concepts and provides data and methods to support the development of cost-benefit analyses.

In July 2000, the NRC issued Revision 3 to NUREG/BR-0058 to address the NRC's policy for the treatment of industry initiatives in cost-benefit analyses, which is addressed in Section 5.3.1 of this document.

In September 2004, the NRC issued Revision 4 to NUREG/BR-0058 to incorporate criteria for the treatment of individual requirements in regulatory analyses, conforming changes based on OMB Circular A-4, "Regulatory Analysis," dated September 17, 2003, and additional discussion on the treatment of uncertainties in cost-benefit analyses.

In 2011, ~~President Obama issued~~ EO 13563, "Improving Regulation and Regulatory Review," was issued to ~~which~~ supplement~~s~~ and reaffirm~~s~~ EO 12866. This updated order explains that an agency "must…propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs." Additionally, EO 13783, "Promoting Energy Independence and Economic Growth," dated March 28, 2017, renews the Federal government's longstanding position that "necessary and appropriate environmental regulations comply with the law [and] are of greater benefit than cost, when permissible," and EO 13771, "Reducing Regulation and Controlling Regulatory Costs," dated January 30, 2017, states that "it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." ~~As stated earlier, the Commission has previously expressed desire to meet the spirit of EO's related to regulatory reform.~~

Additionally, in 2011, the accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion about how the NRC's regulatory framework considers offsite property damage and the associated economic consequences that would result from a significant radiological release from an NRC-licensed facility. In response to this discussion, on August 14, 2012, the NRC staff submitted SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," for

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[2] OMB's "Regulatory Impact Analysis Guidance" was based on EO 12291. Both EO 12291 and OMB's guidance were revoked by EO 12866, but OMB advised Federal agencies to continue to follow the regulatory impact analysis guidance for estimating benefits and costs, pending OMB's review of any potential changes to be made in the guidance pursuant to EO 12866. As a result, the NRC incorporated cost-benefit guidance from OMB's "Regulatory Impact Analysis Guidance" in Revision 2 to NUREG/BR-0058.

Commission consideration. The purpose of SECY-12-0110 was to give the Commission information and options to address the extent, if any, to which the NRC's regulatory framework should be modified when addressing the economic consequences of a significant radioactive release to the environment. In developing SECY-12-0110, the staff examined areas of the regulatory framework, including the guidance and tools that consider economic consequences, and identified potential changes to the framework.

In the March 20, 2013, staff requirements memorandum (SRM) in response to SECY-12-0110, the Commission ~~approved the agency's current approach to the issue of land contamination from reactor accidents and~~ approved the staff's plan for enhancing the currency and consistency of the existing framework through updates to cost-benefit guidance documents. The Commission also found that economic consequences should not be treated as equivalent in regulatory character to matters of adequate protection of public health and safety. This revision to NUREG/BR-0058 responds, in part, to this Commission direction (SRM-SECY-12-0110).

1.1 Purpose

The purpose of this guidance is to aid the NRC regulatory analyst (~~the~~ "analyst") in preparing high-quality regulatory decisionmaking documents and to implement the provisions of the NRC guidelines. Regulatory decisionmaking documents include regulatory analyses, backfit analyses, and NEPA environmental review analyses.

The guidance has several goals:

- Help the analyst understand how current NRC policy impacts are captured in a regulatory decisionmaking document.

- Incorporate changes in policy and advances in methodology that have occurred since the issuance of the 2004 NRC regulatory analysis guidelines. The NRC and other agencies have conducted considerable research on various aspects of regulatory decisionmaking. Also, staff experience has resulted in significant modifications to the regulatory decisionmaking documents. These advances have been incorporated into this guidance.

- Provide one ~~cost-benefit~~ guidance document—NUREG/BR-0058, Revision 5—for cost-benefit analyses that may contribute to regulatory, environmental, or backfit analyses.

Varying degrees of permissive language are used throughout this guidance. The terms are defined as follows:

- "may" = permissive
- "must"= required
- "should" = guidance
- "can" = capability

1.2 Scope of Regulatory Decisionmaking Documents

Most NRC regulatory actions require some form of analysis and supporting documentation. This section discusses the scope of the particular type of analysis termed a "regulatory decisionmaking document."

1.2.1 Regulatory Analysis

~~All mechanisms the NRC proposes to use to establish or communicate requirements, guidance, requests, or staff positions, with generic applicability, that would effect a change in the use of resources by NRC licensees should include supporting information that the benefits of the action justify the costs that would be expended.~~

A regulatory analysis is an integral part of NRC decisionmaking. It is important that the regulatory analysis process begin as soon as it becomes apparent that some type of regulatory action is needed to address an identified problem.

1.2.2 Backfit Analysis and Issue Finality

When the NRC proposes a change in requirements for a facility protected by regulation from certain changes applicable to its licensed activities, this is referred to as a backfit. The NRC's policy is to have an effective program that will ensure that proposed backfitting actions to be imposed on nuclear power reactor licensees, new power reactor licensees,[3] and selected nuclear materials licensees are appropriately ~~justified~~ analyzed on the basis of the backfitting provisions of applicable NRC regulations and the Commission's backfitting policy and guidance.

In 10 CFR 50.109, backfitting for a nuclear power reactor is defined as the modification of or addition to systems, structures, and components (SSCs), or the design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position after certain dates. For select nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, "Backfitting"; 10 CFR 72.62, "Backfitting"; and 10 CFR 76.76, "Backfitting," are slightly different. The term "backfit" is not ~~normally~~ used in discussions relevant to new power reactors licensed under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants"; instead, the related term "issue finality" is used. In this guidance, the NRC uses the terms "backfit" and "backfitting" as general terms to mean backfits as defined in 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 and ~~violations~~ inconsistencies ~~with~~of issue finality matters under 10 CFR Part 52. Applicants for a nuclear power reactor renewed license under 10 CFR Part 54 have similar protections as backfitting~~, due to the limitation in scope of the NRC's review of the application~~.

The NRC's policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities (NRC, 1995b) includes the statement that, where appropriate, PRA should be used to support a proposal for additional regulatory requirements, in accordance with 10 CFR 50.109. Certain requirements specific to a backfit analysis are identified at

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[3] The term "new power reactor licensees" is used here as a general term that refers to a variety of applicants and licensees: holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), and manufacturing licenses; applicants for design certifications (DCs) whose designs are certified in final design certification rules; applicants for COLs if the application references an ESP, design certification rule, or SDA; and applicants for manufacturing licenses if the application references a design certification rule or SDA.

10 CFR 50.109(a)(3) and 10 CFR 50.109(c). These requirements are identified in Table 1-1 and at appropriate parts of the guidance. Table 1-1 also cites where in the CFR each requirement is located and indicates where in the regulatory analysis the discussion of each item should appear. The analyst must be sure to address the 10 CFR 50.109 requirements in the backfit analysis.

Certain regulatory actions are subject to the requirements of 10 CFR 50.109 and to the review of the Committee to Review Generic Requirements (CRGR), and the analyses and information requirements within the CRGR Charter.[4] The NRC intends that, for these actions, the analysis performed in accordance with this guidance will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter (NRC, 2011a) 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. However, a backfit analysis does not rely solely on the safety goal screening criteria to support a staff determination of a "substantial increase in overall protection."

If the proposed regulatory action falls within the scope of the CRGR (as set out in the CRGR Charter), the information requirements identified in the Charter and in this guidance should be incorporated into the backfit analysis. A proposed backfitting action involving a new or amended generic requirement or staff position to be imposed on one or more classes of nuclear power reactor licensees or materials licensees (to the extent directed by NRC management) will ordinarily require CRGR review.

[4] Revision 9 of the Charter for the Committee to Review Generic Requirements can be accessed via ADAMS Accession No. ML17355A532

Table 1-1 Checklist for Specific Backfit Analysis Requirements

CFR Citation[a] (Title 10)	Information Item To Be Included in a Backfit Analysis	Section of the Regulatory Analysis Where Item Should Normally Be Discussed
50.109(a)(3)	Basis and a determination that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for the affected facilities are ~~justified~~ warranted in view of this increased protection	Basis—Presentation of Results Determination—Decision Rationale
50.109(c)	Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility	Implementation
50.109(c)(1)	Statement of the specific objectives that the proposed backfit is designed to achieve	Statement of the Problem and Objectives
50.109(c)(2)	General description of the activities that would be required by the licensee or applicant to complete the backfit	Identification of Alternatives
50.109(c)(3)	Potential change in the risk to the public from the accidental offsite release of radioactive material	Estimation and Evaluation of Values and Impacts
50.109(c)(4)	Potential impact on radiological exposure of facility employees	Estimation and Evaluation of Values and Impacts
50.109(c)(5)	Installation and continuing costs associated with the proposed backfit, including the cost of facility downtime or construction delay	Estimation and Evaluation of Values and Impacts
50.109(c)(6)	Potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements	Estimation and Evaluation of Values and Impacts
50.109(c)(7)	Estimated resource burden on the NRC associated with the proposed backfit and the estimated availability of such resources	Estimation and Evaluation of Values and Impacts Availability—Implementation
50.109(c)(8)	Potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit	Presentation of Results Implementation
50.109(c)(9)	Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis	Decision Rationale
50.109(e)	The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director or his/her designee~~Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility~~	Implementation

[a] Similar provisions detailing what information is to be contained in a backfit analysis are in 10 CFR 70.76; 10 CFR 72.62; and 10 CFR Part 76, "Certification of Gaseous Diffusion Plants," and, for issue finality, 10 CFR Part 52. These provisions should be considered, as appropriate, when considering backfit-related matters for licensees who have strategic nuclear material above a critical mass, independent spent fuel storage installations and the monitored retrievable storage installations, gaseous diffusion plants, and new reactors, respectively.

1.2.3 National Environmental Policy Act Review

NEPA requires Federal agencies to prepare a "detailed statement for major Federal actions significantly affecting the quality of the human environment" (42 U.S.C. 4332). The essential purpose of NEPA is to ensure that environmental factors are given due consideration in decisionmaking by Federal agencies. NRC regulations for implementing NEPA are in 10 CFR Part 51. In its implementation of NEPA, the NRC staff should ensure that a decision is informed by a thorough evaluation of the expected environmental impacts that precedes the agency's decision. The NRC must assess the environmental impact of each proposed and final rulemaking action and include a statement about the environmental impact in the supplementary information section of the preamble to each rulemaking. The procedural requirements for considering the environmental impact of a rulemaking action are described in NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook," issued September 2005 (NRC Regulations Handbook).

The Commission discussed the relationship between cost-benefit analyses and NEPA in *Louisiana Energy Services* (Claiborne Enrichment Center), CLI-98-03, 47 NRC 77 (1998): "Although the statute itself does not mandate a cost-benefit analysis, NEPA is generally regarded as calling for some sort of a weighing of the environmental costs against the economic, technical, or other public benefits of a proposal. The EIS need not, however, always contain a formal or mathematical cost-benefit analysis" (internal citations omitted). Further, the Commission explained that "NRC regulations direct the Staff to consider and weigh the environmental, technical, and other costs and benefits of a proposed action and alternatives, and, 'to the fullest extent practicable, quantify the various factors considered.' If important factors cannot be quantified, they may be discussed qualitatively." (CLI-98-03, quoting 10 CFR 51.71(d)).

1.2.4 Details of Cost-Benefit Guidance

In analyses for proposed materials and reactor regulatory actions, the analyst should include a cost-benefit analysis. The analyst should account for several aspects, including determining the appropriate method and the consideration and identification of the various attributes of cost-benefit analysis. Attributes are the principal components of a cost-benefit assessment used to characterize the consequences of a proposed action. These attributes range from public health to environmental considerations. Other aspects include the quantification of the attributes, consideration of labor rates, present value, and the various discount rates. Chapter 5 of this guidance provides the details needed by the analyst to conduct a comprehensive cost-benefit analysis.

1.3 Regulatory Relaxations

A regulatory analysis is generally required for a proposed relaxation to ensure that it is warranted ~~adequate justification~~. However, the safety goal evaluation process set out in Section 2.4 of this guidance is not applicable to proposed relaxations. If the relaxation is mandatory, then the backfit rule requirements in 10 CFR 50.109 apply.

For all regulatory analyses of proposed relaxations, the decision rationale section (see Section 2.3.5) should present information about the following findings:

- The public health and safety and the common defense and security would be adequately protected if the proposed relaxations were implemented.
- The cost savings would be sufficient to provide a reasonable basis for ~~justify~~ the action.
- The proposed relaxation is optional or mandatory for affected licensees.

As previously discussed in this guidance, the NRC voluntarily complies with the spirit of EO 12866, and in fact, the NRC requires regulatory analyses for a broader range of regulatory actions than just "significant regulatory actions" as defined in EO 12866. In general, each NRC office should ensure that the mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would effect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to regulatory actions that may be initiated by the NRC, from a petition to the NRC, or as a result of industry initiatives. These mechanisms include rules, generic communications, cost-benefit guidance, orders, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, NUREG publications, and standard technical specifications that establish, modify, or withdraw staff positions or guidance for applicants or licensees.

In ~~some~~ certain circumstances, regulatory analyses may be eliminated or performed in a more limited capacity. For example, regulatory analysis requirements for a given action may be waived or modified at the discretion of the Commission, the Executive Director for Operations (EDO), a Deputy Executive Director, or the ~~responsible~~ cognizant NRC Office Director. ~~A~~ One factor that could influence this decision is the degree of urgency associated with the regulatory action ~~(e.g., NRC bulletins and orders may need to be issued without regulatory analyses)~~. In other ~~regulatory applications~~cases, ~~case~~ specific circumstances could ~~justify the preparation of~~ provide a reasonable basis for a more limited regulatory analysis.

For certain regulatory actions, a less detailed cost-benefit analysis may be ~~is~~ sufficient because the proposed changes are of smaller magnitude. These actions include the issuance of generic communications, regulatory guides, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, some NUREG publications, standard technical specifications, and other documents that provide guidance for applicants or licensees. In general, regulatory analysis should be limited only in terms of the depth of discussion and analysis, and not in the reduction of the scope of the regulatory analysis ~~and not~~or in the need to ~~justify~~ provide a reasonable basis for the proposed action.

Generic actions (i.e., actions that affect all, several, or a class of licensees) that may not need a regulatory analysis include notices, policy statements, and generic communications 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) require a specific ~~justification statement~~analysis and are reviewed by the CRGR when directed to one or more classes of nuclear power reactors; however, these requests do not require the type of regulatory analysis discussed in this guidance because they do not impose requirements. New requirements affecting certified nuclear power plant designs will be ~~justified~~ considered through a notice-and-comment rulemaking process, as specified in 10 CFR 52.63, "Finality of Standard Design Certifications." Regulatory analyses may not be necessary for requirements arising out of litigation if an adverse ruling specifies only one method to achieve a specified outcome.[5]

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 that the two following conditions are satisfied:

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[5] In litigation, an adverse ruling may require a specific outcome with only one possible method for compliance. In such a case, cost would not be a factor because there is only a single means to achieve the specific outcome imposed by the adverse ruling, so a regulatory analysis would not be necessary. In contrast, if there are multiple ways of achieving a specific outcome imposed by an adverse ruling, a regulatory analysis would be performed to determine the costs and benefits of each alternative.

(1) Public health and safety and the common defense and security would be adequately protected if the proposed relaxation in requirements or positions were implemented.

(2) The cost savings would be sufficient ~~to~~ to provide a reasonable basis for ~~justify~~ the action.

For all proposed or requested relaxations (including those affecting nuclear power plants), the staff should prepare supporting documentation that gives the basis for concluding that the two conditions listed above will be satisfied. ~~In justifying a proposed relaxation s~~The staff should 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. Proposed or requested regulatory actions that would relax or reduce current requirements should give the licensee the option of whether to take advantage of the relaxation and should not be mandatory. For these voluntary relaxations of requirements, the backfit rule and the safety goal evaluation process and screening criteria are not applicable. ~~However, for all proposed relaxations (including those affecting nuclear power plants), the staff should prepare supporting documentation that gives the basis for concluding that the two conditions listed above 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.~~

When the NRC relaxes or reduces requirements, licensees may choose to voluntarily maintain elements that were previously required. However, a calculation of the cost savings should be based on the assumption that all licensees will take advantage of the change.

2.1 Level of Detail

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

(1) the complexity and policy significance of the particular problem being addressed

(2) the magnitude and likelihood of costs and benefits

(3) the relative amount by which projected benefits exceed costs

(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 EDO, or an NRC Office Director

Approximately 300 hours are sufficient for preparing many regulatory analyses. When larger levels of effort (taking up to a year or more) may be involved, this guidance suggests additional methods and references that can be used. ~~These could entail major efforts of up to a year or more.~~

For the type of information supplied and the level of detail provided, the emphasis should be on simplicity, flexibility, and common sense. The level of treatment given to a particular safety

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 should be sufficiently clear and give sufficient detail to enable the NRC decisionmakers and other interested parties to easily recognize the following:

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

In some instances, it may be beneficial for a regulatory analysis to include supplemental information ~~(e.g., analyses and results~~ that go beyond the guidance in this document~~)~~. This might be the case when, for example, the regulatory action is a "significant regulatory action" (~~e.g.,~~ greater than $100 million annually) as defined in EO 12866 or of such policy importance that considerable public interest is likely. OMB Circular A-4 gives additional regulatory analysis guidance for such initiatives. Among other things, this additional guidance includes the use of a standardized accounting statement, a cost-effectiveness analysis, incremental analyses of costs and benefits, and the calculation of net present value using discount rates. 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 quantified. This includes the use of shadow prices and willingness-to-pay (WTP) measures to monetize attributes where no markets or imperfect markets prevail, and the use of alternative health and safety measures that consider quality-adjusted life years, equivalent lives, and nonfatal risks. ~~In practice~~As a general matter, NRC regulatory actions rarely meet the high economic and policy thresholds of OMB Circular A-4. Therefore, for most NRC regulatory analyses, this level of analysis would not be required ~~or justified~~, given the increased level of effort involved. Rather than provide more detailed guidance in this document, ~~analysts are referred to~~ OMB Circular A-4 should be consulted when a specific regulatory action exceeds these thresholds.

The variety of NRC licensees and potentially disparate sets of available information can add complexity to these analyses. The NRC regulates each phase of the nuclear fuel cycle (except for traditional mining), including nuclear fuel fabrication and dry storage of spent fuel, as well as materials used for medical, industrial, and academic purposes. The information and considerations used in regulatory analyses for these activities are likely to be different than those used for power reactors.

It should be recognized that many benefits of improved regulation are not quantifiable. ~~For example, increased confidence in the margin of safety may be a qualitative benefit of a~~

proposed regulatory requirement. As noted in Appendix A, "Qualitative Factors Assessment Tools," qualitative factors can be significant elements of a regulatory analysis and should be appropriately considered by the analyst and decisionmaker.

2.2 Safety Goal Analysis

Assessing the risk of potential changes to public safety has always been a fundamental part of regulatory decisionmaking. As PRA technology has advanced since the mid-1970s, the NRC staff has applied insights and results from risk assessment in conducting its regulatory activities. The NRC's policy statement on safety goals for the operations of nuclear power plants (NRC, 1986) reflects an example of this change. It defines both qualitative goals and quantitative objectives that can be used to guide regulatory decisionmaking.

The safety goal evaluation is intended to determine whether the residual risk is already acceptably low such that a regulatory requirement should not be imposed generically on nuclear power plants. The intent is to eliminate some proposed requirements from further consideration independently of whether they could be justified supported by a regulatory analysis on their net-value basis. The safety goal evaluation can also be used as one factor in determining whether the substantial additional protection standard of 10 CFR 50.109(a)(3) is met.

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

The NRC safety goal policy addresses a level of acceptable residual individual risk from the operation of nuclear power reactors judged to be lower than the risk level associated with adequate protection. The risk level associated with adequate protection is that level above which continued operation would not be allowed. The following discussion provides guidance on when a safety goal evaluation is required in a regulatory analysis and the sequence in performing the safety goal evaluation.

2.2.1 When a Safety Goal Evaluation Is Needed

The safety goal evaluation, as discussed in this section, is required for 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, for purposes of only the regulatory analysis, that the substantial additional protection standard is met for the proposed new requirement.

As discussed in Section 1.3 of this guidance, voluntary requests to the NRC for relaxations of requirements affecting nuclear power plants are not backfits and thus do not fall within the scope of the backfit rule. Additionally, relaxations of requirements affecting nuclear power plants are not subject to the safety goal evaluation requirements. Nevertheless, a relaxation of requirements is subject to a regulatory analysis and, specifically, to the criteria in Section 1.3 of this guidance. In When justifying considering a proposed backfit under the backfit rule, the burden is on the staff to make a positive showingshould ensure that a generic safety problem actually exists and that the proposed backfit both effectively addresses the problem effectively and provides a substantial safety improvement in a cost-beneficial manner unless the proposed backfitting action meets one of the exceptions in 10 CFR 50.109(a)(4).

2.2.2 Safety Goal Analysis Determination

~~The staff should first determine whether a regulatory action needs to consider safety goals. Section 2.2.1 provides guidance for making this determination.~~ If the proposed regulatory action meets the safety goal screening criteria (see Section 2.4 for a detailed description of the safety goal evaluation process), the regulatory analysis should include the results of the safety goal evaluation. Figure 2-1 shows the steps performed in a regulatory analysis, including the safety goal evaluation. The figure includes cross-references to the appropriate sections of a regulatory analysis related to that element. Depending on the results of steps C and D in Figure 2-1, the regulatory analysis may be terminated with no regulatory action taken. In performing steps C and D, a PRA (see Figure 2-2 for a primer on PRA) should be used to quantify the risk reduction and corresponding values of the proposed new requirement.

The NRC recognizes, however, that not all regulatory actions are amenable to a quantitative risk assessment and that certain evaluations may be based directly on engineering, regulatory judgment, or qualitative analysis. ~~Section 2.4 gives a more detailed description of the safety goal evaluation procedure.~~

2.3 Elements of a Regulatory Analysis

This intent of this section of guidance is to presents the specific elements to be addressed in a regulatory analysis. ~~The intent of this guidance is~~ to ensure uniformity ~~in the elements included in a regulatory analysis~~. A regulatory analysis consists of six elements:

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

(2) identification and preliminary analysis of alternative approaches to address the problem, including the no action alternative

(3) estimation and evaluation of costs and benefits for selected alternatives, including consideration of the uncertainties affecting the estimates

(4) presentation and summary of results, including the conclusion of the evaluation of costs and benefits and, when appropriate, the safety goal evaluation

(5) the decision rationale for selecting the proposed regulatory action

(6) 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, list of acronyms, and references.

Regulatory analyses are reviewed within the NRC and made publicly available. Reviewers include NRC technical staff and managers, as well as formal groups such as the CRGR and the Advisory Committee on Reactor Safeguards. 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 non-NRC stakeholders, the staff typically posts the analysis, with all the supporting documents, as publicly-available documents in the Agencywide Documents Access and Management System (ADAMS) ~~to allow public access to the analyses~~. A good analysis is transparent, with ~~reproducible~~ results that can be reproduced. The assumptions, methods, data underlying the analysis, and discussion of the uncertainties associated with the estimates should be provided. Information obtained from outside the NRC~~, including that from parties interested in a proposed regulatory action,~~ may be used in the regulatory analysis after the staff has validated the reasonableness of the information.

Because regulatory analyses are influential and have a specific role in the agency's rulemaking process, the NRC has established minimum quality standards. The staff should provide documentation to show that the analysis is based on the best reasonably attainable scientific, technical, and economic information available, quantified when possible. The staff should rely on peer-reviewed literature, when available, and provide the source for all original information. Further, the staff is encouraged to have the regulatory analysis peer reviewed and to be able to attest that it satisfies the six elements outlined in the "NRC Information Quality Guidelines" (NRC, 2002a).

The following sections address each of the six elements in detail.

2.3.1 Statement of the Problem and Objective

This element allows the analyst to document the details of the problem and its background, boundaries, significance, and objective.

The statement of the problem consists of several factors. A concise description of the problem or concern includes (1) the basis for the problem statement (e.g., a series of equipment failures during operation or a major incident that reveals an inherent design weakness), (2) the fundamental nature of the problem (e.g., inadequate design, inadequate inspection or maintenance, operator failure, failure to incorporate adequate human factors), and (3) a description of the affected entities.

Defining problem boundaries entails deciding the scope of the regulatory analysis. Systems, equipment, and operational activities at licensed facilities are highly interrelated, and there are typically many ways of viewing any one problem. Consider, for example, the failure of a particular type of valve that serves two different safety-related coolant injection systems while also serving as a containment isolation valve. The problem resulting from a failure of the valve can be viewed as a systemic problem for either of the injection systems or for the isolation valve system, or it could be viewed as part of a larger problem, such as inadequate maintenance or an inadequate quality assurance program.

The analyst should identify other proposed or ongoing NRC programs that may overlap or otherwise interface with the problem ~~under consideration~~being evaluated. The analyst should confer with knowledgeable staff for the identified programs to determine appropriate boundaries. The regulatory analysis document should also identify interfacing programs to facilitate communication between related programs.

The objective statement is a concise statement of the improvement sought by the proposed action. The objective should be as specific as possible. ~~For example, precluding a fire from disabling redundant safety systems or reducing the probability of component failure to some particular level would be acceptably specific.~~ Some elaboration may be required to demonstrate how the objective would resolve the problem.

Background of the Problem

The background discussion should include the following, as applicable:

- a brief history of the problem and the outcome of past efforts (if any) to resolve it
- any statutes or court decisions[6] that directly or indirectly addresses the problem ~~(e.g., the Firearms Guidelines in 74 FR 46800, revised in 79 FR 36100)~~
- 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 to which the immediate problem is part of a larger ~~problem~~issue

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

- ~~the relationship of the problem to other ongoing studies or actions (e.g., the NRC's generic safety issues [NRC, 2011b])~~

- the objectives of the proposed new or revised requirement and the relationship of the objectives to the 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) (NRC, 2014a)~~

- the relationship of the problem to formal positions adopted by national and international standards organizations

- the identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness

- any constraints or other cumulative impacts that pertain to the problem

- the draft papers in development or other underlying staff documents supporting the requirements or staff positions

2.3.2 Identification and Preliminary Analysis of Alternative Approaches

Identifying and evaluating alternative approaches to resolve problems ~~is a~~are key element~~s~~ in meeting the NRC's regulatory analysis policy.

Developing a set of alternative approaches early in the ~~analysis~~ process maintains objectivity and prevents premature conclusions from being drawn.

The initial set of alternatives should be broad and comprehensive but should also be sufficiently different to provide meaningful comparisons and to represent the spectrum of reasonable possibilities. Alternatives that are minor variations of each other should be avoided. Taking no action should be viewed as a viable alternative, except in cases where action has been mandated by legislation or a court decision. If an additional viable ~~new~~ alternative is identified after analysis has begun, it should be added to the list of alternatives and treated in the same manner as the original alternatives.

Once a broad and comprehensive list of alternatives has been developed, a preliminary analysis of the feasibility, benefits, and cost of each alternative should be performed to narrow the list ~~to only viable alternatives~~. Some alternatives may be eliminated based on ~~clearly exorbitant~~disproportionate costs in relation to benefits, technological infeasibility, ~~severe~~ significant enforcement or implementation problems, or other obvious considerations. Reduction of the list of alternatives at this point in the analysis will preserve resources needed to perform a detailed evaluation of the costs and benefits of viable alternatives. The cost-benefit analysis document should list all alternatives identified and considered and give a brief rationale for eliminating certain alternatives during the preliminary analysis.

The level of analytical detail in the preliminary screening of alternatives need not be the same for all alternatives, particularly when one alternative can be shown to be clearly inferior or superior to the others. Rough estimates of costs and benefits should be made using simple analyses. If several alternative actions are considered, comparisons can be based on the expected net benefit of each.

The analyst should estimate the significance of the problem using the rough estimates as well as guidance provided by the Commission, the EDO, or the appropriate NRC Office Director. The level of detail to be provided in the regulatory analysis document and the amount of effort ~~to be made~~expended in performing the regulatory analysis should be commensurate with the significance of the problem, which also informs the priority assigned to its resolution.

Alternative regulatory documents that could be used to address regulatory concerns should also be identified at this time. The most common forms of documents include regulations, policy statements, orders, generic communications, standard review plans, and regulatory guides. Alternatives could include issuance of new documents or revision or deletion of existing ones. Other means of implementation ~~means~~ should be considered ~~when~~ as appropriate ~~(e.g., submission of proposed legislation to Congress)~~.

Regulatory document alternatives should only be subjected to detailed regulatory analysis if a preliminary assessment indicates significant differences in the costs or benefits among such alternatives. For certain types of regulatory actions, a limited regulatory analysis may be appropriate. Otherwise, the means of implementing the proposed action should be discussed in the implementation section of the regulatory analysis document ~~covering implementation~~.

For alternatives that meet preliminary screening and ~~that~~ require a backfit analysis according to 10 CFR 50.109(a)(3), a general description of the activities that would be required by the licensee or license applicant to complete the backfit should be prepared at this point in the cost-benefit analysis process.

The alternative approaches that remain after the preliminary analysis is completed should be subjected to a detailed evaluation ~~according to~~as outlined in the guidance. Alternative instruments will be subjected to detailed regulatory analysis only if the preliminary analysis indicates that significant differences among these alternatives exist.

When appropriate, the analyst should consider including specific rule provisions for the analyzed alternative. Adding the details allows the readers to track specific OMB supporting statements required by the Paperwork Reduction Act (44 U.S.C. 3501) and also aids the OMB desk officer and stakeholders. These details can be provided in the regulatory analysis.

2.3.3 Estimation and Evaluation of Costs and Benefits

The NRC analyst should ~~make every effort to~~ use quantitative attributes relevant to the cost-benefit analysis to the extent practicable. The quantification should employ monetary terms ~~whenever~~ if possible. Dollar benefits should be defined in real or constant dollars (i.e., dollars of constant purchasing power). If monetary terms are not ~~in~~appropriate, the analyst should strive to use other quantifiable benefits. However, despite these ~~analyst's best~~ efforts ~~at quantification~~, there may be some attributes that cannot be readily quantified. These attributes are termed "qualitative" and are handled separately from the quantitative attributes (see Appendix A).

Estimates are made for those attributes that lend themselves to quantification using standard techniques. Obtaining the appropriate data may be more complicated for a major effort. For cases in which a proposed action would result in significantly different attribute measures for different categories of licensees, separate estimates and evaluations should be made for each

distinct category ~~(e.g., older plants and newer plants)~~ (see Appendix B, "Cost Estimating and Best Practices").

Qualitative factors should also be evaluated. While these may be difficult to compare with the quantitative attributes, a consistent approach in their evaluation can result in a useful comparison among competing alternatives.

Depending on the level of effort, the analyst should perform either sensitivity or uncertainty analyses to estimate the results of variations in input parameters. Hypothetical best and worst case consequences may be estimated for sensitivity analyses. The output from the sensitivity analyses is used to determine the importance of various parameters and to approximate the uncertainties associated with the results. Actual uncertainty analyses should be more rigorous. Several techniques are available, each with differences in the usefulness of results and the amount of resources required. Uncertainty analyses should produce actual probability distributions for the overall results, based on assumed distributions for selected input parameters. Appendix C, "Treatment of Uncertainty," discusses the differences between sensitivity and uncertainty analyses and their respective roles in the cost-benefit analysis.

The analyst should complete the estimation and evaluation of costs and benefits for each alternative evaluated.

2.3.4 Presentation and Summary of Results

The following items should be included in the section of the regulatory analysis document that presents the results for each alternative:

- presentation of the estimated net monetized benefit (i.e., the algebraic sum of the attributes) using the discount rate procedures
- estimates of costs and benefits for each attribute ~~for~~ of each alternative
- presentation of any attributes quantified in nonmonetary terms in a manner to facilitate comparisons among alternatives
- distribution of estimated costs and benefits among affected entities
- discussion of key assumptions and the results of sensitivity analyses or uncertainty analyses

The analyst should define assumptions used in the regulatory analysis so that all readers can evaluate its~~the~~ rigor ~~of the results~~. All regulatory analyses should discuss the sources and magnitudes of uncertainties in ~~attribute~~ the estimates and the methods used to quantify sensitivity or uncertainty estimates.

For alternatives projected to result in significantly different costs and benefits for different categories of licensees, separate evaluations should be made for each distinct category. In cases where significant differences exist, their distributions with respect to the various groups involved should be discussed.

Table 2-1 Summary Table Template for Presenting Regulatory Analysis Results

Net Monetary Savings (or Costs) Net Present Value	Comments
Alternative 1: No Action $0	In this section of the table, the analyst should discuss qualitative costs and benefits and special considerations for each alternative. *Qualitative Benefits* Subject of Qualitative Benefit 1: Discussion of qualitative benefit . . . Subject of Qualitative Benefit n: Discussion of qualitative benefit *Qualitative Costs* Subject of Qualitative Cost 1: Discussion of qualitative cost . . . Subject of Qualitative Cost n: Discussion of qualitative cost Special Considerations
Alternative 2: Provide Title **Industry:** $x.xx million using a 7-percent discount rate $x.xx million using a 3-percent discount rate **NRC:** $x.xx million using a 7-percent discount rate $x.xx million using a 3-percent discount rate **Agreement States/Other Entities:** (if appropriate) $x.xx million using a 7-percent discount rate $x.xx million using a 3-percent discount rate **Total:** $x.xx million using a 7-percent discount rate $x.xx million using a 3-percent discount rate	*Qualitative Benefits:* Subject of Qualitative Benefit 1: Discussion of qualitative benefit . . . Subject of Qualitative Benefit n: Discussion of qualitative benefit *Qualitative Costs* Subject of Qualitative Cost 1: Discussion of qualitative cost . . Subject of Qualitative Cost n: Discussion of qualitative cost Special Considerations

This summary table gives a uniform format for recording the results of the evaluation of all quantitative attributes, plus a comments section to discuss qualitative attributes and special considerations. It displays the results for the net-value measure.

All dollar measures should be expressed in terms of the base year. This may require the conversion of some future dollar values to the base year. The gross domestic product price deflator can be used to convert historical nominal dollars to base year dollars.

When recording estimates for an attribute, the analyst should refer to Appendix B on cost estimating, as well as best practices, for further guidance.

In cases where important costs or benefits are difficult to quantify, alternatives that yield equivalent benefits may be evaluated, based on their cost effectiveness. This methodology should also be used when the levels of benefits are specified by statute. See Appendix A and Appendix C for further guidance on the use of qualitative factors and treatment of uncertainty, respectively.

2.3.5 Decision Rationale

This element of the regulatory analysis provides the basis for selecting the preferred alternative. In selecting the preferred alternative, decision criteria are used and reported in the regulatory analysis document. This element gives the minimum set of decision criteria to be used, as well as other considerations.

The net-benefit calculation is a compilation of all attributes that can be quantified in monetary terms. Certain attributes are generally quantified in other than monetary terms (e.g., public health impacts from an accident, which is measured in person-rem of exposure) and converted to monetary terms with an established conversion factor (see NUREG-1530, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy"). These attributes are included in the net-benefit calculation. To aid the decisionmaker, the net benefit is to be ~~computed~~ determined for each alternative.

In considering the net benefit, the analyst should take care in interpreting the significance of the estimate. An algebraically positive monetized estimate would indicate that the action has an overall beneficial effect; a negative monetized estimate would indicate the reverse. However, if the net benefit is only weakly positive or negative, minor errors or uncertainties could easily change the sign of the net benefit.

If the net benefit is calculated to be strongly positive or negative (i.e., variations in the assumptions or data would be much less likely to affect the sign of the net benefit), the result can be given considerable significance. Other considerations may inform the decision supported by the net benefit, such as ~~(e.g.,~~ qualitative factors~~, such as those embodied in the "qualitative" attributes~~).

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) (OMB, 1992). 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 (OMB, 1993).

~~Qualitative attributes can only be factored into the decision in a subjective way.~~ Descriptions of qualitative attributes should be performed at a level that is commensurate with the importance of the attribute to the proposed action. Nonquantifiable attributes that address a significant part of the purpose of the action should be presented in greater explanatory detail than attributes that are ancillary to the purpose of the action. See Appendix A and Appendix C for further guidance on the use of qualitative factors and treatment of uncertainty, respectively.

In addition to being the "best" alternative, based on monetary and nonmonetary considerations, the selected alternative must be both within the NRC's statutory authority and, when applicable, consistent with the NRC's safety goals and policy. A showing of ~~acceptable~~ reasonable costs of the proposed action on other existing and planned NRC programs and requirements is also necessary. This will ensure that there are no negative safety impacts in other areas, that NRC resources are being used responsibly, and that all actions are adequately planned and coordinated. Any other relevant criteria may be used with adequate documentation in the regulatory analysis.

2.3.6 Implementation

An implementation schedule for the proposed action should be prepared. The schedule should identify all major steps or actions to be taken by all affected parties (the NRC, Agreement States, licensees, and any others) and the dates or amounts of time allocated to accomplish each step. The schedule should be realistic and allow sufficient time for such factors as needed analyses, approvals, procurement, installation and testing, and training. Anticipated downtime of licensee facilities to implement the proposed action should be specifically identified. The analysis should address the availability and lead time required for the acquisition and installation of new equipment and replacement parts. For NRC planning purposes, short- and long-term actions are to be clearly differentiated.

The implementation section of the regulatory analysis document should also identify the proposed NRC process (e.g., rule, regulatory guide, policy statement) for implementing the proposed action and the reasons for selecting the proposed process. The relationship of the proposed action to other NRC programs, actions, and requirements, both existing and proposed, should be established. To the extent possible, the analyst should assess the proposed action's effects on the priorities of other actions and requirements as well as the potential need to revisit other regulatory analyses.

2.4 Safety Goal Evaluation for Operation of Nuclear Power Plants

The safety goal evaluation is intended to determine whether the residual risk is already acceptably low such that a regulatory requirement should not be imposed generically on nuclear power plants. The intent is to eliminate some proposed requirements from further consideration independent~~ly~~ of whether they could be ~~justified by~~ warranted based on a regulatory analysis ~~on their net-value basis~~.

When performing a safety goal evaluation, the analyst should be aware of any previous or ongoing safety improvements that have the potential to affect the status quo risks associated with the issues being addressed. Because there is not a formal process for accounting for the potential dependencies between issues, the analyst should resort to a "best effort" approach, such as public outreach, to identify and account for preexisting or concurrent impacts. The analyst should identify any previous or ongoing safety improvements that may affect the issue

being evaluated. For example, an analyst addressing proposed improvements to diesel generator performance at power reactors should be aware of any diesel generator improvements or alternate power supplied by other means (e.g., FLEX mitigating strategies) already addressed in station blackout considerations. To the extent possible, the analyst should modify the PRA model of the representative plant to reflect the upgraded status quo from these other safety improvements. The analyst can then evaluate the difference between this new status quo and the proposed improvements being considered.

2.4.1 Implementation Guidance

In summary, safety goal evaluations are based on 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 standard in the backfit rule and applied to 10 CFR 50.109 analyses associated with substantial safety enhancements, wherein the estimated costs of the implementation are ~~justified~~ compared to ~~in view of~~ the estimated safety improvement.

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

The NRC's philosophy for safety goal evaluations involves the concept of defense in depth and a balance between prevention and mitigation (NRC, 1986). This traditional defense-in-depth approach and the accident mitigation philosophy require the 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 to use when relatively poor containment performance results in the need for greater consideration of issues and associated accident sequences.

2.4.1.1 Prevention of Core Damage Accidents—Comparison with Subsidiary Goal for Mean Core Damage Frequency of $1x10^{-4}$ 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 per reactor year needs to be evaluated and addressed in the regulatory analysis. CDF is defined as "the sum of the accident sequence frequencies of those accident sequences whose end state is core damage," where core damage is defined as "sufficient damage that could lead to a release of radioactive material from the core that could affect public health" (NRC, 2013c). The objective is to ensure that ~~emphasis is placed on~~ preventing core damage accidents is a primary consideration.

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 should be identified and justified as representative of the class. For example, if the class of affected plants is a subset of boiling-water reactors (BWRs), one or more PRAs from individual plant examination (IPE) submittals or from those that have otherwise been conducted for the subset of BWRs should be selected. NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," issued December 1997, gives the staff's summary of all IPE submittals, and NUREG-1742, "Perspectives Gained from the Individual Plant Examination of External Events (IPEEE) Program," issued April 2002, has a similar summary of all IPEEE submittals. These references provide CDF and conditional containment failure probability information for the fleet of operating nuclear power plants in the 1990s. More recent PRAs indicate that a significant reduction in mean internal events CDF has been realized at both the level of individual nuclear power plants and as an average across all operating plants in the U.S. nuclear industry since the completion of the IPE and IPEEE studies. However, the trend over time for the contribution to CDF from external events is more difficult to discern because of a variety of factors, including changes in the external hazard profile for regions of the United States and nuclear power plant sites located within them and changes in the maturity of external hazards PRA technology (i.e., methods, models, data, and analytical tools used to assess the external hazards risk contribution). The analyst can obtain more recent CDF information for the existing fleet of operating nuclear power plants from various data sources, depending on the scope of the regulatory analysis and data source access restrictions. Examples of more recent sources of CDF information include (1) internal NRC Standardized Plant Analysis Risk (SPAR) model databases, (2) reports that document the results of severe accident mitigation alternatives (SAMA) analyses, and (3) the Institute of Nuclear Power Operations Consolidated Events System database (proprietary), which is used as a data source for estimating the plant-specific Mitigating Systems Performance Index for risk-informed decisionmaking in the Reactor Oversight Process. The top portion of Table 2-2 shows PRA-related information compiled from SAMA analyses that were conducted for nuclear power plant license renewal environmental reviews. The NRC documented this information in plant-specific supplements in NUREG-1437, Revision 1, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," issued June 2013, for operating plants that have applied for license renewal.

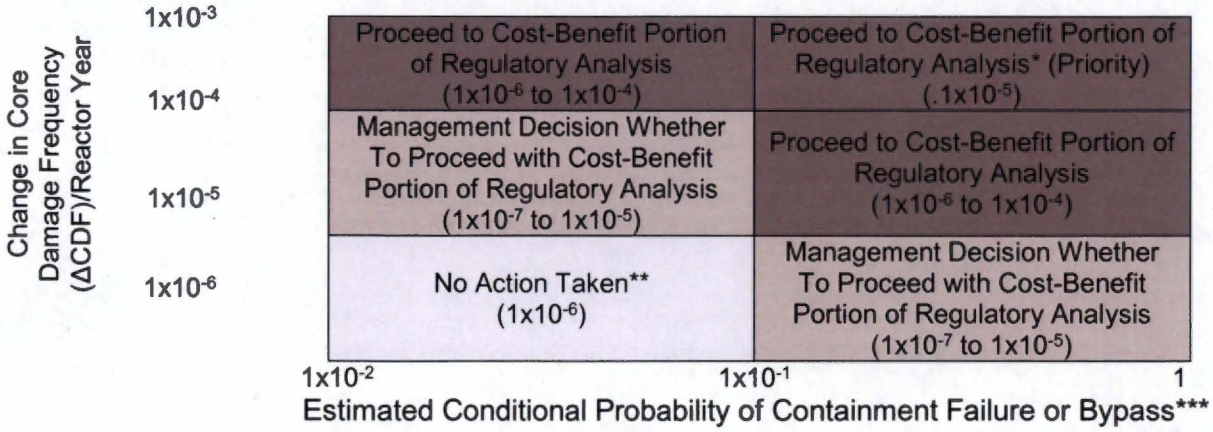
In 10 CFR Part 52, the NRC requires a new reactor DC applicant to submit a description of the design-specific PRA and its results. The PRA is described in Chapter 19 of the design's final safety analysis report (FSAR) and includes both a Level 1 and a Level 2 analysis. A Level 3 analysis that includes an assessment of offsite radiological consequences from postulated radiological releases is described in the design's environmental report (ER). PRAs for new reactors have been developed by applicants and approved by the NRC for several new reactor designs, including the advanced boiling-water reactor (ABWR), AP1000, and economic simplified boiling-water reactor (ESBWR) ~~(10 CFR Part 52)~~. After a new reactor design has been constructed at a site and before operation begins, the PRA for that site-design combination is updated to reflect the as-built configuration of the plant.

The NRC has certified under 10 CFR Part 52 five reactor designs (see Appendices A through E of 10 CFR Part 52) for which a description of the design-specific PRA and its results have been reviewed by the staff. The bottom portion of Table 2-2 shows the key risk-related CDF and large release frequency (LRF) values for the three certified designs where an associated combined license (COL) to build and operate has also been issued by the NRC. In part because of the unique process under 10 CFR Part 52 where PRA insights have been used to make risk-reducing changes during the design process, the related internal events CDFs for the 10 CFR Part 52 certified reactor designs as shown in Table 2-2 are less than those of the current operating reactors because of the removal of certain dominate accident sequences.

before the proposed regulatory change should exceed the CDF after the change by at least $1x10^{-5}$) to ~~justify~~ support the decision to proceed~~ing~~ with further analyses. This safety goal screening criterion was selected to give some assurance that the PRA and data limitations and uncertainties, as well as the variability among plants, will not eliminate issues 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~~ appropriate for implementation after more detailed assessments are performed in accordance with Section 2.5 of this guidance. In this regard, the effect of uncertainties should be considered and discussed.

Figure 2-3 gives guidance for further staff action 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.

Estimated Reduction in CDF	Staff Action
>$1x10^{-4}$/reactor year	Proceed with the regulatory analysis on a high-priority basis.
$1x10^{-4}$–$1x10^{-5}$/reactor year	The decision whether to proceed with the regulatory analysis is to be made by the ~~responsible~~cognizant Division Director.
<$1x10^{-5}$/reactor year	Terminate further analysis unless the cognizant Office Director decides otherwise, based on strong engineering or qualitative ~~justification~~basis.



* A determination is needed regarding adequate protection or compliance. The extent to which costs are considered for compliance is discussed in NUREG-1409.

** Unless an Office Director decides that the screening criteria do not apply (see Section 2.4.1.2).

*** CPCFB is the conditional probability of (early) containment failure or bypass, assuming a core damage accident that releases radionuclides into the containment occurs (see Section 2.4.1.2).

Figure 2-3 Safety Goal Screening Criteria

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~~ basis for the proposed new requirement can be formulated. A class of accident sequences 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 analyst should forward the issue (and include sufficient supporting information) for cognizant Office Director review.

If data is unavailable or it is not practicable to develop adequate quantitative supporting information for the proposed new requirement, a qualitative analysis and associated perspectives should be provided. To the extent practicable, this information should be related to the safety goal screening criteria. For example, how does the proposed initiative affect the CDF and to what extent? What data would need to be collected in order to perform a quantitative analysis of the proposed new requirement? 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 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 facility-specific backfits).

2.4.1.2 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 use when relatively poor containment performance results in the need for greater consideration of safety issues and associated accident sequences. The measure of containment performance to be used in safety goal evaluations is the conditional probability of containment failure or bypass (CPCFB).

CPCFB in this context is the conditional probability of early containment failure or bypass, given core damage. In NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," issued December 1990, early containment failure is defined as "those containment failures occurring before or within a few minutes of reactor vessel breach for PWRs and those failures occurring before or within 2 hours of vessel breach for BWRs. Containment bypass failures (e.g., interfacing-system loss-of-coolant accidents) are categorized separately from early failures" (NRC, 1990). This definition recognizes the effects of early failure and uses that as a baseline from which to assess containment performance (e.g., CPCFB changes). It is important to note that the Fukushima-related orders associated with mitigation strategies and severe accident containments venting for BWR Mark I and II containments may have an impact on CPCFB and should be considered accordingly. 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.

The safety goal screening criteria shown in Figure 2-3 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, a CPCFB of less than 0.1.

The safety goal screening criteria provided in this guidance are based on the recognition that the severe accident risk is dominated by the overall frequency of the following kinds of scenarios:

- those involving core damage and release into an intact containment with early containment failure occurring

- those involving core damage and for which the containment system is breached as a result of accident phenomena either before or early in the core damage or melt progression

- those involving preexisting conditions that cause loss of containment integrity before core damage or other ~~(e.g., large openings)~~

- those for which containment is bypassed entirely and that have a high probability of causing core damage to occur ~~(e.g., such as~~ intersystem loss-of-coolant accident~~)~~

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

Furthermore, note that the safety goal screening criteria described in this guidance do not address issues that deal only with containment performance. Consequently, issues that have no impact on CDF (ΔCDF of zero), such as release mitigating initiatives, cannot be addressed with the safety goal screening criteria and~~. As a result, mitigating initiatives~~ should be assessed on a case-by-case basis with regard to the safety goals. The treatment of proposed release mitigating initiatives in this manner should have little overall impact from a practical perspective on the usefulness of the safety goal screening criteria.

2.4.1.3 Summary of Safety Goal Screening Criteria Guidance

Figure 2-3 illustrates the safety goal screening criteria and provides guidance on when the staff should proceed to the estimation and evaluation of the costs and benefits portion of the regulatory analysis and when a management decision is needed. Upon review of the evaluation and the overall uncertainty and sensitivity of associated estimates, the staff should judge whether substantial additional protection would be achievable and whether continuation of the regulatory analysis process is, therefore, warranted.

2.4.1.4 Regulatory Analysis

If the safety goal evaluation of the proposed regulatory action results in a ~~favorable determination (i.e., any~~ decision ~~except~~ other than no action~~)~~, the analyst may presume the substantial additional protection standard of 10 CFR 50.109(a)(3) is achievable. The initiative should then be assessed in accordance with Section 2.2 of this guidance (see Figure 2-1). If the net-value calculation required by Section 2.2 ~~is not positive~~indicates taking no action, further activities and analyses should be terminated unless there is a qualitative ~~justification~~ basis for proceeding further.

should consult with interested agencies and members of the public 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.

In the event that the OMB disapproves an information collection, independent regulatory agencies, such as the NRC, may override the disapproval or stay of effectiveness of approval of a collection of information by a majority vote of the Commissioners. MD 3.54 gives procedures for Commission override of OMB disapproval.

2.5.2 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 the NRC to prepare a written statement ~~justifying~~ providing a reasonable basis ~~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 request ~~burden imposed on the licensee~~ is ~~justified~~ appropriate in view of the potential safety significance of the issue. All ~~justification~~such written statements must be approved by the EDO or his or her designee before issuance of the information request.

Appendix C to the CRGR Charter contains additional guidance for information requests affecting multiple nuclear power plants and specifies when a written ~~justification~~ analysis is required and what the written statement should include.

MD 8.4, "Management of Backfitting, Issue Finality, and Information Collection," current edition, discusses facility-specific information requests directed at individual nuclear power plants.

Written statements prepared according to the preceding requirements to ~~justify~~ provide a reasonable basis for the information requests are not regulatory analyses within the scope of this guidance. Nevertheless, the written ~~justification~~ analysis will have many of the elements of a regulatory analysis. The elements of a regulatory analysis, as discussed in Section 2.3 of this guidance, can appropriately be included in an analysis for an information request ~~justification~~. An information request ~~justification~~ analysis ~~will~~ should ~~normally~~ be a more concise document than a regulatory analysis.

2.5.3 Regulatory Flexibility Act

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis, to be made available for public comment, 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). The NRC uses the following size standards to qualify a licensee as a small entity, codified at 10 CFR 2.810, "NRC Size Standards":

- a small business that is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $7.0 million or less over its last 3 completed fiscal years

- a manufacturing concern with an average number of 500 or fewer employees, based on employment during each pay period for the preceding 12 calendar months

3 BACKFITTING AND ISSUE FINALITY

3.1 General

Backfitting is expected to occur as part of the regulatory process to ensure the safety of power reactors and radioactive materials. However, it is important for sound and effective regulation that backfitting be conducted by a controlled and defined process. The NRC backfitting process is intended to provide for a formal, systematic, and disciplined review of new or changed requirements or positions before imposing them. The process provides regulatory stability by ensuring that changes in requirements and regulatory staff positions are appropriate ~~justified~~ and suitably defined.

Backfitting is defined in 10 CFR 50.109 as the modification of or addition to SSCs or the design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in Commission rules or the imposition of a regulatory staff position that is either new or different from a previously applicable staff position *and* effective after specific dates described in the backfit rule. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 are slightly different.[8]

The term "backfit" is not ~~normally~~ used in discussions relevant to new power reactors; instead, the concept of "issue finality" is used ~~rather than "backfit."~~ In this guidance, the NRC uses the terms "backfit" and "backfitting" to mean backfits as defined in 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 and ~~violations~~ inconsistencies with~~of~~ issue finality under 10 CFR Part 52. Applicants for a nuclear power reactor renewed license under 10 CFR Part 54 have similar protections as backfitting~~, due to the limitation in scope of the NRC's review of the application~~.

3.2 Relationship of Regulatory Analysis to Backfitting

Regulatory analyses are required for all regulatory actions that involve licensed facilities and for all regulatory actions that impose generic requirements.

The types of costs and averted costs, as addressed in NUREG-1409, should be accounted for in the regulatory analysis. Where the proposed generic requirement impacts facilities with backfit protection and the new requirement meets the definition of a backfit, the analysis should document the following factors in the regulatory analysis to support the preparation of the backfit analysis:

- a statement of the specific objective that the proposed backfitting action is designed to achieve
- a general description of the activity that would be required by the licensee or applicant to complete the backfitting action

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[8] The relevant regulations are 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste"; and 10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

- the potential for change in the risk to the public from the accidental offsite release of radioactive material
- the potential effect of radiological exposure on facility employees
- the installation and continuing costs associated with the backfitting action, including the cost of facility downtime or the cost of construction delay ~~(i.e., resource burden on licensees)~~
- the potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements
- the estimated resource costs for ~~burden on~~ the NRC associated with the proposed backfitting action and the availability of such resources
- the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfitting action
- a statement of whether the proposed backfitting action is interim or final and, if interim, the ~~justification~~ basis for imposing the proposed backfitting action on an interim basis

Generally, the backfit rule requires the NRC to consider the costs for improving public health and safety, which may include facility downtime or construction delay as costs associated with the backfitting action. The one exception is that economic costs cannot ~~will not~~ be considered in cases of ensuring, defining, or redefining adequate protection unless there are two or more ways to achieve a level of protection which is adequate. Should it be necessary or appropriate for the Commission to prescribe a specific action to comply with requirements or to achieve adequate protection, then cost may be a factor in selecting ~~the~~ an action from the options, provided that the objective of adequate protection is met.

Averted onsite costs can ~~arise~~ result when it is estimated that the backfitting action will save money for licensees, such as by reducing forced outage rates. These savings are not treated as a benefit (safety enhancement) unless they result in a reduction in adverse health or environmental effects, such as a decrease in worker dose. They are, however, considered as a negative cost; that is, an offset against other licensee costs. Averted offsite costs should be treated as a benefit when there is a safety enhancement, such as ~~can result from~~ an estimated decrease in accident frequency or severity.

The backfit rule establishes a more difficult standard for imposing new regulations than the cost benefi~~tcial~~ standard used in regulatory analysis. For cost-justified backfitting, the analyst must first show that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfitting action and then, if that step is met, that "the direct and indirect costs of implementation for that facility are justified in view of this increased protection" ~~(emphasis added)~~ per 10 CFR 50.109(a)(3). Many of the factors to be addressed in the analysis may not be easily quantified, and the backfit rule permits consideration of other relevant and material factors, including qualitative factors (see Appendix A).

that there are important qualitative considerations or factors that ~~cannot be~~are not quantified, those considerations or factors should be discussed in qualitative terms. The environmental standard review plan (ESRP), NUREG-1555, provides guidance to the staff on the identification and tabulation of costs and benefits resulting from construction and operation of new nuclear power plants~~)~~.

For combined license EISs, the ESRP sections for costs and benefits explain that the reviewer may rely on an independent analysis of benefits and costs by State or regional authorities, rely on the applicant's analysis, or prepare an independent assessment. If a review of the applicant's analysis is conducted, the reviewers should ensure that the applicant's assumptions, data, and methods are ~~acceptable~~ appropriate~~to other ESRP reviewers, as appropriate (e.g., demographics)~~. If reviewers have relied on an independent analysis, the review directed by the ESRP should be modified accordingly. The scope of the review should include the plant's average annual electrical-energy generation in kilowatt-hours, enhanced reliability of the electrical distribution system, technical benefits such as development of technology, the quantities of other products (e.g., steam) produced, and other benefits (e.g., increased regional productivity, tax revenues, or new or improved recreational facilities) that have been identified. Benefits should be identified for the applicant's proposed project and for any alternatives identified as appropriate and practical to mitigate predicted environmental impacts.

4.4 Costs and Benefits Guidance for Reactors and Material Licensing Actions[9]

For reactors and materials licensing actions, the evaluation of the proposed action and each alternative should include a discussion of costs and benefits and a qualitative analysis of environmental impacts. Assumptions and uncertainties should be part of the discussion.

Applicant-prepared ERs should include the following costs and benefits-related information, as appropriate (NRC, 2003). It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- qualitative discussion of environmental enhancement or degradation (including air, water, soil, and biotic, as well as socioeconomic factors such as noise, traffic congestion, overuse of public works and facilities, and land access restrictions)
- changes to public health and safety
- capital costs or benefits of the proposed action and alternatives, including land and facilities
- operating and maintenance costs
- post-operation restoration (not applicable when the alternative is restoration)
- post-operation monitoring requirements

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9 This section does not apply to ERs prepared at the license renewal stage under 10 CFR 51.53(c), unless costs and benefits are either essential for a determination about the inclusion of an alternative in the range of alternatives considered or relevant to mitigation.

- other costs or benefits of the alternative (e.g., changes to tax revenue, recreational value, and impacts to transportation corridors, as appropriate)
- incremental changes in regional productivity
- changes to recreational values
- other costs or benefits

The staff-prepared EISs must consider the costs and benefits of the proposed action and the alternatives to the proposed action and present them in the EIS (10 CFR 51.71). The costs and benefits should not be limited to a simple financial accounting of project costs for the proposed action and each alternative. Costs and benefits should also be discussed for qualitative subjects (i.e., environmental degradation or enhancement). Extensive or detailed analysis should be presented in an appendix to the EIS to avoid diverting attention away from primary issues such as public health and safety. The cost-benefit analysis is not simply a mathematical formula ~~from which to justify~~used to determine economic parameters; other applicable qualitative factors should be discussed and weighed in the decision.

Qualitative environmental costs and benefits can be compared to the discussion of environmental impacts within the ER. Standard project costs can be reviewed using standard cost-estimating databases. Socioeconomic costs and benefits can be reviewed and compared against similar projects, as applicable. The reviewer should also verify that analyses were performed in accordance with appropriate cost-benefit guidance. Future costs and benefits should be discounted to present worth, as discussed in Executive Order 12866, "Economic Analysis of Federal Regulations under Executive Order 12866." The methods used for discounting should be explained and applied consistently to both costs and benefits.

The NUREG-1727, "NMSS Decommissioning Standard Review Plan," issued September 2000, provides guidance on determining costs and benefits for decommissioning projects, as well as on determining what is deemed as low as reasonably achievable (ALARA) and prohibitive costs related to ALARA. The cost-benefit analysis provides input to determine the relative merits of various alternatives; however, the NRC should ultimately base its decision on public health and safety issues.

4.5 Environmental Justice

The Commission's "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions" (NRC, 2004c) confirmed NRC supports the general goals of EO 12898, "Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994, and the NRC will meet these goals through its NEPA review process.

Office guidance on how to incorporate environmental justice in the NEPA review process can be found in the following:

- NRR Office Instruction LIC-203, Revision 3, "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues," dated July 1, 2013

modifications, and training activities that ~~can be justified~~are appropriate to further reduce the risks of severe accidents.

4.6.1.1 Severe Accident Mitigation Alternatives

In accordance with 10 CFR 51.53(c)(3)(ii)(L), license renewal applicants are to consider alternatives to mitigate severe accidents if the staff has not previously evaluated SAMA for the applicant's plant in an EIS or related supplement or in an EA. The purpose of this consideration is to ensure that changes at nuclear power plants before and during the license renewal term (e.g., hardware, procedures, and training) with the potential for improving the severe accident safety performance are identified and evaluated. Section 4.6.1.2 discusses the use of SAMDA for new reactor applications.

SAMA evaluations are conducted using a four-step approach. In the first step, the applicant quantifies the level of risk associated with potential reactor accidents using a facility-specific PRA. In the second step, the applicant examines the major risk contributors and identifies possible ways (i.e., SAMA) of reducing that risk. Common ways of reducing risk are changes to components, systems, procedures, and training. In the third step, the applicant estimates the benefits and the costs associated with each of the proposed SAMA. The analyst estimates the amount of risk reduced by each alternative. Those estimates are monetized per applicable NRC regulatory analysis guidance. The cost of implementing the proposed SAMA is also estimated. In the fourth step, the cost and benefit of each of the proposed SAMA are compared to determine whether the alternative is cost beneficial, meaning the benefits of the SAMA were greater than the cost (a positive cost-benefit ratio). The potentially cost-beneficial SAMA are then evaluated to determine if they are within the scope of license renewal (i.e., are they subject to aging management). This evaluation considers whether the SSCs associated with these SAMA (1) perform their intended function without moving parts or without a change in configuration or properties and (2) are not subject to replacement based on qualified life or specified time period. If the cost-beneficial SAMA do not relate to adequately managing the effects of aging during the period of extended operation, they need not be implemented as part of license renewal, in accordance with 10 CFR Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants."

The cost-benefit analysis involves determining the net value for each alternative. If the net value of an alternative is negative, the cost of implementing the SAMA is larger than the benefit associated with the SAMA and it is not considered cost beneficial. Two sets of estimates should be developed, one at a 3-percent discount rate and one at a 7-percent discount rate. A sensitivity study using the 3-percent discount rate is performed, as well as additional analyses to evaluate the effect of parameter choices and uncertainties on the results of the SAMA assessment.

The staff reviews the SAMA analysis prepared by the applicant and determines whether the methods used and the implementation of those methods follow the guidance of Nuclear Energy Institute (NEI) 05-01, Revision A, "Severe Accident Mitigation Alternatives (SAMA) Analysis: Guidance Document," which was endorsed by the NRC (72 FR 45466, dated August 14, 2007).

To the extent possible, all attributes should be quantified in monetary terms for each year within the scope of the analysis. For example, person-rem of averted exposure, a measure of safety value, is converted to dollars using a dollar per person-rem conversion factor. Then the future value of each attribute is discounted to present day dollars and summed across all attributes to obtain the discounted net value (in current dollars) of the proposed action. The discounted net-value calculation is generally favored over other measures, such as a cost-benefit ratio or an internal rate of return.

The net-value method calculates a numerical value that is intended to summarize the balance between the favorable and unfavorable consequences of the proposed action. The basic perspective of the net-value measure is national economic efficiency. All costs and benefits are added together, and the total is intended to reflect the aggregate effect of the proposed action on the economy. The net-value measure may not provide any information about the distribution of costs and benefits among affected entities. The costs and benefits to all affected parties are simply added together.

It is important to note that significant differences may exist between the recipients of benefits and those who incur costs. The distribution of costs and benefits for various groups should be presented and discussed.

5.1.2 Attribute Considerations for Materials Licensees

The attribute quantification procedure for a cost-benefit analysis for materials licensees is different for the following six attributes:

(1) public health (accident)
(2) public health (routine)
(3) occupational health (accident)
(4) occupational health (routine)
(5) offsite property
(6) onsite property

The quantification of these attributes may involve both frequencies and population doses associated with accident scenarios. Nonreactor facilities tend to be ~~much simpler~~more straightforward in system configuration than power reactors~~, and the potential consequences to the public from accidents compared to power reactors is much smaller~~. This simplifies the scope of the accident analysis and the accident frequency and population dose data; however, there are fewer data available than for power reactors. Data for nonreactor facilities may be used to quantify the incremental changes resulting from the proposed regulatory action for these attributes.

5.2 Identification of Attributes

For every cost-benefit analysis to be performed, those attributes that could be affected by the proposed action should be identified. Once identified, the attributes may be quantified using the techniques in Appendix B. As stated previously, benefits have positive values and costs have negative values to society.

5.2.1 Public Health (Accident)

This attribute measures expected changes in radiation exposures to the public resulting from changes in accident frequencies or accident consequences associated with the proposed action. Expected changes in radiation exposure from a nuclear power reactor accident should be measured over a 50-mile distance from the licensed facility. Because of the nature of nuclear fabrication facilities and the type of credible potential accidents, a 50-mile radius is not automatically required.

In most cases, the effect of the proposed action would be on public exposure. A decrease in public exposure (given in person-rem) is a benefit. Therefore, this decrease multiplied by the monetary conversion factor (dollar per person-rem) will give a positive monetary value.

It is possible that a proposed action could increase public exposure because of potential accidents. In this case, the increase in public exposure (person-rem) is a cost to society. When this increase is multiplied by the monetary conversion factor (dollar per person-rem), the resulting monetary term is interpreted as negative.

5.2.2 Public Health (Routine)

This attribute accounts for changes in radiation exposures to the public during normal facility operations (i.e., nonaccident situations) that result from the proposed regulatory action. When used, this attribute would employ an actual radiological public exposure estimate; accident probabilities are not involved.

Similar to the attribute for public health (accident), a decrease in public exposure would be a benefit. Therefore, the product of a decrease in exposure and the monetary conversion factor (dollar per person-rem) would be positive. The product of an increase in public exposure and the monetary conversion factor would be a cost of the proposed action.

5.2.3 Occupational Health (Accident)

This attribute accounts for the health effects, both immediate and long-term, associated with site workers (i.e., both plant personnel and external workers assisting at the plant in response to the accident) as a result of changes in accident frequency or accident mitigation. External workers assisting at the plant in response to the accident include those individuals who are participating in the emergency operations for stabilizing and securing the damaged unit, as well as those individuals subsequently involved in the site cleanup and decontamination. A decrease in worker radiological exposures is a benefit; an increase in worker exposures is considered a cost.

As is the case for public exposure, the directly calculated effects of a particular action are given in person-rem. A monetary conversion factor should be used to convert the effect into dollars (see NUREG-1530).

5.2.4 Occupational Health (Routine)

This attribute accounts for radiological exposures to workers during normal facility operations (i.e., nonaccident situations). For many types of proposed actions, there will be an increase in worker exposures; sometimes this will be a one-time effect (e.g., installation or modification of equipment in a hot area), and while others sometimes it will be an ongoing effects (e.g., routine surveillance or maintenance of contaminated equipment or equipment in a radiation area). Some actions may involve a one-time increase with an offsetting lowering of future exposures.

Because this attribute represents an actual estimate of health effects, accident probabilities are not relevant. As is true of other types of exposures, a net decrease in worker exposures is taken as positive; a net increase in worker exposures is taken as negative. This exposure is also subject to the dollar-per-person-rem conversion factor (see NUREG-1530).

5.2.5 Offsite Property

This attribute measures the expected total monetary effects on offsite property resulting from the proposed action. Changes to offsite property can take various forms, both direct (e.g., land, food, water) and indirect (e.g., tourism, employment). This attribute is typically the product of the change in accident frequency and the property consequences resulting from the occurrence of an accident (e.g., costs of interdiction measures such as decontamination, cleanup, and evacuation). A reduction in economic consequences is a benefit; an increase in economic consequences is considered a cost.

5.2.6 Onsite Property

This attribute measures all consequences of an accident that arise within the facility's boundaries—an area controlled by the licensee. The expected monetary effects on onsite property include replacement power for damaged power reactors, decontamination, and refurbishment costs. This attribute is typically the product of the change in accident frequency and the onsite property consequences in the event of an accident. A reduction in expected onsite property damage is a benefit; an increase in onsite property damage is considered a cost.

These onsite property costs include all additional costs for the facility personnel and external workers assisting at the facility during the emergency phase and during long-term cleanup and decontamination of the site.

5.2.7 Industry Implementation

This attribute accounts for the projected net economic impact on the affected licensees to implement mandated changes. Costs will include procedural and administrative activities, equipment, labor, materials, and shutdown costs, including the cost of replacement power in the case of power reactors. For cost-benefit analysis purposes, additional costs above the status quo should be considered costs; cost savings should be considered benefits.

The government entities or general public may seek compensation from the licensee to provide the needed services or to reimburse their incurred costs. Similarly, the purchase of labor and materials may result in local economic benefits. These issues are accounted for in other attributes and should not be discussed under industry implementation to avoid double counting.

5.2.8 Industry Operation

This attribute measures the projected net economic effect due to routine and recurring activities required by the proposed action on all affected licensees. If applicable, short-term replacement power costs (power reactors only) directly attributable to the proposed action (e.g., the unit must be in a refueling outage to install the modification) will be included. Additional costs above the status quo may be considered, along with any beneficial cost savings.

Costs falling in this category generally occur over long periods of time (the facility lifetime). These costs are particularly sensitive to the discount factor used.

The government entities or general public may seek compensation from the licensee to provide the needed services or to reimburse their incurred costs. These costs are accounted for in these other attributes and should not be discussed under industry operation to avoid double counting.

5.2.9 NRC Implementation

This attribute measures the projected net economic effect on the NRC to place the proposed action into operation. Costs already incurred, including those activities performed by the NRC in making the regulatory decision, are viewed as "sunk" costs and are not to be included. NRC activities that are performed after the regulatory decision and other additional costs above the status quo may be considered.

The NRC may seek compensation ~~(e.g., license fees)~~ in the form of fees from affected licensees to provide needed services; any compensation received should not be subtracted from the cost to the NRC, because the NRC is the entity consuming real resources (e.g., labor and capital) to meet its responsibilities. Any fees provided by licensees are viewed as transfer payments, and as such are not real costs from a societal perspective. Any costs that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

5.2.10 NRC Operation

This attribute measures the projected net economic effect on the NRC after the proposed action is implemented. Additional inspection, evaluation, or enforcement activities would be examples of such costs. As with industry operation costs, NRC operation costs generally occur over long periods of time and are sensitive to the discount factor.

Costs falling in this category generally occur over long periods of time (the facility lifetime). These costs are particularly sensitive to the discount factor used.

The NRC may seek compensation from the licensee to provide needed services. Any costs that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

5.2.11 Other Government Entities

This attribute measures the net economic effect of the proposed action on the Federal government (other than the NRC) and State and local governments resulting from the action's implementation or operation.

Other government entities may seek compensation from the licensee to provide the needed services. Any costs that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

5.2.12 General Public

This attribute accounts for direct, out-of-pocket costs paid by members of the general public as a result of implementation or operation of a proposed action. Examples of these costs could include items such as increased cleaning costs because of dust and construction-related pollutants, property value losses due to the action, or inconveniences ~~(e.g.,~~such as the testing of evacuation sirens~~)~~.

This ~~attribute~~ is not related to the attribute associated with economic consequences resulting from accidents. The general public attribute measures real costs that will be paid as a result of implementation of the proposed action. These costs exclude taxes, as they are simply transfer payments with no real resource commitment from a societal perspective. Any costs that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

5.2.13 Improvements in Knowledge

This attribute accounts for the potential value of new information, especially from assessments of the safety of licensee activities. Some NRC actions have as their goal the improvement in the state of knowledge for such factors as accident probabilities or consequences, with an ultimate objective of facilitating safety enhancement or reduction in uncertainty. This attribute is qualitative in nature.

The quantitative measurement of improvements in knowledge depends largely on the type of action being investigated. The value of assessments directed at a fairly narrow problem (e.g., reducing the failure rate of a particular component) may be quantifiable in terms of safety or monetary equivalent. If this is the case, such costs and benefits should be treated by other attributes and not included under this attribute. To avoid double counting, potential benefits from the assessments that are difficult to identify or are otherwise not easily quantified should be addressed under this attribute.

5.2.14 Regulatory Efficiency

This attribute attempts to measure regulatory and compliance improvements resulting from the proposed action. These may include changes in industry reporting requirements and the NRC's inspection and review efforts. Achieving consistency with international standards groups may also improve regulatory efficiency for both the NRC and the groups. This attribute is qualitative in nature.

In some instances, changes in regulatory efficiency may be quantifiable, in which case the improvements should be accounted for under other attributes, such as NRC implementation or industry operation. To avoid double counting, only regulatory efficiency actions that are not quantifiable should be addressed under this attribute. Regulatory efficiency actions that can be quantified should be considered benefits under the appropriate quantifiable attribute.

5.2.15 Safeguards and Security Considerations

The NRC has a legislative mandate to maintain the common defense and security and to protect and safeguard restricted data and national security information in its regulatory actions. This attribute includes such considerations.

In applying this attribute, the analyst should determine whether the existing level of safeguards and security is adequate and what effect the proposed action has on achieving an adequate

level of safeguards and security. If the effect of the proposed action on safeguards and security is quantifiable, then this effect should be included among the quantitative attributes. Otherwise, the contribution of the action should be evaluated in a qualitative way and treated under this attribute.

5.2.16 Environmental Considerations

NEPA requires Federal agencies to consider the environmental impacts of federal actions that affect the human environment. The NRC sets forth its regulations for implementing NEPA in 10 CFR Part 51; NRC's guidance for implementing NEPA for various licensing actions are in documents such as NUREGs 1555, 1748, 0586, and 1437, and in NRR Office Instruction LIC-203. Many of the NRC's regulatory actions are handled through an EIS that considers the environmental impacts (both negative and beneficial) from the proposed action. However, when an environmental analysis has been done, a summary of the salient results of the environmental analysis should be included in the regulatory analysis document. NEPA reviews are handled separately from the cost-benefit analysis described in this guidance. Mitigation or other measures (e.g., protection) resulting from the environmental review may result in cost increases that should be considered in the cost-benefit analysis. The alternatives evaluated in the regulatory analysis should be the same as the alternatives evaluated in the EIS or EA.

5.2.17 Other Considerations

The staff considers the set of attributes described above to be comprehensive for most cost-benefit analyses. Any particular analysis may also identify unique attributes ~~(e.g.~~such as, worker productivity, worker turnover, nonradiological health effects, worker training~~)~~. Any such attributes should be appropriately described and factored into the analysis.

5.3 Quantification of Attributes

The following sections provide guidance and examples for estimating the values of each attribute, and are meant to be generically applicable to all NRC regulatory analyses~~is~~.

Cost and benefit estimates are performed relative to a baseline case, which is typically the no-action alternative. In establishing the baseline case, the analyst should assume that all existing NRC and Agreement State requirements and written licensee commitments are already being implemented and that the costs and benefits associated with these requirements are not part of the incremental estimates prepared for the regulatory analysis. Similarly, the effects of concurrent regulatory actions need to be incorporated into the baseline before calculating the incremental consequences of the regulatory action under consideration.

The treatment of voluntary initiatives on the part of industry also has important implications on the baseline and, therefore, the incremental consequences of the proposed action. Section 5.3.1 of this guidance discusses the treatment of voluntary activities by affected licensees when establishing a baseline reference. For the cost estimate of the base case, analysts should give no credit for voluntary actions. However, for completeness and sensitivity analysis purposes, the analyst should also display results with credit being given for voluntary incremental actions by licensees.

5.3.1 Treatment of Industry Initiatives

Industry initiatives are typically actions by licensees that either form the bases for continued compliance with the regulations or may obviate the need for new regulations. ~~Substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues that will not compromise plant safety, and this substitution 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 need to effectively manage and implement their commitments associated with these industry initiatives, and the NRC should 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 three 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 justified by the increased protection

(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 thus ~~should~~ cannot be addressed through industry initiatives.

The presence of industry initiatives is potentially very important in the estimation of costs and benefits and, as such, its treatment in the regulatory analysis should 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 that complement or substitute for a proposed regulatory action exist, the future role of these industry initiatives needs to be determined. This determination would affect the baseline, which in turn would affect the calculation of incremental costs and benefits. 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 benefits attributable to the proposed regulation are diminished. Alternatively, if "no credit" is given, the incremental benefits assigned to the proposed rule are increased.

For the purposes of the regulatory analysis, calculation of net benefits should be based, to the extent practical, on varied assumptions about the future role of industry initiatives. Initially, the analyst should develop two sets of cost-benefit estimates: (1) the first is based on no credit, and (2) the second is based on full credit for industry initiatives. These results, which bound the range of potential cost impact, should have equal weight and be presented for sensitivity analysis purposes. If the overall cost-benefit result does not change from an overall net cost to an overall net benefit (or vice versa), there is no need to further analyze the industry initiative, and the final results would be reported as a range of benefits that reflect the sensitivity of these results to the implementation of industry initiatives. If the results are highly sensitive to the level of variation, such that the overall net benefit conclusion shifts or the final recommendation changes, the analyst should proceed to develop a "best estimate" base case.

Under this best estimate base case, the staff should evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. Clearly, the more an

industry initiative satisfies criteria that assure the long-term effectiveness of these voluntary approaches, the more credit the analyst should give to the industry initiative. In performing this evaluation, the analyst 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 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~~written commitments.

- The degree to which the industry initiative is noncontroversial and standard industry practice. Factors to consider include whether the industry initiative is consistent with provisions of industry codes and standards, the level of participation among relevant licensees, how long the program has been operating or its effectiveness, and whether the initiative is likely to 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.

- Whether the industry has formally adopted the initiative as mandatory through the NEI's Nuclear Strategic Issues Advisory Committee.

Based on such an assessment, the regulatory analysis would contain, to the extent practical, a best estimate of the cost and benefits of the regulation under consideration with and without credit for the industry initiative. These results would become the basis for the staff's recommendations to the Commission. Careful attention is needed if PRA techniques are used to give partial or no credit to industry initiatives, because risk estimates from PRAs are based on existing conditions that typically include credit for any industry initiative that may be in place. When the cost-benefit analysis and supporting PRA are modified to eliminate or reduce credit for industry initiatives, the analyst needs to ensure that these changes are properly reflected in the details of the PRA model.

5.3.2 Attributes Valuation

When assigning valuation to the identified affected attributes, the cost-benefit analysis should be transparent and the results should be reproducible. The analysis should clearly set out the assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified individual reading the analysis should be able to understand the basic elements of the analysis and the way in which estimates were developed.

When choosing the appropriate time horizon for estimating costs and benefits, the analyst should consider how long the regulation being analyzed is likely to have resulting effects. The time horizon begins when the regulatory action is implemented and ends when those effects are

expected to cease. Ideally, the analyst should use the expected remaining operating license term across affected entities and add an appropriate decommissioning period, if applicable.

A benefit is most commonly calculated for four attributes: public health (accident), occupational health (accident), offsite property, and onsite property. All four of these attributes usually rely on an estimation of the change in probability of occurrence of an accident as a result of the implementation of the proposed action. ~~(~~Changes in the consequence of the accident ~~[(~~i.e., dose or cost~~)]~~ would also affect these attributes.~~)~~

Four attributes involve radiation exposure: (1) public health (accident), (2) public health (routine), (3) occupational health (accident), and (4) occupational health (routine). In quantifying each measure, the analyst should assess the reduction (or risk averted) relative to the existing condition. For accident-related exposures, the measure will be probabilistically weighted (i.e., the potential consequence is multiplied by its probability of occurrence). The nonaccident terms (e.g., routine occupational exposure) are given in terms of annual expected effect. Both types of terms would be integrated over the lifetime that the benefits and costs would be incurred (e.g., the licensed term of the affected facilities) to show the total effect. Each of the attributes involving radiation exposure can be characterized in terms of person-rem, either averted by or resulting from implementation of the proposed action.

The four attributes associated with radiation exposure require a dollar per person-rem conversion factor to be expressed monetarily. The remaining quantitative attributes are normally quantified monetarily in a direct manner. When quantified monetarily, attributes are to be discounted to present value. This operation involves an assumption about the remaining lifetime of a facility. If appropriate, the effect of license renewal should be included in the facility's lifetime estimate. The total dollar figures capture both the number of facilities involved (in the case of generic rulemaking) and the economic lifetime of the affected facilities.

~~Qualitative attributes do not lend themselves to quantification.~~ To the degree to which the considerations associated with qualitative~~these~~ attributes can be quantified, they should be; the quantification should be documented, preferably under one or more of the quantitative attributes. However, if the consideration does not lend itself to any level of quantification, its treatment should take the form of a qualitative evaluation in which the analyst describes as clearly and concisely as possible the precise effect of the proposed action (see Appendix A).

To estimate values for the accident-related attributes in a regulatory analysis, the analyst can draw from detailed risk/reliability assessments or statistically based analyses. However, the analyst will sometimes find limited data or insufficient information for providing a precise quantitative perspective. This situation may often involve nonreactor licensees, because detailed risk assessments, reliability assessments, or statistically-based analyses are less available for these licensees than for power reactor licensees. Two examples illustrate this type of quantitative evaluation.

Example 1: In 1992, the NRC performed a regulatory analysis for the adoption of a proposed rule (NRC, 1992) concerning air gaps to avert radiation exposure resulting from NRC-licensed users of industrial gauges. The NRC found insufficient data to determine the averted radiation exposure. To estimate the reduction in radiation exposure should the rule be adopted, the NRC assumed a source strength of 1 curie for a device with a large air gap, which produces 1.3 rem per hour at a distance of 20 inches from a cesium-137 source. Assuming half this dose rate would be produced, on average, in the air gap, and that a worker is within the air gap for 4 hours annually, the NRC estimated the worker would receive 2.6 rem per year. The NRC estimated

$$Avoided\ Public\ Dose = \sum_{\substack{Release\\Categories}} [Release\ Category\ Frequency\ x\ Category\ Population\ Dose\ Factor]_{\substack{Status\\Quo}}$$

$$- \sum_{\substack{Release\\Categories}} [Release\ Category\ Frequency\ x\ Category\ Population\ Dose\ Factor]_{\substack{After\\Action}}$$

or

$$Avoided\ Public\ Dose = [Accident\ Frequency\ x\ Population\ Dose\ Factor]_{\substack{Status\\Quo}} - [Accident\ Frequency\ x\ Population\ Dose\ Factor]_{\substack{After\\Action}}$$

If the standard analysis is not sufficient because estimation of population doses requires more detail, then a greater effort is necessary to address the expanded scope. The analyst would employ state-of-the-art PRA modeling software and techniques to better capture design-, facility-, and site-specific characteristics that could affect the results.

5.3.2.1.2 Monetary Valuation of Accident-Related Health Effects

Mortality Effects

To quantify mortality effects, a conversion factor is needed that reflects the monetary value of a unit of radiation exposure. This conversion factor is subject to periodic NRC review. ~~The NRC set out the basis for selecting this value in NUREG-1530.~~ The~~is~~ dollar-per-person-rem value, set out by NRC in NUREG-1530, is to be used to calculate the monetary value of the incremental cancer mortality risk resulting from routine and accidental exposure to radiation. ~~Unlike early NRC practice, o~~Offsite property consequences are separately valued and are not part of this person-rem value. Monetary conversion of radiation exposure using the dollar-per-person-rem value is to be performed for the year in which the exposure occurs, and then the monetized value is discounted to present value for purposes of evaluating costs and benefits.

Morbidity Effects

Morbidity effects of radiation exposure consist of the risk of nonfatal health effects from illnesses such as cataracts, cardiovascular disease, or nonfatal cancers. Historically, the NRC has used the International Commission on Radiological Protection nominal risk coefficient, which included a global average risk of morbidity and heritable effects, in conjunction with the value of a statistical life (VSL) in its dollar-per-person-rem conversion factor as a monetary value of the health risks resulting from radiation exposure. This coefficient included allowances for nonfatal cancers and for severe hereditary effects translated into loss-of-life measures based on a perceived relationship between quality of life and loss of life. However, the VSL portion of the calculation only monetizes cancer mortality. Therefore, to better align with the monetized mortality value of the VSL, only the cancer mortality risk coefficient should be used, and morbidity and heritable effects should be estimated separately.

Nonfatal health effects risk valuation differs from that of mortality risk valuation in that the values depend on the type of illness, each with its own unique severity, duration, and effect on quality of life. As with VSL estimates, WTP to reduce the risk of experiencing an illness is the

(3) Discount each reduction in occupational health (routine) risk per facility (dollars).

(4) Sum the reductions and total over all facilities (dollars):

$$V_{OHR} = N\,(H_{ORI} + H_{ORO})$$

where

V_{OHR} = discounted monetary value of reduction in occupational health (routine) risk for all affected facilities (dollars)
H_{ORI} = monetary value of per-facility reduction in routine occupational dose required to implement the proposed action after discounting (dollars/facility)
H_{ORO} = monetary value of per-facility reduction in routine occupational dose to operate following implementation of the proposed action after discounting (dollars/facility)
N = number of affected facilities

Note the algebraic signs for D_{ORI} and D_{ORO}. A reduction in exposure is positive; an increase is negative. The dose for implementation (D_{ORI}) would normally be an increase and therefore negative.

If individual facility values instead of ~~than~~ generic values are used, the formulas can be replaced with the following:

$$V_{OHR} = \sum_i N_i\,(H_{ORI_i} + H_{ORO_i})$$

where

i = facility (or group of facilities) index

5.3.2.3.1 Estimation of Change in Routine Exposure

A proposed NRC action can affect routine occupational exposures in two ways. It may cause a one-time increase in routine dose resulting from implementation of the action (e.g., installing a retrofit). It may also cause a change (either increase or decrease) in the recurring routine exposures after implementing the action. A new coolant system decontamination technique, for example, may cause a small implementation dose but may result in a decrease in annual exposures from maintenance thereafter.

For the standard analysis, the analyst may attempt to make exposure estimates or obtain at least a sample of industry or other technical data for a validation of the estimates developed. The development of an exposure estimate includes two components: (1) estimating the radiation field (rem/hour) and (2) estimating the labor hours required. The product is the exposure (person-rem). The development of operational estimates also requires the annual frequency of the activity.

General estimates of radiation fields can be obtained from a number of sources. For power reactors, FSAR Chapter 12 for the plant will include a partitioning of the power plant into

If a facility is already operating, t_i will be zero, and the equation for C will be simplified to the following:

$$C = \frac{1 - e^{-rt_f}}{r}$$

If the analysis does not discount offsite property damage ~~(e.g.~~, when the timeframe is sufficiently short to mitigate the need for discounting~~)~~, r effectively becomes zero in the preceding equations. In the limit as r approaches zero, $C = t_r = t_i$ (or $C = t_f$ when $t_i = 0$). This new value for C should be used to evaluate D in the undiscounted case.

The quantity D should be interpreted carefully to avoid misunderstandings. It does not represent the expected offsite property damage resulting from a single accident. Rather, it is the present value of a stream of potential losses extending over the remaining lifetime of the facility. Thus, it reflects the expected loss resulting from a single accident (this is given by the quantity B), the possibility that such an accident could occur (with some probability) at any time over the remaining facility life, and the effects of discounting these potential future losses to present value. When the quantity D is multiplied by the annual frequency of an accident, the result is the expected loss over the facility life discounted to present value.

At a more detailed level, but still within the scope of a standard analysis, the analyst can identify the affected facilities and then calculate the proper sum effect instead of relying on generic values. This involves the following steps:

(1) Identify the affected facilities.
(2) Identify reductions in the accident frequency per facility.
(3) Calculate the value of the property damage per facility.
(4) Calculate the avoided property damage value per facility.
(5) Sum the avoided property damage over the affected facilities.

For a major effort beyond the standard analysis, the estimates should be derived from more site-specific information than that used by Strip (1982). For power reactors, the MACCS computer code with the most recent data available should be used. This degree of effort would be relatively costly to conduct, both in terms of computer costs and data collection and interpretation costs. However, it would provide the highest degree of reliability.

Burke et al. (1984) examined the offsite economic consequences of severe light-water reactor accidents and developed cost models for the following:

- population evacuation and temporary sheltering, including food, lodging, and transportation
- emergency-phase relocation, including food, housing, transportation, and income losses
- intermediate-phase relocation, beginning immediately after the emergency phase
- long-term protective actions, including decontamination of land and property and land area interdiction

associated with the action. If the action requires work in a radiation zone, the analyst should account for the extra labor required by radiation exposure limits and low worker efficiency caused by radiation protection gear and tight quarters.

When performing a sensitivity analysis (but not for the best estimate), the analyst should include contingencies, such as the most recent greenfield construction project contingency allowances supplied by Robert Snow Means Co., Inc. (1995). That reference suggests adding contingency allowances of 15 percent at the conceptual stage, 10 percent at the schematic stage, and 2 percent at the preliminary working drawing stage. The Electric Power Research Institute (EPRI) (1986) offers guidelines for use in estimating the costs for "new and existing power generating technologies." EPRI suggests applying two separate contingency factors, one for "projects" to cover costs resulting from more detailed design and one for "process" to cover costs associated with uncertainties of implementing a commercial-scale new technology.

(2) Estimate the costs associated with implementation, both direct and indirect. Direct costs include materials, equipment, and labor used for the construction and initial operation of the facility during the implementation phase. Indirect costs include required services. The analyst should identify any significant secondary costs that may arise. The analyst should account for one-time costs for component replacement and the associated labor costs. Schulte et al. (1978) and United Engineers and Constructors, Inc. (1986, 1988a, 1988b) provide additional information on cost categories, especially for reactor facilities.

(3) If appropriate, discount the costs, and then sum. If costs occur at some future time, they should be discounted to yield present values. If all costs occur in the first year or if present-value costs can be directly estimated, discounting is not required. Generally, implementation costs would occur shortly after adoption of the proposed action.

When performing cost-benefit analyses for nonreactor facilities, the analyst may encounter difficulty in finding consolidated information on industry implementation costs comparable to that for power reactors. The types of nonreactor facilities are quite diverse. Furthermore, within each type, the facility layouts typically lack the limited standardization of the reactor facilities. Specific data may be best obtained through direct contact with knowledgeable sources for the facility concerned, possibly the facility personnel themselves.

For a major effort beyond the standard analysis, the analyst should obtain very detailed information, in terms of the cost categories and the costs themselves. The analyst should seek guidance from NRC contractors or industry sources experienced in this area ~~(e.g.~~ such as~~,~~ architect engineering firms~~)~~. The analyst should define the incremental costs of the action at a finer level of detail. The analyst should refer to the code of accounts in the Energy Economic Data Base (United Engineers and Constructors, Inc., 1986) or Schulte et al. (1978) to prepare a detailed account of implementation costs.

5.3.2.6.1 Short-Term Replacement Power

For power reactors, a regulatory analysis should incorporate the possibility that implementation of the proposed action may result in the need for short-term replacement power. Unlike the long-term costs associated with severe power reactor accidents discussed in Section 5.3.2.6, the replacement power costs associated with industry implementation of a regulatory action would be short term (e.g., for the duration of a maintenance outage).

5.3.2.6.2 ~~Premature~~ Facility Closing Prior to License Expiration

Several nuclear power plants have been voluntarily shut down before the expiration of their operating licenses. Normally, a decommissioning cost of approximately $300 million (1993 dollars) would be associated with an end-of-life shutdown. However, if a proposed regulatory requirement is expected to result in a premature shutdown, this cost is shifted to an earlier time with an associated net increase in its present value. For example, if a plant with an estimated t years of remaining life is prematurely closed, the net increase in present value, for a real discount rate of r, becomes ($300 million) [1 - 1/(1+r)^t]:

$$Premature\ facility\ closing\ cost = Decommissioning\ cost\ x \left[1 - \frac{1}{(1+r)^t}\right]$$

Thus, for this example, a plant closing 20 years (t) early will incur an additional cost of $20 million using a 7-percent real discount rate (r).

5.3.2.7 Industry Operation

This section provides procedures for estimating the industry's incremental costs during the operating phase (i.e., after implementation) of the proposed action. The incremental costs measure the additional costs to industry imposed by the proposed action; they are costs that would not have been incurred in the absence of the action. A reduction in the net cost (i.e., cost savings) is algebraically positive; an increase (cost accrual) is negative (i.e., viewed as negative cost savings). Both NRC and Agreement State licensees should be addressed as appropriate.

In general, the analyst should perform three steps to estimate industry operation costs:

(1) Estimate the amount and types of equipment, materials, and/or labor that will be affected by the proposed action.

(2) Estimate the associated costs.

(3) Discount the costs over the remaining lifetimes of the affected facilities, then sum.

Costs incurred for operating and maintaining facilities may include, but are not limited to, the following:

- maintenance of land and land use rights
- maintenance of structures
- operation and maintenance of hydraulic, pneumatic, and electrical equipment
- scheduled radioactive waste disposal and health physics surveys
- scheduled updates of records and procedures
- scheduled inspection and test of equipment
- scheduled recertification/retraining of facility personnel
- associated recurring administrative costs
- scheduled analytical updates

For the standard analysis, the analyst should proceed as follows:

- preparing handbooks for use by the staff responsible for enforcement and handbooks for use by others responsible for compliance

- supporting and reviewing a licensee's change in its technical specifications

- conducting initial inspections to validate implementation

Sciacca (1992) assists the analyst in calculating these and "other" implementation costs. Implementation costs may include labor costs and overhead, purchases of equipment, acquisition of materials, and the cost of tasks to be carried out by outside contractors. Equipment and materials that would be eventually replaced during operation should be included under operating costs rather than implementation costs.

Three steps are necessary for estimating NRC implementation costs:

(1) Determine what steps the NRC should take to put the proposed action into effect.

(2) Determine the requirements for the staff, outside contractors, materials, and equipment.

(3) Estimate the costs of the required resources, discount if appropriate, and then sum.

Implementation is likely to affect a number of NRC branches and offices. For example, the Office of Nuclear Regulatory Research may develop a regulatory guide, NRR may review any reactor licensee submissions, and the NRC regional offices may conduct an inspection against some portion of the guide in operating facilities. In developing estimates for the implementation costs, the analyst is encouraged to contact all of the NRC components that the proposed action is likely to affect.

For the standard analysis, the analyst should identify the major tasks that should be performed to ensure implementation of the proposed rule, major pieces of equipment (if any) that should be acquired, and major costs of materials. Major tasks are then assessed to estimate the approximate level of effort (in professional staff person-hours) necessary to complete them. The number of person-hours for each task is multiplied by the appropriate NRC labor rate and then summed over all of the tasks. The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627.

Similarly, the costs to complete tasks that would be contracted out also need to be estimated. To obtain a reasonably good approximation of contractor costs, the analyst should contact the NRC component that would be responsible for contracting for the tasks. Finally, the analyst should add the costs of major pieces of equipment and quantities of materials to the labor and contract costs.

When other data are unavailable, the analyst may assume as an approximation that, for a noncontroversial amendment to an existing rule or regulation, implementation will require a total of one professional staff person-year with no additional equipment and no additional materials. For a new rule or regulation, it is much more difficult to supply a rough but reasonable estimate of the implementation cost because the level of effort and types and quantities of machinery and materials can vary dramatically. One recourse would be to use as a proxy the implementation costs for a recently adopted regulatory requirement that is similar to the proposed measure. The relative similarity of the two requirements should be judged with respect to the effort required to implement the proposed measure.

For a major effort beyond the standard analysis, a more detailed and complete accounting would be expected. The analyst can request the responsible NRC office to provide available information, such as paper submittals or records of initial inspections.

5.3.2.9 NRC Operation

After a proposed action is implemented, the NRC is likely to incur operating costs. These are the recurring costs that are necessary to ensure continued compliance. For example, adding a new regulation may require the NRC to perform periodic inspections to ensure compliance. The analyst should determine whether operations resulting from the proposed action will be conducted entirely by the NRC or in cooperation with one or more Agreement States. A reduction in the net cost (i.e., cost savings) is algebraically positive; an increase (cost accrual) is negative (i.e., viewed as negative cost savings).

The analyst should perform three steps for estimating NRC operating costs:

(1) Determine the activities that the NRC should perform after the proposed action is implemented.

(2) Estimate staff labor, contractor support, and any special equipment and material required.

(3) Estimate the costs of the required resources, discount (usually over the remaining lifetimes of the affected facilities) to yield present value, and then sum.

In determining the required post-implementation activities, the analyst should carefully examine the proposed action and ask the following questions:

- How is compliance with the proposed action to be ensured?
- Is a periodic review of industry performance required?
- What is an appropriate schedule for such a review?
- Does this action affect ongoing NRC programs; if so, will it affect the costs of those programs?

Because several NRC branches and offices may incur recurring costs attributable to the proposed action, the analyst is encouraged to contact all of the NRC components that are likely to be affected.

For the standard analysis, the analyst should obtain estimates of the number of full-time equivalent professional staff person-hours that would be required to ensure compliance with the proposed rule. The analyst should use the methodology in Abstract 5.2 of NUREG/CR-4627 to determine the NRC's labor rates.

Major recurring expenditures for special equipment and materials, and for contractors, should be added. Because operating costs are recurring, they should be discounted, usually over the remaining lifetimes of the affected facilities.

After a proposed action is implemented, the Federal (non-NRC) Government and State and local governments may incur operating costs. These are the recurring costs that are necessary to ensure continued compliance. For example, adding a new regulation may require that other government agencies in addition to the NRC perform periodic inspections to ensure compliance. The analyst should determine whether operations resulting from the proposed action will be conducted entirely by the NRC or in cooperation with one or more other government agencies.

The analyst should perform three steps for estimating the other government operating costs:

(1) Determine the activities that the other governments should perform after the proposed action is implemented.

(2) Estimate government staff labor, contractor support, and any special equipment and material required.

(3) Estimate the costs of the required resources, discount (usually over the remaining lifetimes of the affected facilities) to yield present value, and then sum.

In determining the required post-implementation activities, the analyst should carefully examine the proposed action and ask the following questions:

- Does compliance with the proposed action require non-NRC cooperation?
- Is periodic review of industry performance required beyond that of the NRC?
- What is an appropriate schedule for such a review?
- Does this action affect ongoing government programs; if so, will it affect the costs of those programs?

Because several government branches and offices may incur recurring costs attributable to the proposed action, the analyst is encouraged to contact all components that are likely to be affected.

For the standard analysis, the analyst should obtain estimates of the number of full-time equivalent professional staff person-hours that would be required to ensure compliance with the proposed rule. The analyst should cost each person-hour at the appropriate labor rate and may use it as a substitute if no more specific value is available. Major recurring expenditures for special equipment and materials, and for contractors, should be added. Because operating costs are recurring, they should be discounted, usually over the remaining lifetimes of the affected facilities.

A major effort beyond the standard analysis would proceed along the lines described above; however, a more detailed and complete accounting would be expected. The analyst could ask the responsible government agencies to provide available information.

5.3.2.11 General Public

This attribute measures costs incurred by members of the general public, other than additional taxes, as a result of implementation of a proposed action. Taxes are viewed simply as transfer

payments with no real resource commitment from a societal perspective. A reduction in the net cost (cost savings) is algebraically positive; an increase (cost accrual) is negative (i.e., viewed as negative cost savings).

Typically, costs to the general public cover such items as increased cleaning as a result of dust and construction-related pollutants, property value losses, or inconveniences such as testing of evacuation sirens. Care should be taken not to double count for general public and other government costs. If a cost could be assigned to either group, it should be assigned where it is more appropriate; the analyst should remember not to account for it again in any other attribute.

The analyst should perform two steps to estimate costs to the general public:

(1) Identify the adverse impacts incurred by the general public to implement the proposed action.

(2) Estimate the costs associated with these adverse impacts, discount if appropriate, and then sum.

The NRC does not expect regulatory actions to commonly affect this attribute. However, if relevant, the standard analysis would require the analyst to identify the major activities necessary to implement the proposed action that will result in adverse impacts to the general public. Public records or analogous experience from other communities could be used as information sources to estimate the costs to the general public.

5.3.2.12 Improvements in Knowledge

This attribute relates primarily to proposals for conducting assessments of the safety of licensee activities. At least four major potential benefits are derived from the knowledge produced by such assessments:

- improvements in the materials used in nuclear facilities
- improvements in or development of safety procedures and devices
- production of more robust risk assessments and safety evaluations to reduce uncertainty about the relevant processes
- improvement in regulatory policy and regulatory requirements

To the extent that the effects of regulatory actions can be quantified, they should be treated under the appropriate quantitative attributes. On the other hand, if the effects from the assessments are not easily quantified, the analyst must still ~~still has the burden of justifying~~provide a reasonable basis for the effort and indicat~~e~~ing its effect. If necessary, this ~~justification~~ factor would be expressed qualitatively under this attribute. An effort should be made to identify the types of costs and benefits that are likely to be accrued and who will incur them.

Consider the following statement:

> This assessment effort has a reasonable prospect of reducing our uncertainty regarding the likelihood of containment failure resulting from hydrogen burning. Such an accident may be a significant source of risk. The knowledge from the proposed assessments would enable us to assess more accurately the overall accident risk posed by nuclear reactors, and this, in turn, should benefit the public through better policy decisions.

Although this statement describes why the proposed assessment is needed, it does not provide any information for evaluating the merits of the proposed assessment.

Answering the following questions would help to fill this information gap:

- What are the likely consequences of a hydrogen-burning accident?
- To what extent would the proposed assessment reduce the uncertainty in the likelihood of a hydrogen-burning accident?
- Given our current information, what is the contribution of hydrogen burning to overall accident risk?

The above questions are specific to a particular topic. For the broader problem of providing a cost-benefit analysis of an assessment proposal, the analyst should answer the following general questions:

- What are the objectives?
- If the assessment is successful in meeting its objectives, what will the social benefits be?
- Is there a time constraint on the usefulness of the results?
- Who will benefit from the results, by how much, and when?
- What is the likelihood that the assessment will fail to meet its objectives within the time and budget constraints?
- What will be the social costs (and benefits) if the assessment is not successful or if the assessment is not undertaken?

5.3.2.13 Regulatory Efficiency

Regulatory efficiency is an attribute that is frequently difficult to quantify. If it can be quantified, it should be included under one or more of the other quantifiable attributes. If quantification is not practical, regulatory efficiency can be treated in a qualitative manner under this attribute. For example, achieving consistency with international standards groups may increase regulatory efficiency for both the NRC and such groups. However, this increase may be difficult to quantify.

If necessary, this ~~justification~~ factor would be expressed qualitatively under this attribute. The analyst should try to identify the types of cost and benefits that are likely to be accrued and who will incur them. If the proposed NRC action is expected to have major effects on regulatory

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APPENDIX A
QUALITATIVE FACTORS ASSESSMENT TOOLS

QUALITATIVE FACTORS ASSESSMENT TOOLS

A.1 PURPOSE

The purpose of this appendix is to provide guidance and best practices for use in ~~estimating~~ considering qualitative factors (i.e., intangible costs and benefits ~~(i.e., qualitative factors)~~ to improve the clarity, transparency, and consistency of the U.S. Nuclear Regulatory Commission's (NRC's) regulatory, backfit, and environmental analyses. In the staff requirements memorandum (SRM) to SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015, the Commission directed the NRC staff "to encourage quantifying costs to the extent possible and use qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data)."

Consistent with this direction, the analyst should make every effort to use quantitative attributes relevant to the cost-benefit analysis. The quantification should use monetary terms whenever possible. Dollar benefits should be defined in real or constant dollars (i.e., dollars of constant purchasing power). If monetary terms are inappropriate, the analyst should try to use other quantifiable benefits.

However, there may be ~~some~~ attributes that cannot be readily quantified~~, despite the analyst's best efforts~~. These attributes are termed "qualitative," and this appendix captures best practices for the consideration of such qualitative factors by providing methods that can be used to support the NRC's evidence-based, ~~quantitative, and~~ analytical approach to decisionmaking. This guidance provides a toolkit to enable analysts to clearly present analyses of qualitative results in a transparent way ~~that~~ for decisionmakers, stakeholders, and the general public ~~can understand~~. The methods described in this appendix should be used when quantification is not practical or possible. ~~They are not a substitute for collecting accurate information to develop realistic estimates of costs and benefits, and they do not constitute an expansion of the consideration of qualitative factors in regulatory, backfit, or environmental analyses.~~

Commented [BJ1]: Pull this sentence up from stand alone paragraph.

A.2 TYPES OF COSTS AND BENEFITS

A.2.1 Tangible Costs and Benefits

Quantifiable costs and benefits have numeric values such as dollars, physical counts of tangible items, or percentage changes of a quantifiable factor. ~~Monetized benefits are always quantifiable.~~ Monetized benefits are always quantifiable and measured in dollars or are tangible items with known conversion factors to monetize the variable (e.g., the person-rem conversion factor described in NUREG-1530, Revision 1, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy").

Examples of nonmonetized, quantifiable costs and benefits include the following:

- number of commodities or items produced for each alternative
- maintainability or supportability measures (i.e., mean-time-to-repair or average downtime)
- accuracy, timeliness, and completeness of data produced by systemic performance and operational effectiveness

A.2.2 Intangible Costs and Benefits

Intangible costs and benefits do not easily lend themselves to direct, quantitative modeling or measurement. In other words, these types of attributes (1) do not have readily available standard measurement scales and (2) tend to be subject to greater variability in modeling and results. ~~Although subjective, q~~Qualitative measures can be used to account for such benefits and make a positive contribution to the cost-benefit analysis. The analyst should use the best analytical practices (e.g., surveys and interviews) to include difficult-to-quantify costs and benefits. Examples of nonmonetized, nonquantifiable costs and benefits[1] that lend themselves to qualitative measures include the following:

- defense in depth
- perception/image
- aesthetics
- morale
- terrestrial or aquatic habitat
- quality of material or service
- safeguards and security

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[1] This list of nonquantifiable costs and benefits is based in part on that in SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," Attachment 1, dated August 14, 2014.

- operational readiness
- regulatory efficiency
- improvements in knowledge
- incorporation of advances in science and technology
- greater flexibility in practice or less prescriptive requirements
- greater specificity in existing generally stated requirements
- correction of significant flaws in current requirements

While quantifying costs and benefits helps decisionmakers understand the magnitude of the effects of alternative regulatory actions, some benefits may be difficult to quantify in monetary terms. However, they can also be too important to ignore. In ~~this~~these situations, the analysts should use accurate information to develop realistic estimates to quantify parameters and ~~should~~ then use the methods in this appendix to inform decisionmaking when quantitative analyses are difficult or would provide an incomplete analysis if presented alone~~if omitted~~.

A.3 METHODS

To facilitate the selection of consistent methods, this section provides analysts with several methods for modeling qualitative attributes and explains the circumstances best suited for ~~when~~ each method ~~would be useful~~. The use of consistent methods enables analysts to present qualitative results in a transparent way ~~that~~ for decisionmakers, stakeholders, and the general public ~~can understand~~.

Several tools are available ~~if some~~for attributes that do not lend themselves to quantification. When possible, considerations associated with these attributes should be quantified using market data, shadow pricing, or willingness-to-pay (WTP) techniques. The WTP principle captures the notion of opportunity cost by measuring what individuals are willing to forgo or ~~(~~pay~~)~~ to enjoy a particular benefit.

~~Some~~ Examples of potential data sources for quantifying cost estimates include the following:

- budget submissions
- historical cost data reports
- manpower use records and reports
- construction materials cost database

Because data collection can be time consuming, a formal data collection plan may be useful. Such a plan would include tasks to identify the types of data available; to acquire the data with supporting documentation; to determine which estimating methods and models will be used with which dataset; and to verify, validate, and normalize the data.

If an attribute does not lend itself to monetized costs and benefits, then the analyst should describe it in sufficient detail so that the decisionmaker can determine whether the benefits for the alternative outweigh the costs. This section briefly describes some methods and references for qualitative analyses~~and provides references~~. The selection of an appropriate method depends on the issues being considered and the desired objectives. By carefully considering the descriptions and applicability of the qualitative tools in this appendix ~~when selecting the appropriate tool~~, the analyst can ensure consistency with prior regulatory analyses performed by the staff. The sophistication of the method selected should be commensurate with the complexity of the issue, and ~~the particular method selected by the analyst should~~ will depend on the nature and importance of the qualitative factor, as described below for each method.

Analysts should remember that, because these alternatives do not estimate the net benefits of a policy or regulation, they ~~fall short of~~ are not the same as cost-benefit analyseis in their ability to identify an economically efficient policy. The analyst should discuss such shortcomings when presenting the results.

A.3.1 Narrative

When there are potentially important effects that cannot be quantified, the analysts should include a discussion of the resulting benefits ~~results. The analysts should discuss~~ as well as the strengths and limitations of the information. This discussion should also include ~~information on~~ the key reason(s) that the effects are difficult to quantify. In one instance, the analysts may know with certainty the magnitude of a risk to which a substantial, but unknown, number of

individuals are exposed. In another instance, based on ~~highly speculative~~ unverified assumptions, a postulated consequence may result in an ~~highly~~ uncertain magnitude of risk.

For cases in which these costs or benefits affect a recommendation, the analysts should clearly explain the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the costs and benefits. Also, the analyses should include a summary table that lists all the quantified and unquantified costs and benefits. After careful consideration of these factors using techniques described in this appendix, the analyst should document and highlight (e.g., with categories or rank ordering) those factors that are most important for decisionmaking. Examples identified in Office of Management and Budget (OMB) Circular A-4, "Regulatory Analysis," dated September 17, 2003, in the section "Time Preference for Non-Monetized Benefits and Costs," under "Benefits and Costs that Are Difficult to Quantify," are "the degree of certainty, expected magnitude, and reversibility of effects."

While the analysis often focuses on difficult-to-quantify benefits of regulatory actions, some costs are difficult to quantify as well. For example, in its document "Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities," issued September 2003, the OMB stated that certain permitting requirements (e.g., the U.S. Environmental Protection Agency's New Source Review program and Clean Power Plan) have the following effects:

> [They] restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motorcycles, may adversely affect the performance of the vehicles in terms of drivability and zero to 60 miles per hour acceleration.

The cost associated with the loss of these attributes may be difficult to quantify and monetize, so the attributes should be analyzed qualitatively.

A.3.2 Cost-Effectiveness Analysis

Cost-effectiveness analysis can ~~provide a rigorous way to~~ identify options that most effectively use the resources available without requiring the monetization of all relevant benefits or costs. Generally, a cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement). This type of analysis is commonly used to compare alternatives when the value of costs or benefits cannot be adequately monetized. If it can be assumed that the benefits are the same for all alternatives being considered, then the task is to minimize the cost of obtaining them through a cost-effectiveness analysis. This method may be used in cases with substantial uncertainties or with important values that are difficult to quantify. In such instances, alternatives that yield equivalent benefits may be evaluated based on their cost-effectiveness. A regulatory analysis incorporating this method may also be used, if there are multiple ways to achieve compliance or reach a level of adequate protection and the Commission finds it necessary or appropriate to specify the way to achieve that level of protection. A cost-effectiveness analysis of the various alternatives under consideration improves technical efficiency in achieving a desired outcome that may be valuable to a decisionmaker.

The cost-effectiveness of an alternative is calculated by dividing the present value of total costs of the option by the nonmonetary quantitative measure of the benefits it generates. The ratio is an estimate of the costs incurred to achieve a unit of the outcome from a particular policy option. For example, in a security scenario, the analyst should determine the costs expressed in dollars incurred to save a person's life or mitigate a security event. Presumably, there are alternative ways to achieve these objectives and determine their costs. The analysis does not evaluate benefits in monetized terms but in an attempt to find the least-cost option to achieve a desired quantitative outcome.

One technique for comparing and prioritizing a list of alternatives is the decision matrix. This flexible technique may be used to evaluate most quantitative and nonquantitative costs and benefits.

In this example, some decision elements are monetized, but others are evaluated ~~subjectively~~ qualitatively because they are not readily quantifiable. While both types of decision elements could be evaluated directly using a decision matrix, the NRC recommends evaluating only nonmonetized data using this technique ~~to avoid weakening or degrading the value of the quantified data~~. The optimum approach is to use a decision matrix to evaluate the nonmonetized criteria, evaluate the monetized data separately, and then consider both monetized and nonmonetized data to develop a recommendation. Tables A-1 and A-2 provide an example of this technique in which weighting factors are assigned based on the importance of the attribute in meeting the regulatory objective, and the rating factor is a measure assigned to determine the overall performance with respect to the decision element.

Table A-1 Example of a Decision Matrix—Quantification of Intangible Benefits

Decision Element	Normalized Weighting Factor	Alternative 1			Alternative 2			Alternative 3		
		Data	Rating	Score	Data	Rating	Score	Data	Rating	Score
Maintenance Downtime	.40	7 h	9	3.6	10 h	7	2.8	14 h	4	1.6
Reduced Error Rate	.25	5 per 100	5	1.25	2.5 per 100	7	1.75	8 per 100	2	.50
Suitability	.20	Very Good	4	.80	Good	2	.40	Excellent	6	1.20
Improved Productivity	.15	240 per cycle	8	1.20	230 per cycle	7	1.05	200 per cycle	6	.90
Total Weight	1.00	Total Score		6.85	Total Score		6	Total Score		4.2

For each criterion, the score is determined by multiplying the weighting factor for the criterion by the rating for the alternative (the weighting factor and rating being subjective numbers). The cost of the alternatives would be divided by the total scores in the bottom row to produce a cost-benefit index to arrive at a recommendation. To achieve this cost, multiply the benefit score by the cost-benefit index. Table A-2 shows an example.

Table A-2 Example of a Cost-Benefit Index

Cost-Benefit Index	Alternative 1	Alternative 2	Alternative 3
Cost	24	20	19
Benefit Score	6.85	6	4.2
Cost-Benefit Index	3.50	3.33	4.52

Cost-effectiveness results based on averages should be considered carefully. They are limited by the same drawbacks as cost-benefit ratios. The alternative that exhibits the smallest cost-effectiveness ratio, or the alternative with the highest cost-benefit ratio, may not be the preferred alternative that maximizes net benefits. Incremental cost-effectiveness analysis can help avoid mistakes that can occur when proposed regulatory actions are based on average cost-effectiveness. The incremental cost-effectiveness ratio determines the marginal or incremental cost for an additional unit of benefit when choosing between mutually exclusive alternatives.

A cost-effectiveness analysis can also be misleading when the "effectiveness" measure does not appropriately weigh the consequences of the alternatives. For example, when effectiveness is measured in a quantity of reduced emissions, cost-effectiveness estimates may be misleading, unless the reduced emission outcomes result in the same health and environmental benefits.

Likewise, if the range of alternatives considered results in different levels of stringency, the analysts should determine the cost-effectiveness of each option compared with the baseline, as well as its incremental cost-effectiveness compared with successively more stringent requirements. The analysts should prepare an array of cost-effectiveness estimates that would allow a comparison across different alternatives. However, if analyzing all possible combinations is not practical (because there are many alternatives or possible interaction effects), then the analysts should use professional judgment to choose reasonable alternatives for consideration.

Some caveats exist for the measurement of the associated costs using the cost-effectiveness technique:

- The marginal cost-effectiveness should be calculated. It is the marginal or incremental cost-effectiveness of the alternative that should be compared with the baseline cost-effectiveness alternative (i.e., the status quo). The policy that has the lowest marginal cost per unit of effectiveness will be the most efficient way to use resources.
- The costs include all compliance costs incurred by both the private and public sectors. Such costs should be based on resource or opportunity costs, not merely the monetized costs of goods and services.
- The costs should be properly defined and measured in the calculation of cost-effectiveness.
- The costs incurred may be private (i.e., capital or operating expenditures) or societal costs that are spread over ~~many~~ a number of years. To compare alternative options, both the costs and benefits should be discounted to a common time period.

In 1992, the NRC used a regulatory break-even analysis to evaluate the adoption of a proposed rule regarding air gaps to avert radiation exposure resulting from NRC-licensed users of industrial gauges (published in Volume 57 of the *Federal Register* (FR), page 56287 (57 FR 56287). The NRC found insufficient data to determine the averted radiation exposure. To estimate the reduction in radiation exposure, the NRC performed a break-even analysis. The analysis assumed a source strength of 1 curie for a device with a large air gap, which produces 1.3 rem per hour at a distance of 50.8 cm (20 inches) from a cesium-137 source. Assuming half this dose rate would be produced, on average, in the air gap, and that a worker is within the air gap for 4 hours annually, the NRC estimated the worker would receive a radiation dose of 2.6 rem per year. The agency estimated that adopting the proposed air-gap rule would be cost-effective if it saved 347 person-rem per year. At an averted occupational radiation dose of 2.6 person-rem per year for each gauge licensee, incidents involving at least 133 gauges would have to be eliminated. Given the roughly 3,000 gauges currently used by these licensees, the proposed rule would have to reduce the incident rate only by roughly 4 percent, a value the NRC believed to be easily achievable. As a result, the staff recommended adoption of the air-gap rule.

A.3.4 Bounding Analysis

A bounding analysis is ~~an analysis~~ designed to ~~identify~~ limit or provide a specified~~the~~ range of potential impacts or risks in order to calculate best case and worst case results. Such an approach might be used in a cost-benefit analysis as a screening tool to simplify assumptions and modeling, to address uncertainty, or to address unavailable or unknown data. These bounding analyses (or enveloping scenarios) should be chosen so that they present the greatest possible extremes and are limiting values for the inputs to the analysis. For the best case scenario, the analyst would use assumptions and inputs that maximize the benefits and minimize the costs. For the worst case scenario, the analysts would use assumptions and inputs that minimize the benefits and maximize the costs. The results of such bounding analyses can be used to inform the decisionmakers of the extent or of the severity of the results. If the sign of the net benefit estimate is positive across this range, there is confidence that the proposed regulatory action is beneficial. Analysts should carefully identify judgments or assumptions made in selecting appropriate bounding input values to describe whether they used absolute limits or reasonable maximum limits. In explaining the results, the analyst should communicate to the decisionmakers that the use of bounding analysis results may be unnecessarily conservative.

A.3.5 Rank Order/Weight-Based Analysis

This analysis allows for selection based on quantifiable and nonquantifiable costs and benefits and allows the Commission to adjust criteria based on perceived importance. A ~~major~~ drawback to this method is that ~~it implies objectivity when~~ there is no objective ~~reliable~~ basis for the ranking, which may draw criticism as it is difficult to make quantitative statements about the actual difference between alternatives.

A.3.6 Maximin and Maximax Analysis

The maximin and maximax analyses are two criteria of decision theory where multiple alternatives can be compared against one another under conditions of uncertainty. In the maximin analysis, the analyst looks at the worst that could happen in each alternative for a given outcome and then chooses the least worst alternative (i.e., the alternative where the loss

of false positives for some outcome. Examination of the results of each alternative shows the following:

(1) For alternative 1, the lowest number of false positives is three for testing 10 times a year.
(2) For alternative 2, the lowest number of false positives is one for testing 10 times a year.
(3) For alternative 3, the lowest number of false positives is two for testing 10 times a year.

According to the maximax analysis, the analyst would choose alternative 2 for testing 10 times a year, because it has the lowest number of false positives ~~(i.e., one is less than two and three)~~.

The choice (maximin or maximax) depends on the ~~personal~~ preference of the decisionmaker. The maximin criterion involves selecting the alternative that maximizes the minimum payoff achievable, and so a decisionmaker who ~~values~~ prefers a guaranteed minimum at the risk of losing the opportunity to make big gains would opt for the maximin result. The maximax criterion involves selecting the alternative that maximizes the greatest payoff available, so this approach would be more suitable for ~~an optimist, or a~~ "risk-seeking" investor, who ~~seeks~~ wants to achieve the best results if the best happens.

A.3.7 Conjunctive and Disjunctive Analysis

The conjunctive and disjunctive analysis method requires a satisfactory performance, rather than the best, in each decision criterion. The conjunctive step requires an alternative to meet a minimal performance threshold for all criteria. The disjunctive step requires the alternative to exceed the given threshold for at least one criterion. Any alternative that does not meet the conjunctive or disjunctive rule is not considered further. These screening rules can be used to select a subset of alternatives for analysis by other, more complex methods.

A.3.8 Lexicographic Analysis

This analysis involves lexicographic ordering, which ranks alternatives one at a time, starting with the most important and heavily weighted criterion. If two or more alternatives are preferentially tied for the most important criterion, then they are compared on the second most important criterion. The surviving alternatives are then compared on the third most important criterion, and so on, until the tie is broken, resulting in the chosen alternative. This method is appealing because of its simplicity; however, it will require subjective agreement by participants on the ordering of criteria and the assumption of independent assessments when considering two or more criteria simultaneously.

One example of lexicographic ordering would be the evaluation of alternatives where attributes of each alternative are considered. For example, such an evaluation could consider six attributes over three alternatives, represented by a 6 x 3 matrix of potential evaluative information. An example of a set of attributes could consist of the following:

(1) averted occupational exposure
(2) reduction in core damage frequency
(3) training and certifications
(4) required operator actions outside the control room
(5) nuclear consequence management
(6) standard operating procedures

Based on this information, questionnaires can be prepared that will collect and present evaluative information in a format similar to that found in product ratings summaries. The questionnaires can then be distributed to a populace, in which respondents~~subjects~~ can be asked to evaluate the information provided by the questionnaire and rank order the attributes in terms of decreasing preference. In addition to the ranking task, the respondents~~subjects~~ can be asked to assign importance weights to various characteristics of each attribute, rate each alternative's characteristics on a desirability scale, and identify a minimum acceptability limit on each attribute's characteristic contained in the questionnaire.

A.3.9 Decision Matrix

The decision matrix is a popular method for comparing and prioritizing a list of alternatives. This highly flexible tool effectively evaluates nonmonetized and difficult to quantify costs and benefits.

Monetized decision criteria are ~~objective and~~ quantifiable; nonmonetized criteria are ~~subjective and~~ not directly quantifiable. While a cost-benefit analysis considers both types of criteria, the monetized criteria demand a more rigorous analysis, specifically because they are objective and quantifiable and less influenced by subjective assessment. If the monetized criteria and nonmonetized criteria are used in a single decision matrix, then the analysts would need to apply ~~subjective~~ qualitative evaluation to the monetized data~~, which would weaken or degrade the value of that data~~. Therefore, quantified costs and benefits should be kept separate from nonmonetized costs and benefits and not combined in a single decision matrix. The best approach is to use a decision matrix to evaluate the ~~subjective~~ qualitative criteria, evaluate the quantified monetized data separately, and then consider both monetized and nonmonetized data to develop a staff recommendation.

When considering a regulatory issue in generalized form with m qualitative criteria and n alternatives, let $C_1,\ldots,C_m$ and $A_1,\ldots,A_n$ denote the difficulty in quantifying criteria and alternatives, respectively. As shown in Figure A-1, each row belongs to a criterion, and each column describes the performance of an alternative. The score a_{ij} describes the performance of alternative A_j against criterion C_i. For simplicity, the specified convention is that a higher score value means a better performance, since any goal of minimization can be easily transformed into a goal of maximization.

		x_1	.	.	x_n
		A_1	.	.	A_n
w_1	C_1	a_{11}	.	.	a_{m1}
.	.	.	.	.	.
.	.	.	.	.	.
w_m	C_m	a_{m1}	.	.	a_{mn}

Figure A-1 The Decision Matrix

As shown in Figure A-1, weights $w_1,\ldots,w_m$ are assigned to the criteria. Weight w_i reflects the relative importance of criterion C_i to the decision and, by convention, is assumed to be positive. The weights of the criteria are usually determined subjectively and represent the opinion of the analysts or the synthesized opinions of a group of experts using a group decision technique.

The values $x_1,\ldots,x_n$ associated with the alternatives in the decision table are the final ranking values of the alternatives. By convention, a higher ranking value means a better performance of the alternative, so the alternative with the highest ranking value is the best of the alternatives.

This technique can partially or completely rank the alternatives: a single most preferred alternative can be identified or a short list of a limited number of alternatives can be selected for subsequent detailed appraisal using other methods.

The multiattribute utility theory (MAUT), described next, and outranking methods, described in Section A.3.10, are two main techniques for assigning weights in decision matrices.

A.3.9.1 Multiattribute Utility Theory Technique

The family of MAUT methods consists of aggregating the different criteria into a function, which is maximized. Thereby, the mathematical conditions of aggregations are examined. As described in NUREG-1530, Revision 1, this theory allows for the complete compensation between criteria (i.e., the gain on one criterion can compensate for the loss on another).

In most of the approaches based on the MAUT, the weights associated with the criteria can properly reflect the relative importance of the criteria only if the scores a_{ij} are from a common, dimensionless scale. The basis of MAUT is the use of utility functions. Utility functions can be applied to transform the raw performance values of the alternatives against diverse criteria, both factual (objective, quantitative) and judgmental (subjective, qualitative), to a common, dimensionless scale. In practice, the intervals [0,1] or [0,100] are used for this purpose. Utility functions play another ~~very~~ important role: they convert the raw performance values so that a ~~more~~ preferred performance obtains a higher utility value. A good example is a criterion reflecting the goal of cost minimization. The associated utility function should result in higher utility values for lower cost values.

It is common for some normalization to be performed on a nonnegative row in the matrix of the a_{ij} entries. The entries in a row can be divided by the sum of the entries in the row, by the maximum element in the row, or by a desired value greater than any entry in the row. These normalizations can also be formalized as applying utility functions.

A.3.9.2 Simple Multiattribute Rating Technique

The simple multiattribute rating technique (SMART) is the simplest form of the MAUT methods. The ranking value x_i of alternative A_j is obtained simply as the weighted algebraic mean of the utility values associated with it, as shown in the equation below:

$$x_j = \frac{\sum_{i=1}^{m} w_i a_{ij}}{\sum_{i=1}^{m} w_i}, j = 1, \ldots, n.$$

where:
a = alternative
m = number of criteria (i.e., 1 to m)
n = number of alternatives (i.e., 1 to n)
w = weights (i.e., w_1 reflects the relative importance of criteria a_1 to the decision)
x_j = ranking value of alternative A_j

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APPENDIX B
COST ESTIMATING AND BEST PRACTICES

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COST ESTIMATING AND BEST PRACTICES

B.1 PURPOSE

The purpose of this appendix is to provide uniform guidance and best practices for the methods and procedures recommended for use by the U.S. Nuclear Regulatory Commission (NRC) staff when preparing cost estimates, including, but not limited to, those for regulatory analyses, backfit analyses, and environmental analyses. The appendix describes practices relative to estimating a life-cycle cost (LCC). LCCs include all anticipated costs associated with a project or program alternative throughout the life of a nuclear facility ~~(i.e.~~, from authorization through end-of-life-cycle operations~~)~~.

Before following this guidance and beginning a cost estimating process, the NRC staff should determine as a threshold matter whether applying a new requirement to an already licensed facility is necessary for adequate protection of public health and safety. This ensures that when a new regulatory requirement is necessary for adequate protection, the staff does not impermissibly consider costs.

This appendix does not impose new requirements, establish NRC policy, or ~~instruct~~ direct the actions of NRC staff ~~in preparing cost estimates~~. Rather, this appendix provides information on accepted industry standards on best practices and processes for cost estimating, including practices promulgated by the Government Accountability Office (GAO) in its guide, "Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs," issued April 2009 (GAO, 2009). In GAO-15-98, "NRC Needs to Improve Its Cost Estimates by Incorporating More Best Practices," issued December 2014 (GAO, 2014), the GAO specifically recommended that NRC cost estimating guidance be aligned with relevant cost estimating best practices identified ~~in~~ by GAO ~~15-98~~ to ensure that future cost estimates are prepared in accordance with relevant cost estimating best practices. This appendix includes other recommendations from GAO ~~15-98~~.

B.2 GUIDANCE OVERVIEW

High-quality cost estimates provide an essential element for successful project and program management. The main objective of this appendix is to provide guidance ~~that should~~to improve the quality of cost estimates that ~~support~~ inform Commission decisionmaking. The cost estimating principles and processes described in this appendix meet or exceed Federal and NRC requirements while referring to industry standards and best practices, where appropriate.

High-quality cost estimates should satisfy four characteristics established by industry best practices~~—they should be credible, well documented, accurate, and comprehensive~~ (GAO, 2009):

- **Credible when the assumptions and estimates are realistic**—The estimate discusses any limitations of the analysis from uncertainty or biases surrounding data or assumptions~~has been cross-checked and reconciled with independent cost estimates, the level of confidence associated with the point estimate[1] has been identified, and a sensitivity analysis[2] has been conducted~~.

- **Well-documented**—The supporting documentation for the estimate ~~includes~~ is thoroughly documented, including source data and significance, clearly detailed calculations and results, and explanations~~a narrative explaining the process, sources, and methods used to create the estimate, and the estimate identifies the underlying data and assumptions used to develop the estimate~~.

- **Accurate**—The ~~actual costs deviate little from the assessment of costs likely to be incurred.~~estimate is unbiased, the work is not overly conservative or overly optimistic, and is based on an assessment of most likely costs.

- **Comprehensive**—The estimate's level of detail ensures that cost elements are neither omitted nor double counted~~The estimate accounts for all possible costs associated with a project, it is structured in sufficient detail to ensure that costs are neither omitted nor duplicated, and it has been formulated by an estimating team with the composition commensurate with the assignment~~.

This appendix contains industry best practices for carrying out these steps. Enclosure B-5 (Table B-7) contains a cross-reference of the 12 key ~~GAO estimating~~ steps to estimating (GAO, 2009) and the~~ir implementing~~ tasks related to implementing ~~to the sections of this appendix that discuss the NRC guidance for accomplishing~~ those steps.

B.2.1 Purpose of a Cost Estimate

The purpose of a cost estimate is determined by its intended use (e.g., regulatory analyses, backfitting analyses, environmental analyses), ~~and its intended use~~which, in turn, determines ~~its~~

~~[1] A point estimate is the best guess or the most likely value for the cost estimate, given the underlying data. The level of confidence for the point estimate is the probability that the point estimate will actually be met.~~

~~[2] A sensitivity analysis is an examination of the effect of changing one variable relative to the cost estimate while all other variables are held constant to identify which variable most affects the cost estimate.~~

the scope and detail of the effort. Accordingly, the principal purposes of a regulatory cost estimate are to help ensure the following:

- Regulatory decisions made in support of statutory responsibilities are based on adequate information concerning the need for and consequences of proposed actions.
- Appropriate alternative approaches to achieve regulatory objectives are identified and analyzed.
- The proposed action is the clearly preferred alternative.
- Proposed actions subject to the backfit rule (Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting"), and not within the exceptions in 10 CFR 50.109(a)(4), provide a substantial increase in the overall protection of public health and safety and the common defense and security, and the direct and indirect costs of implementation are justified in view of this substantial increase in protection.

B.2.2 Overview of the Cost Estimating Process

Traditionally, cost estimates are produced by gathering input, developing the cost estimate, ~~and its documentation~~documenting the process, and generating the necessary output. Table B-1 explains the steps in the GAO cost estimating process that should be followed to ensure the development of accurate and credible cost estimates. These best practices represent an overall process of established, repeatable methods that result in high-quality cost estimates that are comprehensive and accurate and that can be easily and clearly traced, replicated, and updated.

This cost estimating process contains 12 steps that should result in reliable and valid cost estimates that can be used to ~~make~~ inform~~ed~~ decisions. Table B-1 lists the 12 steps, extracted from GAO-09-3SP (GAO, 2009).

Table B-1 The 12 Steps of a High-Quality Cost Estimating Process

Step	Description	Associated Tasks
1	Define the estimate's purpose.	• Determine the estimate's purpose, required level of detail, and overall scope. • Determine who will receive the estimate.
2	Develop an estimating plan.	• Determine the composition of the cost estimating team ~~and develop the master schedule~~. • Determine who will do the independent cost estimate. • Outline the cost estimating approach. • Develop the timeline for the estimate ~~timeline~~.
3	Define program characteristics.	• In a technical baseline description document, identify the program's purpose and its system and performance characteristics, as well as all system configurations. • Identify any technology implications. • Develop the program acquisition schedule and acquisition strategy. • Determine the relationship to other existing systems, including predecessor or similar legacy systems. • Identify support (e.g., ~~manpower~~FTE/contract work, training) and security needs and risk items. • Determine system quantities for development, test, and production.

B.3 COST ESTIMATING INPUTS

Cost estimate development is initiated by inputs to the process. These inputs are ~~process~~ elements that can either occur one time or be iterative. Internal NRC reviews or external feedback may identify the need to revise various process elements to improve the quality of the cost estimate. Cost estimates that are developed early in the analysis of proposed regulatory alternatives may not be derived from detailed engineering designs and specifications, but the cost estimate should be sufficiently developed to support the intended purpose. During the life of the project, cost estimate inputs become increasingly definitive and reflect the scope and specificity defined for the project.

Before following this guidance and beginning a cost estimating process, the NRC staff should determine as a threshold matter whether applying a new requirement to an already licensed facility is necessary for adequate protection of public health and safety. This ensures that when a new regulatory requirement is necessary for adequate protection, the staff does not impermissibly consider costs.

B.3.1 Project Requirements

Cost estimates are performed for regulatory analyses, backfitting analyses, and environmental analyses. Each analysis may have specific, detailed, or different requirements based on the intended purpose of the analysis.

B.3.2 Documentation Requirements

The analyst should document scope assumptions, regulatory baseline determinations, and likely alternatives. The analyses consider the accuracy of supporting estimates and project-specific evaluations.

B.4 COST ESTIMATING CHARACTERISTICS AND CLASSIFICATIONS

B.4.1 Planning the Cost Estimates

Table B-2 describes the planning steps required to produce credible cost estimates.

Table B-2 Basic Characteristic of Credible Cost Estimates

Cost Estimate Planning Step	Description
Clear Identification of Task	The cost analyst should receive the scope description, ground rules and assumptions, and technical and performance characteristics. Clearly identify estimate constraints and conditions to ensure the preparation of a well-documented estimate.
Broad Participation in Preparing Estimates	Stakeholders should participate in providing requirements, system parameters, and cost data based on stated regulatory objectives. Independently verify external data for accuracy, completeness, and reliability.
Use of Valid Data	Use numerous sources of suitable and relevant data. Use relevant, historical data from similar work to project costs of the new work. The historical data should be directly related to the performance characteristics of the new scope.
Standardized Structure for the Estimate	Use a standard WBS that is as detailed as appropriate, continually refining it as the maturity of the scope develops and the regulatory actions become more defined. The WBS helps to ensure that no necessary portions of the estimate (and schedule) are omitted or duplicated. This makes it easier to make comparisons to similar work.
Provision for Uncertainties and Risk	Identify the confidence level (e.g., 80 percent) appropriate for the cost estimate. Identify uncertainties and develop an allowance to mitigate the cost effects of uncertainties.
Recognition of Escalation	Ensure that the cost estimate properly and realistically reflects economic escalation (i.e., inflating the price of goods and services using an appropriate consumer price index to account for changes in prices over time). Clearly note assumptions. Identify the source of escalation information and explain and justify the applicability of the rates.
Recognition of Excluded Costs	Include all costs associated with the scope of work; if any cost has been excluded, disclose and include a rationale for the exclusion.
Independent Review of Estimates	Conduct an independent review of an estimate as a crucial step to establishing confidence in the estimate. Ensure that the independent reviewer verifies, modifies, and validates an estimate to ensure realism, completeness, and consistency.
Revision of Estimates for Significant Changes	Update estimates to reflect changes during the project. Large changes that affect costs can significantly influence decisions. Give appropriate justification and explanation for such changes.

Source: Based on GAO-09-3SP, Table 1 (GAO, 2009).

B.4.2 Cost Estimate Classifications

Cost estimates have common characteristics, such as. ~~The most common characteristics are~~ levels of definition, requirements, and techniques used. These characteristic levels are generally grouped into cost estimate classifications. Cost estimate classifications may be used with any type of project or work and may include consideration of (1) where a project stands in its life cycle, (2) level of definition (amount of information available), (3) techniques to be used in the estimation (e.g., parametric vs. definitive), and (4) time constraints and other estimating variables.

estimating techniques used, the level of effort or time budgeted to prepare the estimate, and extraneous market conditions (e.g., periods of rapid price escalation, labor climate factors).

As a general rule, particularly for potential regulatory actions that are in the early stages of development, the estimate should be developed using a combination of estimate classifications. In these situations, the analyst should use a combination of detailed unit cost estimating (Class 1) techniques for work that will be executed in the future, preliminary estimating (Class 3) techniques for work that is currently in the planning stages but less defined, and order of magnitude estimating (Class 5) techniques for future work that has not been well defined. For example, the regulatory basis phase is a Class 5 estimate, the proposed rule phase is a Class 4 estimate, and the final rule phase is a Class 3 estimate, although specific cost elements within any of these three phases may be estimated at more-detailed levels (e.g., Class 1 or Class 2).

B.4.3 Cost Estimate Ranges

When preparing cost estimates for early conceptual designs, it is important to recognize that variations in the basis for the design will have the greatest impact on costs. Estimating tools and methods, while important, should not be the main focus during the early stages of a project when estimate accuracy is poorest. In the early phases of defining and evaluating proposed regulatory requirements, effort should be directed toward establishing a better design basis than on using more detailed estimating methods.

The cost estimate range (lower and upper bounds) is determined by independently assessing the lower and upper cost estimate range for each cost element. In some situations, the range may, in part, be a function of scope variability (e.g., if a decision to add 5 or 10 submittals is pending) or could result from cost and schedule estimate uncertainties as part of the risk analysis.

The lower bound of the cost range may represent a scenario where the analyst has determined a low likelihood of impact and, therefore, may not need additional resources to modify the current design or practice.

The upper bound of the cost range may represent a scenario where the analyst determined a large cost uncertainty associated with the required regulatory treatment for the modification, lack of specificity in the process steps or controls, or other cost drivers. Regardless, the cost estimates should be unbiased. The analyst should reflect such uncertainty in the estimate range and not by increasing the costs of each element or component of the estimate. GAO-09-3SP defines two types of contingency—contingency reserve and management reserve. Contingency reserve represents funds held at or above the program office for "unknown unknowns" that are outside a contractor's control. In this context, contingency funding is added to an estimate to allow for items, conditions, or events for which the state, occurrence, or effect is uncertain and that experience shows are likely to result in additional costs. Management reserve funds, in contrast, are for "known unknowns" that are tied to the contract's scope and managed at the contractor level. Unlike contingency reserve, which is funding related, management reserve is budget related. The value of the contract includes these known unknowns in the budget base, and the contractor decides how much money to set aside.

NRC regulatory analysis cost estimates do not use either of these types of contingency (GAO, 2009). The use of sensitivity analysis and uncertainty analysis (discussed in Appendix C, "Treatment of Uncertainty," to NUREG/BR-0058, Revision 5) provides a means to determine the contingency amount required for a project budget. Therefore, the analyst should not add contingency to the upper range cost estimate.

B.5 COST ESTIMATING METHODS

Many cost estimating methods and techniques are available to use in performing a cost estimate. Depending on project scope, estimate purpose, level of project definition, and availability of cost estimating resources, the analyst may use one, or a combination, of these techniques. As shown in Table B-3, as the level of project definition increases, the estimating methodology tends to progress from conceptual (judgment, analogy, parametric) techniques to more detailed (activity-based, unit-cost) techniques. The following sections include techniques that may be employed in developing cost estimates.

B.5.1 Engineering-Buildup Estimating Method

Activity-based, detailed, or unit-cost estimates are typically the most definitive of the estimating techniques and use information down to the lowest level of detail available. These types of estimates are also the most commonly understood and used estimating techniques.

The accuracy of activity-based, detailed, or unit-cost techniques depends on the accuracy of available information, the resources spent to develop the cost estimate, and the validity of the bases of the estimate. Analysts typically use a work statement and set of drawings or specifications to identify activities that make up the project. Nontraditional estimates may use a WBS, team input, and work statement to identify the activities that make up the work.

The analyst separates each activity into detailed tasks to itemize and quantify labor hours, material costs, equipment costs, and subcontract costs. Standard estimating practices use an action verb as the first word in an activity description. Use of verbs provides a definitive description and clear communication of the work that is to be accomplished. Subtotaled, the detailed items comprise the direct costs. Indirect costs, overhead costs, contingencies, and escalation are then added, as necessary. Many of these factors may not be appropriate when performing an incremental cost estimate (e.g., regulatory analyses). The analyst should include contingencies when performing a sensitivity analysis for a regulatory analysis (i.e., a high estimate). Appendix C, "Treatment of Uncertainty," to NUREG/BR-0058 discusses the concept of sensitivity analysis as a subset of contingency analysis.

The analyst may revise the estimate as details are refined. The activity-based, detailed, or unit-cost estimating techniques are used mostly for Class 1 and Class 2 estimates, and they should always be used for proposal or execution estimates.

Activity-based, detailed, or unit-cost estimates imply that activities, tasks, work packages, or planning packages are well defined, are quantifiable, and are to be monitored so that performance can be reported accurately. The NRC staff does not use cost estimates in regulatory analyses ~~to estimate regulatory burden~~ to develop work ~~packages~~ or planning packages, nor does it update the estimate after the Commission decision on the proposed action. Therefore, the NRC does not monitor those estimated costs.

Quantities should be objective, discrete, and measurable. These quantities provide the basis for an EVM of the work within the activities and the WBS. The 2012 DOE "Work Breakdown Structure Handbook" is a suitable reference for use in developing a product-oriented WBS.

The advantages of using the parametric cost estimating include the following:

- **Versatility**—If the data are available, parametric relationships can be derived at any level (e.g., system, subsystem, component). As the design changes, CERs can be quickly modified and used to answer "what-if" questions about design alternatives.

- **Sensitivity**—Simply varying input parameters and recording the resulting changes in cost will produce a sensitivity analysis. Typically, a sensitivity analysis characterizes the effect of one input at a time, but can be used to characterize the effect of multiple inputs together on the outcomes. A sensitivity analysis typically does not assess the relative likelihood of different outcomes.

- **Statistical output**—Parametric relationships derived through statistical analysis will generally have both objective measures of validity (statistical significance of each estimated coefficient and of the model as a whole) and a calculated standard error that can be used in risk analysis. Analysts can use this information to provide a confidence level for the estimate based on the CER's predictive capability.

The disadvantages of using parametric-estimating techniques include the following:

- **Database requirements**—The underlying data should be consistent and reliable. While it may be time consuming to normalize the data or to ensure that the data were normalized correctly, without understanding how data were normalized, the analyst is accepting the database on faith, thereby increasing the estimate's risk.

- **Currency**—CERs should be periodically updated to capture the most current cost, technical, and programmatic data.

- **Relevancy**—Using data outside the CER range may cause errors because the CER loses its predictive capability for data outside the development range.

- **Complexity**—Complicated CERs (e.g., nonlinear CERs) may make it difficult to readily understand the relationship between cost and its independent variables.

B.5.2.2 End-Product-Unit Method

The end-product-unit method is used when enough historical data are available from similar work based on the capacity of that work. The method does not take into account any economies of scale, or the location or timing of the work.

Consider an example of estimating the cost of reviewing a routine submittal. From a previous estimate, the total cost was found to be $150,000 to review 10 submittals, or $15,000 per submittal. For a new reporting requirement of similar complexity, the estimated cost would be $15,000 per review for two submittals, or $30,000. As another example, when estimating the overnight construction cost (construction costs without loan costs) of a nuclear power plant, the generally accepted industry practice is to multiply the planned megawatt capacity of the proposed plant by a dollars-per-megawatt value obtained by calculating the dollars-per-megawatt construction costs of recently completed nuclear power plants.

B.7 COST ESTIMATING DEVELOPMENT PROCESS

Cost is defined as the resources that will be consumed if an objective is undertaken. The value of consumed resources, which can be quantified, is measured in dollars. This makes different cost elements comparable with themselves, as well as with benefits. In addition, because resource value indicates what resources are required for a particular proposed objective, it is a measure of the cost of other objectives that cannot be pursued. Each alternative method of accomplishing the regulatory objective will have its own associated cost. Costs include all incremental capital, labor, and natural resources required to undertake each alternative, whether they are explicitly paid out of pocket, involve an opportunity cost, or constitute an external cost that is imposed on third parties. Costs may be borne by the NRC, other governmental agencies, industry, the general public, or some other group. All costs borne by all groups should be included to measure the total value of what should be forgone to undertake each alternative and to avoid errors in answering the economic questions.

B.7.1 Overview of the Cost Estimating Process

Section B.2.2 of this appendix explains the overall cost estimating process model. This section discusses the cost estimating development process following the 12-step model recommended by the GAO (GAO, 2009) as it applies to regulatory decisionmaking. Table B-1 identifies the implementing tasks related to the GAO 12-step cost estimating development process. Systematically performing these tasks enhances the reliability and validity of cost estimates.

B.7.2 Estimate Planning

The estimate planning task (input in Table B-1) includes the following:

- establishing when the estimate is required
- determining who will prepare the estimate
- producing a plan or schedule for estimate completion
- selecting and notifying individuals whose input is required
- collecting scoping documents
- selecting estimating technique or techniques
- conducting an estimate kickoff meeting

These activities are conducted in the following steps:

- **Develop Estimate-Purpose Statement**—State the purpose in precise, unambiguous terms. Indicate why the estimate is being prepared and how the estimate is to be used. Describe any relevant regulatory or cost drivers. In many cases, this activity will be performed in conjunction with the NRC rulemaking project manager and ~~his or her~~the working group.

- **Develop Technical Scope**—Provide a detailed description of the work included in the estimate. Identify the activities included in the cost estimate, as well as relevant activities excluded from the cost estimate and the rationale for their exclusion. For performance-based rulemaking, the cost analyst will work closely with the rulemaking project manager and ~~his or her~~the team to develop, in sufficient detail, how the proposed regulatory changes could be implemented.

Regulations can be either prescriptive or performance-based. Prescriptive requirements specify features, actions, or programmatic elements to be included in the design or process as the means for achieving a desired objective. Performance-based requirements rely upon measurable (or calculable) outcomes (i.e., performance results) to be met but provide more flexibility to the licensee as to the means of meeting those outcomes. A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decisionmaking and incorporates the following principles: (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee, performance; (2) objective criteria to assess performance are established based on risk insights, deterministic analyses, and performance history; (3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not, in and of itself, constitute or result in an immediate safety concern (NRC, 1999).

- **Determine Approaches To Be Used to Develop the Estimate**—Decide on the estimating techniques and methodologies that will be used to develop the cost estimate, such as those described in Section B.5.

The cost analyst completes this task ~~when he or she has~~with a concise statement of the regulatory problems. The statement describes 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, the cost analyst can develop ~~his or her~~ a plan for deciding on the ~~measure of the~~ safety importance of a proposed regulatory change ~~safety importance~~, ~~what~~ regulatory alternatives ~~are~~ available to address the issue, ~~what~~ cost benefit attributes ~~are~~ affected, ~~the~~ estimating methodology or methodologies the analyst will use, and potential sources of data. The cost analyst completes this task when ~~he or she has~~ a clear plan for preparing the cost estimate and can describe these planning elements in the regulatory analysis.

B.7.3 Cost Estimate Inputs

It is essential that cost analysts plan for and gain access—where feasible—to cost, technical, and program data to develop a complete understanding of the underlying data needed to prepare a comprehensive, well-documented, accurate, and credible cost estimate. This section describes sources of cost estimate data and development considerations.

B.7.3.1 Sources of Cost Estimate Data

Because all cost estimating methods are data driven, the cost analyst should know the best data sources (see Table B-1, step 6). Whenever possible, cost analysts should use primary data sources. Primary data are obtained from the original source, are considered the best in quality, and are the most useful. Secondary data are derived, rather than obtained, directly from a primary data source. Because secondary data were derived (and thus changed) from the original data, they may be of lower overall quality and usefulness. In many cases, data may have been "sanitized" for a variety of reasons (e.g., proprietary data) that may further complicate their use, as full details and explanations may not be available. Cost analysts should understand if and how data were changed before determining if the data will be useful or how that data can be adjusted for use. Of course, it is always better to use actual costs, rather than estimates, because actual costs represent the most accurate data available.

Document No.	Title
Nuclear Power Plant Worker Radiation Dose Estimating Method	
NUREG/CR-5035	"Data Base of System-Average Dose Rates at Nuclear Power Plants"

- **Databases**—Commercial databases are readily available and provide the cost analyst with the ability to retrieve cost estimating data. The Energy Economic Data Base (EEDB) provides complete plant construction cost estimates for boiling-water reactors and pressurized-water reactors. The generic cost estimating methods developed for the NRC use the EEDB cost data as a basis for estimating the costs of physical modifications to nuclear plants.

- **Industry Estimates**—Industry estimates can provide ~~for a greater~~ confidence of real-time accuracy.~~,~~ ~~although~~ However, the cost analyst should use caution when using industry-supplied or secondary cost estimates. ~~As when using secondary data, t~~The NRC cost analyst should seek to understand how the data were normalized, what the data represent, how old the data are, and whether the estimates were generated with incomplete or preliminary information. Other times, only a few industry estimates may be provided, which could potentially skew the cost data.

- **Level-of-Effort Data**—As discussed in Section B.5.3.1, LOE activities are of a general or supportive nature, usually without a deliverable end product. Such activities do not readily lend themselves to measurement of discrete accomplishment and are generally characterized by a uniform rate of activity over a specific period of time. Value is earned at the rate that the effort is being expended. Cost analysts should use LOE activity cost estimates minimally for Class 1 and 2 estimates.

- **Expert Opinions (Subject-Matter Experts)**—As described in Section B.5.3.3, expert opinions can provide valuable cost information in the early stages of a project; that is, for Class 5, 4, and 3 cost estimates. The data collected should include a list of the experts consulted, their relevant experience, and the basis for their opinions. The analyst should document any formalized procedure used.

- **Benchmarking**—Benchmarking is a way to establish rule-of-thumb estimates. ~~Benchmarks may be useful when other means of establishing reasonable estimates are unavailable.~~ Benchmark examples include the statistic indicating that design should be 6 percent of the construction cost for noncomplex facilities. If construction costs can be calculated (even approximately) using a parametric technique, design should be approximately 6 percent. Typical benchmarks include such rules as the following:

  – Large equipment installation costs should be X percent of the cost of the equipment.

  – Process piping costs should be Y percent of the process equipment costs.

  – Licensee facility work should cost approximately Z percent of current, local, commercial work.

- **Team/Individual Judgment Data**—Team or individual judgment data are used when the maturity of the scope has not been fully developed or the ability to compare the work to historical or published data is difficult. This involves relying on information from individuals or team members who have experience in the work that is to be estimated. This process

B.8 COST ESTIMATING OUTPUTS

B.8.1 Baselines

Typically, NRC cost estimates are performed to analyze proposed regulatory changes and are used to quantify the incremental impacts of this change. The problem statement should justify the need for regulatory action within the context of what would prevail if regulatory action were not taken. This discussion~~justification~~ requires assumptions about whether, and to what degree, voluntary practices may change in the future. In general, the no-action alternative serves as the regulatory baseline and is central to the estimation of incremental costs and benefits.

B.8.2 Analysis

The regulatory analysis process, including the supporting cost-benefit analysis, 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 should not be used to produce after-the-fact rationalizations to justify decisions already made, nor to unnecessarily delay regulatory actions. The conclusions and recommendations included in a regulatory analysis document are neither final nor binding but, rather, are intended to enhance the soundness of decisionmaking by NRC managers and the Commission.

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licenses. Executive Order (EO) 12866, "Regulatory Planning and Review," dated October 4, 1993, requires executive agencies to prepare a regulatory analysis for all significant regulatory actions. Significant regulatory actions defined in EO 12866 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.

The NRC requires regulatory analyses for a broader range of regulatory actions than for significant regulatory actions, as defined in EO 12866. In general, each NRC office should ensure that all mechanisms the staff uses 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, cost-benefit guides, orders, standard review plans, branch technical positions, and standard technical specifications.

More information on parametric cost estimates, including the parametric estimating initiative, and on cost estimating and analysis, can be found through the International Cost Estimating and Analysis Association at http://www.iceaaonline.com/.

More information on cost engineering can be found through the AACEI at http://www.aacei.org/.

B.9 COST ESTIMATING EXPECTATIONS

This section summarizes what could be expected from the use of NRC cost estimates that are prepared to support regulatory analyses, backfitting analyses, and environmental analyses.

B.9.1 Summary of Expectations

An NRC cost estimate, regardless of purpose, classification, or technique employed, should demonstrate sufficient quality to indicate that it is appropriate for its intended use, is complete, and has been subjected to internal checks and reviews. It should also be clear, concise, reliable, fair, reasonable, and accurate within some probability or confidence levels. In addition, it is expected to have followed accepted standards, such as the GAO's 12-step cost estimating development process (GAO, 2009), as applicable.

Common elements of good cost estimates are expected to be constant. Enclosure B-1 summarizes suggested review criteria.

B.9.2 Independent Cost Estimates

In December 2014, the GAO published GAO-15-98 (GAO, 2014), which examines the extent to which the NRC's cost estimating procedures support development of reliable cost estimates and follow specific best practices identified in GAO-09-3SP (GAO, 2009). As a result of these evaluations, the GAO recommended that the NRC align its cost estimating procedures with the relevant cost estimating best practices in GAO-09-3SP and ensure that future cost estimates are prepared in accordance with relevant cost estimating best practices. The GAO recommended, among other aspects, that the NRC demonstrate the credibility of its cost estimates by cross-checking agency results with independent cost estimates developed by others, providing confidence levels, and conducting a sensitivity analysis to identify the variables that most affect cost estimates.

In response to the GAO concerns and recommendations, the NRC conducted a pilot program to have selected independent cost estimates performed for the same proposed action. The NRC, based on this pilot will use ~~of~~ independent cost estimates to cross-check NRC cost-benefit analyses on a case-by-case basis.

Probability—the likelihood of an event occurring, expressed as a qualitative or quantitative metric

Probability distribution function—a probability distribution, also described as a probability density function, representing the distribution of the probability of an outcome. As an example, the Monte Carlo analysis may be designed to estimate the cost of an alternative. The probability distribution function represents the number of times a certain estimated cost or benefit is achieved

Productivity—the consideration of factors that affect the efficiency of construction labor (e.g., location, weather, work space, coordination, schedule)

Program evaluation and review technique (PERT) distribution—a special form of the beta distribution with a minimum and maximum value specified. The shape parameter is calculated from the defined *most likely* value. The PERT distribution is similar to a triangular distribution, in that it has the same set of three parameters

Qualitative risk analysis—an analysis that involves assessing the probability and impact of project risks using a variety of subjective and judgmental techniques to rank or prioritize the risks

Quantitative risk analysis—an analysis that involves assessing the probability and impact of project risks and using more numerically based techniques, such as simulation and decision tree analysis for determining risk implications

Range (cost estimate range)~~—an expected range~~a spectrum of estimated costs or benefits for a proposed regulatory alternative. Ranges may be established based on ~~a range of~~ alternatives, confidence levels, or expected accuracy and are dependent on a proposed alternative's stage of development, size, complexity, and other factors

Reconciliation—the comparison of a current estimate to a previous estimate to ensure that the difference between the two is appropriate and reasonably expected. A formal reconciliation may include an account of those differences

Risk—a factor or element that introduces an uncertainty of outcome, either positively or negatively, that could affect the cost estimate of the considered regulatory alternative. This narrow definition is limited to risk, as it pertains to performing cost-benefit analyses

Risk analysis—the process by which risks are examined in further detail to determine the extent of the risks, how they relate to each other, and which risks ~~are~~ present the highest consequences

Risk analysis method—the technique used to analyze the risks associated with a regulatory alternative. Three categories of risk analysis methods are as follows:

(1) **Qualitative**—based on project characteristics and historical data (e.g., check lists, scenarios)

(2) **Risk models**—a combination of risks assigned to parts of the estimate to define the risk of the total estimate

(3) **Probabilistic models**—combining risks from various sources and events (e.g., Monte Carlo, Latin hypercube, decision tree, influence diagrams)

ENCLOSURE B-3: INDEPENDENT COST REVIEW AND INDEPENDENT COST ESTIMATE GUIDANCE

General Guidance

Independent cost review (ICR) and independent cost estimate (ICE) teams should be comprised of individuals with appropriate experience and credentials. Ideally, teams will include individuals with appropriate industry certifications (e.g., professional engineer, certified cost engineer, project management professional) and subject matter experts knowledgeable in the areas addressed by the project (in particular, any unique technical areas or project execution strategies).

It is important to establish a charter or scope of work that clearly defines the boundaries of the ICR and ICE teams. For example, the team members should clearly understand that the purpose of an ICR or ICE is to establish an independent cost estimate for a project, based on the same execution strategy, conditions, technical scope, and schedule as the project team uses. The ICR or ICE team may propose or recommend alternatives based on observation and expert opinion; however, attempting to use those alternatives to compare project estimates is not appropriate. It is not appropriate for an ICR or ICE team, for example, to question the regulatory need or develop new alternatives and then generate an estimate based on these new strategies, scope, or alternatives. ~~The ICR or ICE team may propose or recommend alternatives based on observation and expert opinion; however, attempting to use those alternatives to compare project estimates is not appropriate.~~

Table B-6 provides a typical schedule for performing either an ICR or an ICE.

Table B-6 ICR/ICE Schedule (suggested; would vary by project size and complexity)

Activity	Typical Duration (weeks)
Establish ICR or ICE requirements and approved budget.	1–2
Develop task order and complete negotiations with ICE contractor.	2–4
Hold kickoff meeting and initial site briefings.	1–2
Develop ICR or ICE and draft report.	2–10 (varies with project and ICE type)
Reconcile ICE and project estimate.	1–2
Complete and issue final report.	1–4
Overall Duration	**8–24**

Typical Information Requirements for an Independent Cost Review and Independent Cost Estimate

The following data needs are typical for supporting an ICR or ICE and should be addressed with consideration for the stage and nature of the project:

- Project status and management and technical briefings should include, but not be limited to, the following:
  - project history and overview
  - technical baseline

ENCLOSURE B-4: EXPECTATIONS FOR QUALITY COST ESTIMATES

Expectations for Quality Cost-Benefit Analyses

It is important that analysts validate that cost-benefit elements are credible and can be justified by acceptable estimating methods, adequate data, and detailed documentation. This step ensures that a high-quality cost-benefit analysis is developed and presented to management. This process verifies that the cost-benefit analysis adequately reflects the incremental changes to the regulatory baseline and provides a reasonable estimate of the costs and benefits resulting from these changes. It also confirms that the cost-benefit analysis is traceable, accurate, and reflects realistic assumptions.

Cost Estimating Best Practices

There are four characteristics of a high-quality, reliable cost-benefit analysis. These characteristics are that the cost-benefit analysis is: (1) well-documented, (2) comprehensive, (3) accurate, and (4) credible. Each of these four characteristics is briefly described below.

- The cost-benefit analysis must be thoroughly documented, including input data, clearly detailed calculations and results, and explanations of why particular methods and references were chosen. Data should be cited to their source documents.

- The cost-benefit analysis must be comprehensive and have sufficient detail to ensure that analyzed cost-benefit elements are neither omitted nor double counted. Additionally, assumptions used in the cost-benefit analysis are documented and justified.

- The analyst should ensure that the cost-benefit estimates are unbiased, not overly conservative or overly optimistic, and are based on an assessment of most likely costs and benefits. The analysis contains few, if any, mathematical mistakes; and if any exist, they are minor.

- Any limitations of the analysis because of uncertainty, data bias, or assumptions are discussed. Major assumptions are analyzed and sensitivity analysis may be performed to determine how sensitive the results are to changes in the assumptions. Uncertainty analysis is performed to determine the level of confidence associated with the results. The analysis results are reviewed for concurrence and approval. An independent cost estimate (ICE) may be performed to determine whether other estimating methods produce similar results.

Table B-~~Table B-~~7 shows how the 12 steps of a high-quality cost estimating process can be mapped to these four characteristics of a high-quality, reliable cost-benefit analysis.

model can predict costs or benefits. An alternative approach is to use the model to prepare an estimate and then compare its result with an independent cost estimate (ICE), which is based on another estimating technique.

4. Determine That the Cost-Benefit Analysis Is Credible

Credible cost-benefit analyses clearly identify limitations resulting from uncertainty or bias surrounding the data or assumptions. The analyst should evaluate major assumptions to determine how sensitive outcomes are to changes in the assumptions. In addition, an uncertainty analysis should be performed to quantify the level of uncertainty associated with the results.

To determine a cost-benefit analysis's credibility, key cost-benefit elements should be identified and evaluated to determine whether additional resources should be applied to reduce the uncertainty. It is also important to determine how sensitive the results are to changes in key assumptions and inputs. Typically, the analyst uses a "tornado" diagram (as provided in appendix C, figure C-2) to identify key cost-benefit elements that drive changes in the mean value of the net benefit. This uncertainty information enables management to know the confidence in the results, the range of potential changes in the net benefit results, and the key drivers that could cause these changes.

The uncertainty analysis adds to the credibility of the cost-benefit analysis, because it identifies the level of confidence associated with achieving the result. The uncertainty analysis produces more realistic results because it assesses the variability in the cost-benefit analysis results from changes in inputs, assumptions, or other effects. An uncertainty analysis gives the decisionmakers perspective on the potential variability of the calculated results should facts, circumstances, and assumptions change. By performing an uncertainty analysis, the analyst can quantify the degree of uncertainty, and the net benefit result can be expressed with a range of potential costs or benefits that is qualified by a factor of confidence.

Other ways to reinforce the credibility of the cost-benefit analysis are to issue the analysis for public comment, use a different estimating method to determine whether similar results are produced, or perform an independent cost estimate. Using any of these methods increases the level of confidence in the cost-benefit analysis, thereby leading to greater credibility.

An independent cost estimate (ICE) is considered one of the best and most reliable validation methods. An ICE is typically performed by a separate organization or specialized function (e.g., a program office) that cannot be influenced by the office that performed the cost-benefit analysis. An ICE provides an independent view of expected costs and benefits that tests the cost-benefit analysis's results for reasonableness. Therefore, an ICE can provide decisionmakers with additional insight and confidence in the net benefit results—in part, because an ICE typically uses different methods and data sources and may be less affected by organizational bias.

The ICE has the same scope as the cost-benefit analysis so that the results are comparable. One benefit of performing an ICE is that it provides an independent estimate of each cost-benefit element and its resulting net benefit. If the ICE is performed by a contractor, the ICE team may not have insight or access to the details in which the proposed regulatory change may be required to be implemented, so the ICE team may be forced to estimate the costs and benefits at a higher level or to use analogous estimating techniques. It is important that the results from the cost-benefit analysis and the ICE team are reconciled and that the differences in results are understood and documented.

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APPENDIX C
TREATMENT OF UNCERTAINTY

TREATMENT OF UNCERTAINTY

C.1 INTRODUCTION

~~Analyses contain uncertainties for a variety of reasons, including limitations in our state of knowledge and ability to model the issue to a certain level of precision, variability in populations, and inability to predict the timing and magnitude of random events. Assessing~~ Identifying and assessing ~~and representing~~ uncertainties are important aspects of a good analysis ~~components~~. ~~Various tools can be used to assess uncertainty and its effects on the outcomes or results~~When approrpriately considered in an assessment, uncertainty provides insight regarding the effects that varying inputs can have on a range of outcomes and results. ~~In general~~In this appendix, ~~the tools fall into T~~two ~~broad~~ categories of such an analyses are considered for cost estimation purposes: (1) sensitivity analysis and (2) uncertainty analysis.

A sensitivity analysis assesses how sensitive outcomes are to variations in inputs. Typically, a sensitivity analysis characterizes the effect of one input at a time, but the analysis can also be used to characterize the effect of multiple inputs together on ~~the~~ a given outcome~~s~~. A sensitivity analysis typically does not assess the relative likelihood of different outcomes. ~~The~~ An uncertainty analysis assesses the range of outcomes, and usually the relative probabilities of different outcomes within the range, produced from a combined propagation of uncertainty in model inputs. ~~The purpose of this appendix is to describe cost estimating uncertainty and sensitivity.~~

This appendix is responsive to the U.S. Government Accountability Office (GAO) guidelines that require uncertainties to be addressed in regulatory analyses both for radiological exposure and economic cost measures. In addition, the NRC's "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," issued August 16, 1995, states that sensitivity studies, uncertainty analyses, and importance measures should be used in regulatory matters, where practical within the bounds of the state of the art. Uncertainties in radiological exposure measures, especially those related to facility accidents, have traditionally not been estimated. For power reactor facilities, uncertainty analysis in risk assessments has been well vetted. Uncertainty analysis in ~~R~~risk assessments for nonreactor facilities often identify best estimates only.

C.2 TREATMENT OF UNCERTAINTY IN COST-BENEFIT ANALYSES

~~The NRC staff should determine the appropriate level of effort to apply to the determination and discussion of uncertainty.~~ Regulatory, backfit, and environmental analysis reviews should consider the magnitude of uncertainties in cost-benefit estimates. In general, the detail and breadth of the uncertainty treatment should be commensurate with the overall complexity, as well as the perceived significance of the uncertainties to the overall finding and conclusion. ~~To the extent applicable, the regulatory analysis, backfit analysis, and environmental analysis reviews should consider the sources and magnitudes of uncertainties in cost-benefit estimates.~~

Additionally, peer-reviewed studies and data collected by accepted or best available methods should be considered and used, as appropriate. To the extent practicable, the cost-benefit analysis should report 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 cost-benefit estimates. Hypothetical best and worst case costs and benefits can also be estimated from sensitivity analyses, which can be used in addition to formal uncertainty analysis. This appendix will provide guidance on the appropriate treatment of uncertainty in cost-benefit analyses.

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APPENDIX D
GUIDANCE ON REGULATORY ANALYSIS RELATED TO AMERICAN SOCIETY OF MECHANICAL ENGINEERS (ASME) CODE RULES

GUIDANCE ON REGULATORY ANALYSIS RELATED TO AMERICAN SOCIETY OF MECHANICAL ENGINEERS (ASME) CODE RULES

D.1 ASME CODE RULEMAKINGS

Title 10 of the *Code of Federal Regulations* (10 CFR) 50.55a, "Codes and Standards," requires nuclear power plant licensees to construct, inspect, and test certain components following specified codes of the American Society of Mechanical Engineers (ASME). Under 10 CFR 50.55a, licensees must construct ASME Boiler and Pressure Vessel (BPV) Code Class 1, 2, and 3 components following the rules of the ASME BPV Code (Section III, Division 1). Under 10 CFR 50.55a, licensees must inspect Class 1, 2, and 3, Class MC (metal containment), and Class CC (concrete containment) components following the rules of the ASME BPV Code (Section XI, Division 1). Finally, under 10 CFR 50.55a, licensees must 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 U.S. Nuclear Regulatory Commission (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. These rulemakings are referred to as ASME Code rulemakings.

The NRC's convention for regulatory analysis for most rulemakings is to perform a regulatory analysis for the proposed and final versions of a rule. However, for NRC rulemakings incorporating by reference into 10 CFR 50.55a the latest ASME Boiler and Pressure Vessel Code (BPV Code) and the ASME Operations and Maintenance Code (OM Code), the NRC utilizes a different approach in determining whether to prepare a regulatory analysis to support the proposed or final ASME Code rulemaking.

The NRC need not prepare a regulatory analysis for those ASME Code rulemakings that do not impose additional conditions or exceptions beyond those in the updated ASME Code provisions. The NRC believes this is appropriate for several reasons:

- The ASME codes are voluntary consensus standards, developed with participation by interested parties, including representatives from the NRC, the nuclear power industry, and licensees.
- It has been longstanding NRC policy to incorporate later versions of the ASME Code into its regulations. Further, it is a condition of NRC licenses to adopt revisions to some parts of the ASME Code on a periodic basis: 10 CFR 50.55a requires licensees to revise their inservice inspection (ISI) and inservice testing (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. Through this practice, the NRC has established an expectation that future revisions to the ASME Code, developed through the consensus standards process, will be incorporated by reference into the NRC's regulations. Thus, licensees know when receiving their operating licenses that incorporating updates to the ASME Code is part of the regulatory process.
- Endorsement of the ASME Code 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, inservice inspection, and inservice testing by rulemaking.

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APPENDIX E
SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

E.1 INTRODUCTION

This appendix is designed to assist the analyst in preparing effective regulatory analyses, backfit analyses, and environmental analyses and to provide a consistent approach and methodology for preparing cost-benefit analyses. The guidance in this appendix is consistent with U.S. Nuclear Regulatory Commission (NRC) policy and, if followed, should result in an acceptable analysis. Although this document is comprehensive, it is not exhaustive and thus does not anticipate all conceivable possibilities. Further, the methods used in regulatory analyses, backfit analyses, and environmental analyses continue to evolve, and applicable data may change over time. This appendix is intended to provide general guidance to assist the analyst in working through such circumstances. In addition to the examples provided in this appendix, the NRC and other Federal agencies (e.g., the U.S. Office of Management and Budget (OMB), the U.S. Environmental Protection Agency, the U.S. Government Accountability Office, and the U.S. Department of Transportation) continue to undertake research and development to improve the regulatory decisionmaking process, which may provide additional help in performing these analyses.

This appendix also discusses the relationship of regulatory analyses to certain statutory procedural requirements applicable to the NRC. The documentation that the Regulatory Flexibility Act requires may be included as an appendix to the regulatory analysis or within the *Federal Register* notice. Documentation required by the Paperwork Reduction Act, though not appended to the regulatory analysis, will be developed and approved in tandem. The remaining procedural requirements addressed in this appendix involve issues closely related to those examined in the regulatory analysis.

E.2 SPECIAL CIRCUMSTANCES

E.2.1 Safety Goal Screening

The evaluation of core damage frequency (CDF) reduction helps to calibrate the significance of the proposed regulatory action. If an action results in a small change in CDF (less than 1×10^{-5} per reactor-year), the regulatory analysis should, in general, proceed only if an alternative rationale~~justification~~ for the proposed new requirement can be formulated. A class of accident sequences involving the potential for early containment failure or containment bypass should receive further consideration even if the reduction in CDF is less than 1×10^{-5} per reactor-year. However, there may be other special circumstances that should be analyzed. The NRC staff should refer such issues (and include sufficient supporting information) to the appropriate office director for review.

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

For the purpose of evaluating regulatory actions against safety goals, the analysis should consider the magnitude of the change in CDF when determining whether the substantial additional protection criterion of the backfit rule is met. Specifically, the analyst should use a single common criterion when determining whether a regulatory action involving a reduction in CDF (1) meets the substantial additional protection standard identified in the backfit rule (e.g., Title 10 of the *Code of Federal Regulations* (10 CFR) 50.109, "Backfitting") and (2) is appropriate, considering the subsidiary safety goal of 10^{-4} in mean CDF per reactor-year. The staff has determined that a subsidiary safety goal of 10^{-4} in mean CDF per reactor-year is a useful benchmark, but it is not a Commission-approved safety goal. For this usage, CDF is defined as "the sum of the accident sequence frequencies of those accident sequences whose end state is core damage," where core damage is defined as "sufficient damage that could lead to a release of radioactive material from the core that could affect public health" (NRC, 2013a).

If it is not possible to develop adequate, quantitative supporting information for the proposed new requirement, then the analysis should provide a bounding, quantitative analysis to the extent practical. Points and insights should be related to the safety goal screening criteria. For example, the quantitative analysis should indicate how the proposed regulatory action affects the CDF and to what extent. It should address how risk and the expected improvement is measured or estimated. If important factors cannot be quantified, they may be discussed qualitatively. Appendix A, "Qualitative Factors Assessment Tools," provides additional guidance for performing qualitative analyses.

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," then the situation should be noted for specific regulatory followup (e.g., for evaluations about potential facility-specific backfittings).

The NRC recognizes that, in certain instances, the screening criteria may not adequately address certain accident scenarios of unique safety or risk interest. One example is an event 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 occurred before effective implementation of accident management measures). Another example is an event involving the spent fuel pool. In these circumstances, the analyst should make the case that the screening criteria do not apply and that the decision to pursue the issue should be subject to further management decision.

E.2.2 Sunk Costs

Sunk costs are costs incurred before the start of the analysis period and for which there is no value to the resources in some alternative use. Common examples include the costs of policy development, feasibility studies, or voluntary actions undertaken at an earlier date. The cost-benefit analysis does not include sunk costs because there is no opportunity cost involved and because including such costs may distort the analysis by requiring a very high return on the investment. In other words, sunk costs are irrelevant because they are the outcome of past decisions and should therefore be excluded from future decisions.

E.2.3 Criteria for the Treatment of Individual Requirements

In evaluating a proposed regulatory action, 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. If a rule provides a voluntary alternative to current requirements, the net benefit from relaxing 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 a backfit analysis,[1] the net benefit from one requirement could potentially support another requirement that is not cost justified. This discussion does not apply to backfittings that the Commission determines to qualify under one of the exceptions in 10 CFR 50.109(a)(4)(ii) and (iii), ensuring adequate protection, or defining or redefining what constitutes adequate protection. Those types of backfitting actions require a documented evaluation rather than a backfit analysis, and cost cannot ~~is not a~~be consider~~ation~~ed in deciding whether the exceptions are justified (although costs may be considered in determining how to achieve a certain level of protection).[2]

Therefore, when analyzing and making decisions about regulatory actions that are composed of individual requirements, the NRC should determine whether 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

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1 These cost-benefit guidelines were developed so that a regulatory analysis that conforms to this guidance should meet the requirements of the Backfit Rule (i.e., 10 CFR 50.109) and the provisions of the Committee to Review Generic Requirements (CRGR) Charter.

2 In a December 2016 memorandum, the NRC Solicitor provided guidance stating that some consideration of costs must be performed when the staff is invoking the compliance exception provided in 10 CFR 50.109(a)(4)(i) (NRC, 2016).

E.3 PROCEDURAL REQUIREMENTS

E.3.1 Committee to Review Generic Requirements

The Committee to Review Generic Requirements (CRGR) has the responsibility to review and recommend to the NRC Executive Director for Operations whether to approve or disapprove requirements or staff positions applicable to ~~to be imposed on~~ one or more classes of power reactors and, in some cases, on nuclear materials licensees. The CRGR reviews proposed requirements or positions that would reduce existing requirements or positions and also reviews proposals that would increase or change requirements. The CRGR Charter sets out the CRGR's purpose, membership, scope, operating procedures, and reporting requirements.

The CRGR Charter lists the information that is required to be submitted to the CRGR for review of proposed actions within its scope. One item is a regulatory analysis conforming to the direction in this guidance.[5]

When a regulatory analysis has been prepared in accordance with this guidance document, it will not be necessary to prepare a separate document to address the information required for CRGR review, except to address the CRGR requirement relating to the concurrence of affected program offices or an explanation of any nonconcurrences. However, the NRC staff can address this exception in the transmittal memorandum forwarding the matter to the CRGR for review.

Preparation of a regulatory analysis, including an evaluation of cost and benefits, is necessary for all proposed facility-specific and generic backfitting to facilities regulated under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," except when one of the following three conditions, identified in 10 CFR 50.109(a)(4), applies:

(1) a modification is necessary to bring a facility into compliance with a license, a Commission requirement, or a written commitment by the licensee

(2) a regulatory action is necessary to ensure that the facility provides adequate protection to public health and safety and is in accord with the common defense and security

(3) the regulatory action involves defining or redefining what level of protection to public health and safety or the common defense and security is regarded as necessary for adequate protection

If a backfit meets either of the second or third exception criterion above, costs are not to be considered in justifying the proposed action. For compliance exception backfitting (i.e., the first exception criterion above), costs must be considered under 10 CFR 50.109. The analyst should prepare a documented evaluation that includes the objectives of and reasons for the backfitting action as well as the reasons for invoking the particular exception (under 10 CFR Part 50). Procedural requirements for preparing and processing the documented evaluation are in NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information

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[5] Appendix C, item (ix), of the CRGR Charter states that, for adequate protection or compliance backfits affecting power reactors, new reactors, or materials licensees, documented evaluations are required instead of backfit analyses.

sets out procedural requirements for preparation of regulatory flexibility analyses. The NRC public Web site summarizes these procedures.

E.3.5 National Environmental Policy Act

The National Environmental Policy Act (NEPA) requires Federal agencies to prepare a "detailed statement for major Federal actions significantly affecting the quality of the human environment" (42 U.S.C. 4332). To satisfy this obligation, the NRC prepares environmental impact statements (EIS) according to NRC regulations in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Additionally, an environmental assessment (EA) may be prepared to determine whether an EIS is necessary (Spensley, 1997).

Under NEPA, the NRC must assess the environmental impact of each rulemaking action; the NRC includes a statement about the environmental impacts in the supplementary information section of the preamble to each rulemaking. When preparing a regulatory analysis to support a rulemaking, the analysis may include a brief summary of information from the EIS or EA instead of information listed in Sections 2.3.1– through 2.3.3 of this guidance. Where appropriate, the EIS or EA should be referenced at other points in the regulatory analysis to avoid duplication. For example, the alternatives evaluated in the regulatory analysis should be the same as the alternatives evaluated in the EIS or EA.

E.3.6 Information Requests under 10 CFR 50.54(f)

Requirements for NRC information requests directed to production and utilization facility licensees appear in 10 CFR 50.54(f). The regulation requires the NRC to prepare a written statement of ~~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 should establish that the information request ~~burden imposed on the licensee~~ is warranted~~justified~~ in view of the potential safety significance of the issue. The cognizant NRC office director or regional administrator should approve the ~~justification~~ statement before issuance of the information request.

Appendix C, item (x), of the CRGR Charter 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 required, it should~~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 other than submittal of the requested information

- the proposing office director's determination that the cost forburden to be imposed on the respondents is warrantedjustified in view of the potential safety significance of the issue

NRC Management Directive 8.4 discusses facility-specific information requests directed at individual nuclear power plants. Written statements prepared according to the preceding requirements to explain the basis forjustify information requests are not regulatory analyses within the scope of this document. Nevertheless, the written statementjustification will have many of the elements of a regulatory analysis. The elements of a regulatory analysis discussed in this document can appropriately be included in an information request statementjustification. An information request statementjustification will normally be a more concise document than a regulatory analysis.

E.3.7 Supporting Analysis for Compliance and Adequate Protection

As discussed in the body of this document, a proposed backfitting of one or more facilities regulated under 10 CFR Part 50 does not require a backfit analysis if the proposed action is required for purposes of compliance or adequate protection under 10 CFR 50.109(a)(4). Instead, the NRC must prepare a documented evaluation, including a statement of the objectives of and the reasons for the action, along with the basis for invoking the exception. Requirements for the documented evaluation are stated in 10 CFR 50.109(a)(6). Additional guidance for preparing and processing the documented evaluation appears in Management Directive 8.4. In the case of compliance exceptions under 10 CFR 50.109(a)(4)(i), some consideration of costs is required (NRC, 2016).

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NUCLEAR REGULATORY COMMISSION

[NRC-2017-0091]

Regulatory Analysis Guidelines

AGENCY: Nuclear Regulatory Commission.

ACTION: NUREG; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. NRC." This revision to NUREG/BR-0058 updates and restructures the NRC's cost-benefit guidance documents by incorporating information contained in NUREG/BR-0184, "Regulatory Analysis Technical Handbook," into NUREG/BR-0058 and provides cost-benefit guidance for NRC's regulatory analyses, backfit analyses, and National Environmental Policy Act (NEPA) reviews across NRC program offices. Additionally, the update incorporates improvements in methods for assessing factors that are difficult to quantify, incorporates relevant cost estimating best practices, and includes improvements in uncertainty analyses for use in cost-benefit analyses.

ADDRESSES: Please refer to Docket ID NRC-2017-0091 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

SUPPLEMENTARY INFORMATION:

I. Discussion

Revision 5 to NUREG/BR-0058 is the first of two phases of updates to the NRC's cost-benefit guidance documents, ~~namely~~ NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. NRC," and NUREG/BR-0184, "Regulatory Analysis Technical Handbook." This update consolidates these two guidance documents and identifies changes to current methods and tools related to performing cost-benefit analyses in support of regulatory analyses, backfitting analyses, and environmental analyses.

The 2011 accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion regarding how the NRC's regulatory framework would consider offsite property damage and the associated economic consequences caused by a significant radiological release from an NRC-licensed facility. In response to this discussion, the NRC staff recommended enhancing the ~~currency and~~ consistency of the agency's existing regulatory analysis guidance and bringing it up-to-date through ~~updates~~ revisions to cost-benefit analysis guidance documents, including aligning cost-benefit guidance across the agency in both reactor and materials program areas~~, in SECY-12-0110, "Consideration of Economic Consequences in the NRC's Regulatory Framework," dated August 14, 2012~~.[1] ~~In the staff requirements memorandum (SRM) to SECY-12-0110, dated March 20, 2013, t~~The Commission approved this recommendation and directed the NRC staff to identify potential changes to current methodologies and tools to perform cost-benefit analyses in support of regulatory, backfit, and

[1] SECY-12-0110, "Consideration of Economic Consequences in the NRC's Regulatory Framework," dated August 14, 2012

environmental analyses. Further, the Commission directed the NRC staff to provide a regulatory gap analysis prior to developing new cost-benefit guidance.

In response to Commission direction, the NRC staff prepared SECY-14-0002, "Plan for Updating NRC's Cost-Benefit Guidance;" dated January 2, 2014; SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses;" dated August 14, 2014; and SECY-14-0143, "Regulatory Gap Analysis of the NRC's Cost-Benefit Guidance and Practices," dated December 16, 2014. Further details regarding these documents are provided in the discussion that follows.

~~In response to the SRM to SECY-12-0110, t~~The NRC staff issued SECY-14-0002, a paper ~~. In that SECY paper, the NRC staff~~that identified potential changes to current methodologies and tools related to performing cost-benefit analyses in support of regulatory, backfit, and environmental analyses. In this document, t~~T~~he NRC staff recommended a two-phased approach to revise the content and structure of the cost-benefit guidance documents. ~~Phase 1 begins to align regulatory guidance across the agency in both reactor and materials program areas by restructuring and pursuing policy revisions. SECY-14-0002 describes~~ Phase 1 ~~as~~ is a restructuring of the three main NRC cost-benefit guidance documents, where NUREG/BR-0184 and NUREG-1409, "Backfitting Guidelines," would be incorporated into NUREG/BR-0058. However, in response to Commission direction,[2] ~~the SRM to COMSECY-16-0020, "Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," and the "Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission's Implementation of~~

[2] *See* NRC "Staff Requirements - COMSECY-16-0020 - Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," SRM-COMSECY-16-0020, November 29, 2016. *See also* NRC "Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission's Implementation of Backfitting and Issue Finality Requirements," July 19, 2017. Available at https://www.nrc.gov/docs/ML1719/ML17198C141.pdf

~~Backfitting and Issue Finality Requirements," dated July 19, 2017,~~ the NRC staff determined that NUREG-1409 should be kept as a standalone document and the revision to NUREG-1409 will be addressed through a separate but parallel effort. In Phase 1, the staff begins to align regulatory guidance across the agency in both reactor and materials program areas by restructuring cost-benefit guidance documents and pursuing policy revisions. Specifically, NUREG/BR-0058, Revision 4, and NUREG/BR-0184 will be revised and consolidated into a single guidance document that will also include updated data, methods, and references~~;~~, ~~and~~as well as best practices from GAO audit findings and case-study recommendations. Subsequently, Phase 2 will identify and discuss policy issues for Commission consideration that could affect the NRC's cost-benefit guidance. If approved by the Commission, ~~C~~cost-benefit information related to backfitting will be incorporated into the proposed revision to NUREG/BR-0058 during Phase 2. ~~Phase 1 now consists of revising and consolidating NUREG/BR-0058, Revision 4, and NUREG/BR-0184 into a single NUREG; updating data, methods, and references; and addressing audit findings and case-study recommendations. Subsequently, Phase 2 will identify and discuss policy issues for Commission consideration that could affect the NRC's cost-benefit guidance.~~

~~The NRC staff wrote SECY-14-0087 in response to the SRM to SECY-12-0157, "Consideration of Additional Requirements for Containment Venting Systems for Boiling Water Reactors with Mark I and Mark II Containments," dated March 19, 2013, which directed the NRC staff to seek guidance regarding the use of qualitative factors. In SECY-14-0087~~In response to Commission direction, the NRC staff proposed updating the cost-benefit guidance to include a set of methods that could be used for qualitative consideration of factors within a cost-benefit analysis for regulatory and backfit analyses.[3] ~~In the SRM to SECY-14-0087, dated~~

[3] NRC "Staff Requirements - SECY-14-0087 – Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," SRM-SECY-14-0087, March 4, 2015.

~~March 4, 2015, t~~The Commission approved the staff's plans for updating guidance regarding qualitative factors, including the treatment of uncertainties, and directed the update to focus on capturing best practices for the consideration of qualitative factors. The Commission also directed the NRC staff to develop a "toolkit" for ~~the~~ analysts to assist ~~help~~ them in clearly articulating ~~clarify their thinking with regard to~~ how they considered qualitative factors. Appendix A, "Qualitative Factors Assessment Tools," of the revision to NUREG/BR-0058 provides this toolkit ~~for considering qualitative factors~~.

In 2014, the U.S. Government Accountability Office (GAO) conducted a performance audit ~~in which~~to review the NRC's cost-estimating procedures ~~were reviewed~~. The ~~GAO audit~~resulting report, GAO-15-98, "NRC Needs to Improve Its Cost Estimates by Incorporating More Best Practices," recommended that the NRC align its cost estimating procedures with relevant cost estimating best practices identified in the "GAO Cost Estimating and Assessment Guide" (GAO-09-3SP). The NRC staff has addressed the GAO recommendations in Appendix B, "Cost Estimating and Best Practices," of the revision to NUREG/BR-0058.

This revision to NUREG/BR-0058 makes three main changes. First, ~~the revision to NUREG/BR-0058~~it consolidates cost-benefit guidance that is used across the agency. The document provides additional discussion of cost-benefit guidance for NRC's regulatory analyses, backfit analyses, and NEPA reviews.

Second, this revision provides methods for assessing factors that are difficult to quantify, incorporates cost-estimating best practices, and expands on methods to quantify uncertainties. This ~~revision provides~~includes guidance intended to enhance the clarity, transparency, and consistency of analyses for the decisionmaker.

Finally, this revision's ~~uses~~ appendices ~~to~~ provide detailed technical material that is subject to future changes. These appendices will be issued and controlled separately to ~~facilitate the maintenance of~~keep this information current and relevant. The following Appendices were developed during Phase 1: Appendix A, "Qualitative Factors Assessment

Tools;" Appendix B, "Cost Estimating and Best Practices;" Appendix C, "The Treatment of Uncertainty;" Appendix D, "Guidance on Regulatory Analysis Related to American Society of Mechanical Engineers (ASME) Code Rules;" and Appendix E, "Special Circumstances and Relationship to Other Procedural Requirements."

The NRC staff held a Category 3 public meeting on July 16, 2015, to discuss the proposed structure and changes to the ~~NRC~~ cost-benefit guidance in Phase 1. The ~~NRC~~ staff's presentation can be found in ADAMS under Accession No. ML15189A463, and the meeting summary can be found ~~in ADAMS~~ under Accession No. ML15217A415. The NRC staff held another Category 3 public workshop on March 3, 2016, to discuss ~~NRC~~ activities to improve ~~its~~ the agency's cost-benefit guidance including the newly developed qualitative factors assessment tools, cost estimating and best practices, and the treatment of uncertainty. The NRC presentation can be found in ADAMS under Accession No. ML16061A139, and the meeting summary can be found ~~in ADAMS~~ under Accession No. ML16084A167. The NRC staff published the draft ~~NUREG/BR-0058, Revision 5~~revision, in the *Federal Register* (82 FR 18163, April 17, 2017) for a 60-day public comment period. To further encourage public comment, ~~T~~the NRC also held a Category 3 public meeting on May 22, 2017, during the public comment period, to present the proposed changes to the cost-benefit guidance ~~update to inform the public's comments on the draft NUREG/BR-0058, Revision 5~~. The NRC staff's presentation can be found in ADAMS under Accession No. ML17135A037, and the meeting summary can be found ~~in ADAMS~~ under Accession No. ML17156A014. The NRC staff received three comment submissions with a total of 58 individual comments. Two submissions were from the Nuclear Energy Institute, and one submission was from a private citizen. The public comment response document can be found in ADAMS under Accession No. ML17221A011. The NRC staff briefed the Committee for Review of Generic Requirements (CRGR) on January 10, 2017. Additionally, the NRC staff met with the Advisory Committee on Reactor Safeguards (ACRS) Regulatory Policies and Practices Subcommittee on February 7, 2017, and with the ACRS Full Committee

on March 9, 2017. During this meeting, the staff indicated that seven of the twelve appendices remained under development. The ACRS determined ~~that the NRC staff's proposed changes at the final stage were not sufficient to warrant further review~~ that, "[b]ecause . . . conforming changes are expected to be required as the appendices are completed . . . [t]he Committee should have another opportunity to review Revision 5 to NUREG/BR-0058 after all appendices are completed and prior to its issuance." ~~However, t~~The ACRS plans to review the NUREG in its entirety during Phase 2 of the update.

II. Availability of Documents

The documents identified in the following table are publicly available ~~to interested persons through one or more of the following methods, as indicated~~.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION
NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. NRC"	ML17221A000 (Package)
NRC Response to Public Comments on Draft NUREG/BR-0058, Revision 5	ML17221A011
NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. NRC"	ML042820192
NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook"	ML050190193
SECY-14-0002, "Plan for Updating NRC's Cost-Benefit Guidance," January 2, 2014	ML13274A519
SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," September 11, 2014	ML14127A458 (Package)
SECY-14-0143, "Regulatory Gap Analysis of the NRC's Cost-Benefit Guidance and Practices," December 16, 2014	ML14280A426 (Package)
SECY-12-0110, "Consideration of Economic Consequences within the U.S. NRC's Regulatory Framework," August 14, 2012	ML12173A478 (Package)
SRM-SECY-12-0110, "Consideration of Economic Consequences within the U.S. NRC's Regulatory Framework," March 20, 2013	ML13079A055
SRM-SECY-14-0087, "Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," March 4, 2015	ML15063A568
NUREG-1409, "Backfitting Guidelines"	ML032230247
"Tasking in Response to Committee to Review Generic Requirements Report on the U.S. Nuclear Regulatory Commission's Implementation of Backfitting and Issue Finality Requirements," July 19, 2017	ML17198C141

Notation Vote

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Caputo

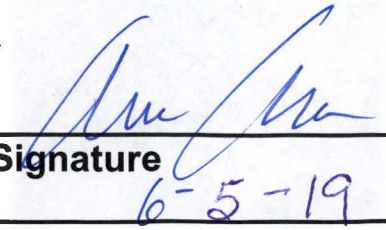
SUBJECT: SECY-18-0042: Draft Final NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission"

Approved ____ **Disapproved** XX **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** XX **Attached** _____ **None** _____

In SECY-18-0042 the staff proposes publication of the final version of the Phase 1 portion of NUREG/BR-0058, Revision 5, which is one element of the staff's plan to update the agency's cost-benefit guidance. This guidance plays an integral part in the agency's backfit determinations. The staff's proposal was delivered to the Commission on March 28, 2018, and since that time the Commission has issued direction (*see* SRM-SECY-16-0142, Mitigation of Beyond-Design-Basis Events; SRM-SECY-18-0104, Draft Final Rule: Amendments to Material Control and Accounting Regulations) to the staff that impacts the agency's approach to its cost-benefit determinations, particularly in its backfit analyses. In particular, the recent revisions to Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," (SRM-SECY-18-0049) incorporates recent Supreme Court and Commission decisions regarding consideration of costs in regulatory actions. These recent changes impact the direction proposed by the staff in SECY-18-0042. For this reason, I agree with Commissioner Wright that the staff should reexamine NUREG/BR-0058 to incorporate the Commission direction given in those recent decisions. Staff should resubmit the revision to the Commission for approval within six months. I therefore disapprove of publication of this guidance at this time.

Entered in STARS
Yes X
No _____



Signature

6-5-19

Date

Notation Vote

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Wright

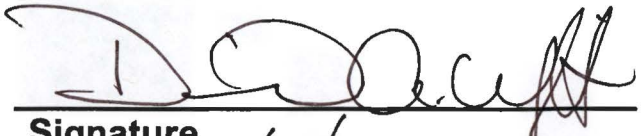
SUBJECT: SECY-18-0042: Draft Final NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission"

Approved ____ **Disapproved** __X__ **Abstain** ____ **Not Participating** ____

COMMENTS: **Below** __X__ **Attached** _____ **None** _____

The staff recommends that the Commission approve publication of the final version of the Phase 1 portion of NUREG/BR-0058, Rev. 5 and five appendices. While I do not approve the staff's recommendation at this time, I take no position on the contents of the NUREG or the staff's laudable efforts to revise it. Instead, I disapprove publication of the NUREG because of the intervening Commission direction on cost-benefit analysis in support of regulatory, backfit, and environmental analyses since SECY-18-0042 was provided to the Commission. This direction is reflected in several recent Commission decisions, including the final rules related to material control and accounting and the mitigation of beyond-design-basis events (SRM-SECY-18-0104 and SRM-SECY-16-0142, respectively) and in the SRM for Management Directive 8.4 (SRM-SECY-18-0049). In light of this direction, the staff should make any necessary conforming changes to NUREG/BR-0058, Rev. 5 and its appendices and resubmit the revision to the Commission for approval.

Entered in STARS
Yes ✓
No ____



Signature

6/3/2019

Date