POLICY ISSUE
NOTATION VOTE

RESPONSE SHEET

TO: Annette L. Vietti-Cook, Secretary

FROM: CHAIRMAN SVINICKI

SUBJECT: SECY-20-0008: Draft Final NUREG/BR-0058, Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission"

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

COMMENTS: **Below** XX **Attached** XX **None** ____

I approve the draft final NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," subject to the attached edits.

Kristine L. Svinicki

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SIGNATURE

5/12/20

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Entered on "STARS" Yes ____ No ___

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

NUREG/BR-0058, Revision 5

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

Final Report

Office of Nuclear Material Safety and Safeguards

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KLS Edits

NUREG/BR-0058, Revision 5

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

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

Final Report

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Office of Nuclear Material Safety and Safeguards

ABSTRACT

The purpose of this NUREG is to provide guidance to the analyst to promote the preparation of high-quality regulatory and cost-benefit analysis documents and to implement the policies of the U.S. Nuclear Regulatory Commission. This NUREG provides standardized methods for agencywide use in the preparation and presentation of regulatory and cost-benefit analyses. Information on the objectives of the safety goal evaluation process and potential data sources for preparing a safety goal evaluation are also included. Consistent application of the methods in this guidance will result in more directly comparable analyses, thereby aiding decisionmakers in the evaluation and comparison of various regulatory actions.

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* The electronic index of all appendices is available online for NUREG/BR-0058, Rev. 5, Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission, Final Report, at https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0058/.

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ACKNOWLEDGMENTS

The authors of this report thank the U.S. Nuclear Regulatory Commission staff members, industry representatives, staff from other Federal agencies, and members of the public who helped to develop this report.

ABBREVIATIONS AND ACRONYMS

ABWR	advanced boiling-water reactor
ADAMS	Agencywide Documents Access and Management System
ALARA	as low as is reasonably achievable
AP1000	advanced passive 1000
APR1400	advanced power reactor 1400
BLS	Bureau of Labor Statistics (U.S. Department of Labor)
BWR	boiling-water reactor
CDF	core damage frequency
CFR	*Code of Federal Regulations*
COE	cost of enhancement
COL	combined license
CPCFB	conditional probability of (early) containment failure or bypass
CRGR	Committee to Review Generic Requirements
DC	design certification
DOE	U.S. Department of Energy
EA	environmental assessment
EDO	Executive Director for Operations
EEDB	Energy Economic Data Base
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
ER	environmental report
ESBWR	economic simplified boiling-water reactor
ESP	early site permit
ESRP	environmental standard review plan
FONSI	Finding of No Significant Impact
FR	*Federal Register*
FSAR	final safety analysis report
FV	future value
GAO	Government Accountability Office
GE	General Electric

GEH	General Electric-Hitachi Nuclear Energy
GEIS	generic environmental impact statement
IAEA	International Atomic Energy Agency
IPE	individual plant examination
IPEEE	individual plant examination of external events
LERF	large early release frequency
LRF	large release frequency
MACCS	MELCOR Accident Consequence Code System
MD	management directive
MWe	megawatts electrical
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
OMB	Office of Management and Budget
PRA	probabilistic risk assessment
PV	present value
PWR	pressurized-water reactor
QALY	quality-adjusted life-year
SAMA	severe accident mitigation alternatives
SAMDA	severe accident mitigation design alternatives
SDA	standard design approval
SEIS	supplemental environmental impact statement
SPAR	Standardized Plant Analysis Risk
SRM	staff requirements memorandum
SSC	system, structure, and component
TMI	Three Mile Island
TMI-2	Three Mile Island, Unit 2
U.S.C.	United States Code
VSI	value of statistical illness
VSL	value of a statistical life
WTP	willingness-to-pay

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. The use of this guidance will ensure that the staff considers costs appropriately in regulatory analyses. Before following this guidance, the NRC staff should determine as a threshold matter whether applying a new requirement to a~~n already~~ licensed facility is necessary for adequate protection of public health and safety as cost is not considered in such cases. ~~This will ensure that the staff considers costs appropriately in regulatory analyses.~~

Cost-benefit evaluations help the staff provide an adequate basis for ~~the~~a proposed action and document a clear explanation of why the proposed action was recommended. This guidance contains the framework for (1) identifying the problem[1] 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.

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 Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," issued September 20, 2019, and NUREG-1409, "Backfitting Guidelines" to address changes in procedures associated with estimating costs and benefits for backfitting and forward fitting. NUREG/BR-0058 provides cost-benefit guidance for NRC's regulatory, backfit, forward fit, issue finality, and National Environmental Policy Act (NEPA) environmental review analyses 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.

1.1 Purpose

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

The guidance has several goals:

[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 or security enhancement.

- 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 guidance document—NUREG/BR-0058, Revision 5—for cost-benefit analyses that may contribute to regulatory, backfit, forward fit, issue finality or environmental review analyses.

Varying degrees of permissive language are used to characterize the analyst's freedom of action throughout this guidance. These terms are ~~defined~~ intended to allow the analyst flexibility in the choice of courses of action as follows:

- Actions for which the guidance uses "may" ~~=~~are permissive in nature and the analyst has the options of performing the action, omitting the action, or performing an alternative action to accomplish the analysis.

- Actions for which the guidance uses "must" ~~=~~are ~~required~~mandatory actions that the analyst will include to accomplish the analysis.

- Actions for which the guidance uses "should" ~~= guidance~~are optional, but the default, actions that generally are performed to accomplish the analysis, but the analyst may omit the action or perform an alternate action to accomplish the analysis if there is a sound reason to do so. Sound reasons to omit an aspect of an analysis would include, for example, instances where the aspect of the analysis in question would not impact the final result of the analysis due to insensitivity of the aspect to postulated changes or predominance of the analysis to changes in other aspects. When departing from the guidance by omitting or taking an alternative course of action, the analyst should briefly document the reasons for the departure.

- Actions for which the guidance uses "can" ~~= capability~~are options that have been identified for the analyst to choose to take in performing the analysis.

1.2 Background

~~Although t~~The NRC ~~is not required to conduct cost-benefit analyses, it voluntarily~~ began performing ~~them~~ cost-benefit analyses in 1976. In preparing cost-benefit analyses, the NRC ensures that decisions 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 are 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 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, Executive Order (EO) 12291, "Federal Regulation," directed executive agencies to prepare 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 NRC issued the original version of these guidelines as NUREG/BR-0058 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 philosophy for the NRC staff to use in its regulatory analysis process for proposed actions that may affect commercial nuclear power reactors. The policy provides a "safety first" test that gives added strength to the regulatory decisionmaking process for new requirements that are considered appropriate 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 ultimately determine that a proposed action would not substantially improve the existing level of plant safety. By defining a clear level of 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 are warranted. Thus, the safety goal evaluation can reduce 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, 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. 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. This guidance reflects the intent of the EO, 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, EO 13563, "Improving Regulation and Regulatory Review," was issued to supplement and reaffirm 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."

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 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

[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.

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 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 (NRC, 2013b).

In the May 29, 2019, SRM-SECY-18-0049, "Management Directive and Handbook 8.4, 'Management of Backfitting, Issue Finality, and Information Collection,'" the Commission approved the revision to MD 8.4 and its companion Directive Handbook. The Commission then directed the staff in SRM-SECY-18-0042, "Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'" to conform this document to MD 8.4, as approved.

The Commission's Safety Goals

The Commission has directed that the NRC's regulatory actions affecting nuclear power plants be evaluated for conformity with the NRC's policy statement on safety goals for the operations of nuclear power plants (NRC, 1986). The policy statement sets out two qualitative safety goals and two quantitative objectives. Both the goals and the objectives apply only to the risks to the public from the accidental or routine release of radioactive materials from nuclear power plants.

The policy statement has the following qualitative safety goals:

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

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

The two quantitative objectives in the policy statement are to be used in determining achievement of the qualitative safety goals. The objectives are as follows:

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

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

This guidance contains specific information on implementing the quantitative objectives that the analyst should carefully follow. It states that a safety goal evaluation is needed for a proposed generic safety enhancement to nuclear power plants that is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). Thus, proposals for a facility-specific backfit or for generic backfits within the exceptions at 10 CFR 50.109(a)(4)(i–iii) do not require a safety goal evaluation. Further, it states that a safety goal evaluation is not needed for a proposed relaxation of a requirement affecting nuclear power plants.

This guidance also states that a PRA should normally be used in performing a safety goal evaluation to quantify the risk reduction and corresponding values of a proposed new requirement. The NRC's final policy statement on the use of PRA methods in nuclear regulatory activities (NRC, 1995a) states the following:

> The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.

If conducted, a safety goal evaluation should be included in Chapter 3 of the regulatory analysis document that covers "estimation and evaluation of cost benefit." The results of the safety goal evaluation should be included in Chapter 4 of the regulatory analysis document that covers "presentation of results."

1.3 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."

1.3.1 Regulatory Analysis

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.

1.3.2 Backfitting, Forward Fitting, and Issue Finality

Staff actions that may involve backfit, forward fit, or issue finality require analyses unless certain exemptions apply. When the NRC changes requirements for a facility protected by regulation from certain changes applicable to its licensed activities, this ~~is referred to as~~may be 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 analyzed ~~on the basis of~~based on the

[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.

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's rules or the imposition of a regulatory staff position interpreting the Commission's 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 issue finality matters under 10 CFR Part 52.

MD 8.4 provides guidance to the analyst on how to conduct a forward fit analysis. A forward fit is defined in MD 8.4 as "the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or 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 as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation."

The NRC's policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities (NRC, 1995a) includes the statement that, where appropriate, PRA should be used to support a proposal for additional regulatory requirements under 10 CFR 50.109. Certain requirements specific to a backfit analysis are identified at 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 staff must 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 using this guidance will satisfy the cost and benefit inputs needed for the documentation requirements of the Backfit Rule and the provisions of the CRGR Charter (NRC, 2018). 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" as discussed further in NUREG-1409.

[4] https://www.nrc.gov/about-nrc/regulatory/crgr/charter.html.

Table 1-1 Checklist for Specific Backfit Analysis Requirements

CFR Citation[a] (Title 10)	Information Item tTo 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 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	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 76.76, 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.

1.3.3 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." 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. 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)).

1.3.4 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.

1.4 Regulatory Relaxations

A regulatory analysis is generally required for a proposed relaxation to ensure that it is warranted. 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 backfitting requirements 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 the action.
- The proposed relaxation is optional or mandatory for affected licensees.

2 REGULATORY ANALYSIS

The U.S. Nuclear Regulatory Commission (NRC) uses this guidance to evaluate the costs and benefits of proposed regulatory actions to protect public health and safety, promote the common defense and security, and protect the environment. Accordingly, the principal purposes of a regulatory analysis are to ensure the following:

- The NRC's regulatory decisions made in support of its statutory responsibilities are based on adequate information about the need for and consequences of proposed actions.

- Alternative approaches to meet the regulatory objectives are identified and analyzed, and no preferable alternative is available to the proposed action.

- A determination of whether the proposed actions meets the safety goal screening criteria to provide early indication whether the backfitting criteria can be met for proposed actions subject to the Commission's backfitting rules in 10 CFR Parts 50, 70, 72, and 76 and issue finality provisions in 10 CFR Part 52, but not within the exceptions at 10 CFR 50.109(a)(4), 10 CFR 70.76(a)(4), 10 CFR 72.62(b), and 10 CFR 76.76(a)(4).

The regulatory analysis process should begin when it becomes apparent that some type of action to address an identified problem may be needed. Initial efforts should be focused on the nature, extent, and magnitude of the problem being addressed, why NRC action is required, and identification of alternative solutions. Detailed information-gathering and analysis activities should be focused on the most promising alternatives.

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

The NRC performs regulatory analyses to support many NRC actions affecting reactor and materials licenses. EO 12866 requires executive agencies to prepare a regulatory analysis for all significant regulatory actions. Significant regulatory actions are defined in EO 12866 to include actions that:

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

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, regulatory guides, 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 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 cognizant NRC Office Director. One factor that could influence this decision is the degree of urgency associated with the regulatory action. In other cases, specific circumstances could provide a reasonable basis for a less detailed regulatory analysis. The analyst should note that in MD 8.4, however, the Commission directed that "[i]f the agency issues a new or modified regulatory staff position (e.g., a revision to regulatory guidance), and the prior regulatory staff position is no longer available for use by current licensees, then the new or modified regulatory staff position should include a regulatory analysis."

For certain regulatory actions, a less detailed cost-benefit analysis may be 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 or in the need to 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 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 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]

[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.~~

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:

(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 provide a reasonable basis for 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. 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, backfitting and the safety goal evaluation process and screening criteria are not applicable.

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.

For the type of information supplied and the level of detail provided, the emphasis should be on simplicity, flexibility, and logic. The level of treatment given to a safety issue 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 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 to determine that the proposed new or revised safety or security requirement was appropriate
- 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 that goes beyond the guidance in this document. This might be the case when, for example, the regulatory action is a "significant regulatory action" (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. 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, given the increased level of effort involved. Rather than provide more detailed guidance in this document, 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~~ in limited cases, benefits of improved regulation ~~are~~may not be quantifiable. As noted in Appendix A, "Qualitative Factors Assessment Tools," to this NUREG, qualitative factors can be significant elements of a regulatory analysis and should be appropriately considered in a judicious and disciplined manner by the analyst and decisionmaker when it is not possible or practical to quantify costs and benefits. The appropriate degree of weight of application of qualitative factors in regulatory decision making ultimately lies with the Commission.

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 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 staff operationally uses the safety goal screening criteria for nuclear power reactors to determine if the substantial additional protection standard is achieved to determine whether consideration of the regulatory change should continue. For nuclear materials licensees, the staff uses a risk–informed decisionmaking framework as input into whether the substantial additional protection criterion is met (NRC, 2008).

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, requests to the NRC for relaxation 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. When considering a proposed backfit under the Backfit Rule, the staff must ensure that the proposed backfit effectively addresses a safety problem and provides substantial additional protection improvements in a cost-justified 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

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.

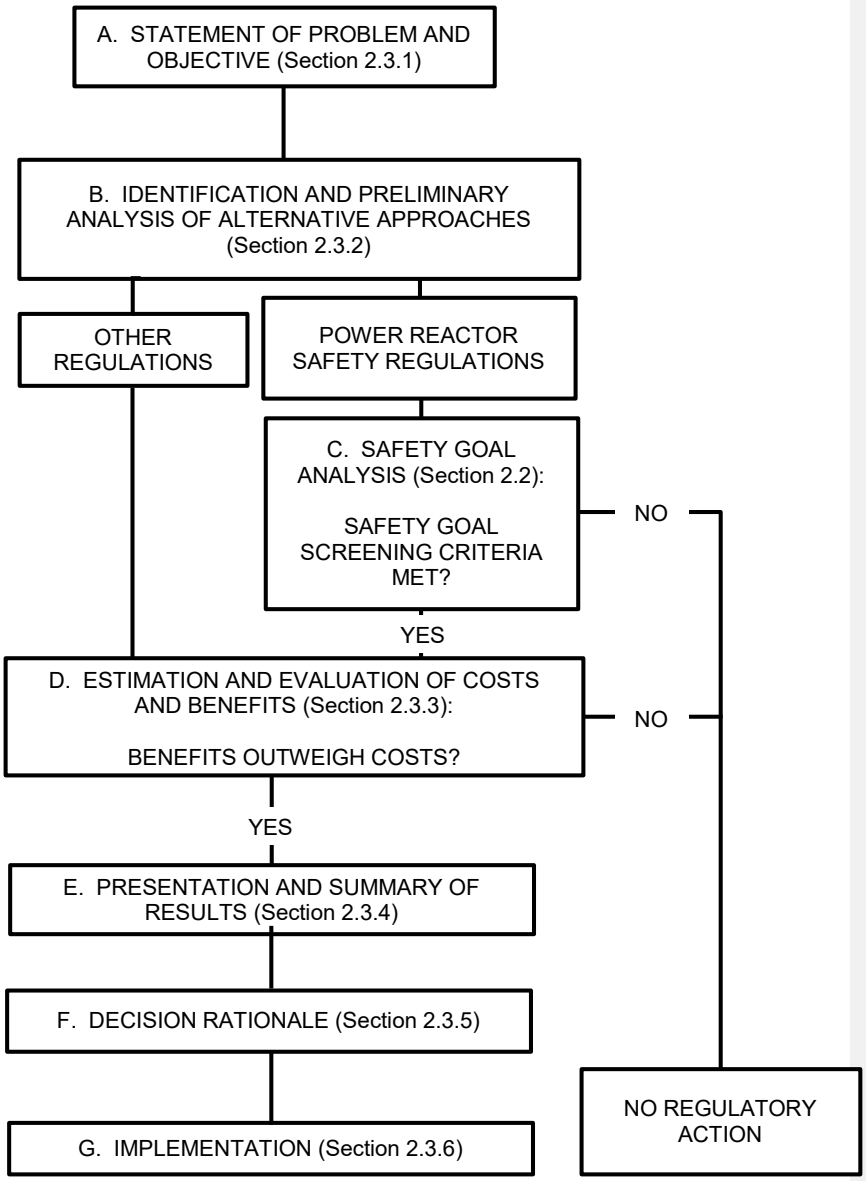
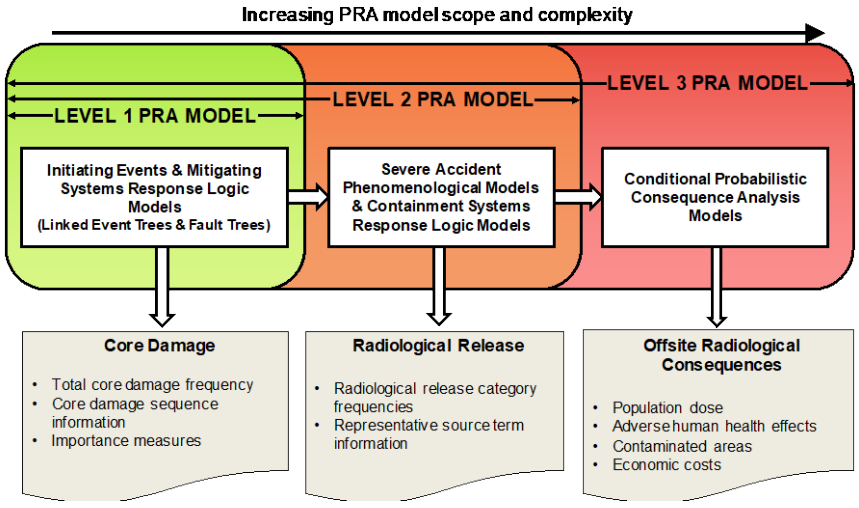


Figure 2-1 Elements of a Regulatory Analysis

PRA is a subset of risk analysis techniques that can be used to support risk management, safety, or environmental decisions involving complex engineered systems. The traditional scenario-based approach to PRA involves systematic application of methods, models, data, and analytic tools to develop answers to three fundamental questions that underlie Kaplan and Garrick's widely accepted quantitative definition of risk: (1) *What can go wrong?* (2) *How likely is it to occur?* and (3) *If it does occur, what are the consequences?* In this framework, a *risk triplet* comprising an accident scenario, its frequency, and its conditional consequences represents the risk attributed to a specified class of accident scenarios (Kaplan and Garrick, 1981). The set of risk triplets that encompasses a reasonably complete spectrum of possible accident scenarios is then assumed to represent the total risk attributed to accidents caused by failures within the modeled system.

PRAs for nuclear power plants have traditionally been organized into three analysis levels, with the scope and level of complexity of the PRA model increasing with each level. These levels are defined by three sequential adverse outcomes that can occur in postulated accident scenarios: (1) damage to nuclear fuel in the reactor core ("*core damage*"), (2) release of radioactive materials from the containment structure to the surrounding environment ("*radiological release*"), and (3) adverse human health, environmental, and economic consequences that occur beyond the site boundary ("*offsite radiological consequences*"). Relationships between these outcomes and the scope of Level 1, Level 2, and Level 3 PRA models are displayed below.



Core damage frequency (CDF) estimates from Level 1 PRAs and conditional probability of (early) containment failure or bypass (CPCFB) estimates from Level 2 PRAs can be compared to corresponding safety goal screening criteria to determine the need for a cost-benefit analysis as part of the regulatory analyses. The principal outputs from a Level 3 PRA that then serve as inputs to a cost-benefit analysis are (1) averted population dose, which is monetized using a conversion factor that ascribes a monetary value to each unit of population dose averted~~,~~ and (2) averted economic costs, including offsite property damage. Together with CDF and release-category frequency estimates, these Level 3 PRA outputs may also provide input to the analysis of severe accident mitigation (design) alternatives performed as part of NEPA reviews.

Figure 2-2 Primer on Probabilistic Risk Assessment

2.3 Elements of a Regulatory Analysis

This intent of this section of guidance is to present the specific elements to be addressed in a regulatory analysis to ensure uniformity. 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 include an executive summary, list of acronyms, and references.

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 regulatory analysis, with all the supporting documents, as publicly-available documents in the Agencywide Documents Access and Management System (ADAMS). The regulatory~~A good~~ analysis should be~~is~~ transparent, with 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 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 may~~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."

The following sections address each of the six elements listed above 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, or 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 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 and should avoid unnecessarily aggregating problems and solutions that can be analyzed separately. 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] legal authorities that directly or indirectly address~~es~~ the problem
- whether existing requirements have created or contributed to the problem and whether these requirements can be modified to achieve the regulatory objective more effectively
- the extent to which the immediate problem is part of a larger issue
- the relationship of the problem to other ongoing studies or actions

[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 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
- 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 are key elements in meeting the NRC's regulatory analysis policy.

Developing a set of alternative approaches early in the 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. Separate alternatives should be developed to ensure that appropriate combinations of distinct provisions that could be imposed separately are considered on their own merits (see Appendix E of this NUREG.) 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 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. Some alternatives may be eliminated based on disproportionate costs in relation to benefits, technological infeasibility, 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 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 should be considered as appropriate.

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.

For alternatives that meet preliminary screening and require a backfit analysis ~~according to~~under 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 ~~as outlined in the guidance~~. Alternative approaches~~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 and 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 analyst should use quantitative attributes relevant to the cost-benefit analysis to the extent practicable. The quantification should employ monetary terms if possible. Dollar benefits should be defined in real or constant dollars (i.e., dollars of constant purchasing power). If monetary terms are not appropriate, the analyst should strive to use other quantifiable benefits. However, despite these efforts, there may be some limited cases in which attributes ~~that~~ cannot be readily quantified. These attributes are termed “qualitative” and are handled separately from the quantitative attributes in a judicious and disciplined manner (see Appendix A to this NUREG).

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 (see Appendix B, “Cost Estimating and Best Practices” to this NUREG).

~~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," to this NUREG, 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 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 rigor. All regulatory analyses should discuss the sources and magnitudes of uncertainties in 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.

The analysis should assess the effects of the proposed action on other NRC programs. These could include eliminating or creating a need for other programs; using NRC resources, resulting in postponement or rescheduling of other programs; modifying accident probabilities, resulting in changes to the priority of, or need for, other programs; or developing information with a bearing

on other programs. Effects on other government agencies, if any, should also be assessed and reported.

Having completed the cost-benefit analysis for one or more alternatives of the proposed action, the analyst should summarize the results for each alternative using a summary table as shown in Table 2-1.

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 (add other entities/categories as necessary) **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 provide further discussion as needed ~~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 limited cases, ~~where~~ important costs or benefits ~~are~~ may be 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 should~~is to~~ be 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 qualitative factors.

~~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).

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 to this NUREG 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 reasonable costs of the proposed action on other existing and planned NRC programs and requirements is also necessary. This will help 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 of whether they could be warranted based on a regulatory analysis.

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 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 additional protection, wherein the estimated costs of the implementation are compared to 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 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) portions of environmental review documents ~~reports~~ that document licensee activities to study and reduce plant-specific CDF and ~~document the results of~~ provide the results of staff 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), advanced passive 1000 (AP1000), economic simplified boiling-water reactor (ESBWR), and advanced power reactor 1400 (APR1400). 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 six reactor designs (see Appendices A through F 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.~~

Analysts should use Table 2-2 or more recent data, as appropriate, to perform a preliminary screening of the merit of the proposed new requirements for the appropriate class of nuclear power plants. This will result in identifying and assessing the range of reduction in CDF, as well as estimating the representative change for the class. Uncertainties and limitations should be discussed and addressed quantitatively, to the extent practicable, in the supporting documentation for the proposed regulatory action. This would include, for example, addressing plant-to-plant variability within a class of nuclear power plants. The analyst should consider that the internal events CDF entries capture only part of the total plant risk. The SAMA analyses documented in the NUREG-1437 supplements report external events multipliers in the range of 1.2 to 12, with an average value of 3.2 (based on 51 of the 57 supplements published between 1999 and 2016 that reported external events multipliers for 82 individual reactors). This means that the total CDF was estimated to be 1.2 to 12 times the internal events CDF, with an average value of 3.2 times the internal events CDF. When using data from SAMA analyses, the analyst should be aware that the agency undertakes SAMA analyses to meet NEPA's "hard look" requirement; as a result, some aspects of SAMA analyses may require further consideration before the agency relies on them to meet its obligations under the AEA.

Table 2-2 PRA-Related Information for Use in Preliminary Screening Analyses

Operating Nuclear Power Plants					
Reactor Type	**Containment Type**	**Internal Events CDF[a] (Average) per Reactor Year**		**Internal Events LERF[bc] (Average) per Reactor Year**	
		(Range)		**(Range)**	
PWR[d]	Dry, Ambient Pressure	3.9E-05		4.1E-06	
		1.6E-06	7.7E-05	1.8E-07	8.0E-06
PWR	Dry, Subatmospheric	2.1E-05		1.4E-06	
		4.0E-06	3.8E-05	7.4E-07	2.1E-06
PWR	Ice Condenser	3.9E-05		4.3E-06	
		2.8E-5	5.0E-5	2.6E-06	5.9E-06
BWR	Mark I	2.3E-05		5.3E-06	
		1.9E-6	4.5E-5	6.2E-08	1.1E-05
BWR	Mark II	3.0E-05		5.6E-07	
		2.0E-6	5.8E-5	1.4E-07	9.8E-07
BWR	Mark III[e]	2.9E-06		1.1E-07	
		NA	NA	NA	NA
New Reactor Designs					
New Reactor		**At-Power Internal Events CDF per Reactor Year**		**At-Power Internal Events LRF[f] per Reactor Year**	
ABWR (GEH)[g]		1.6E-07		<1.0E-8	
AP1000[h]		2.4E-07		2.0E-08	
ESBWR[i]		1.7E-08		1.4E-09	

Note: This table will be updated in the future.

a. Source: CDF data from NUREG-1437 supplements.

b. Large early release frequency (LERF) is defined as "the frequency of a rapid, unmitigated release of airborne fission products from the containment to the environment that occurs before effective implementation of offsite emergency response, and protective actions, such that there is a potential for early health effects" (NUREG-2122, "Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking," issued November 2013).

c. Pressurized-water reactor (PWR).

d. Source: LERF data from NUREG-1437 supplements, submitted risk-informed applications, or SPAR models.

e. There was only one Mark III plant in NUREG-1437 supplements.

f. LRF: The Commission has not approved a formal definition of a large release or LRF. One informal definition for LRF is "the frequency of an unmitigated release of airborne fission products from the containment to the environment that is of sufficient magnitude to cause severe health effects, regardless of its timing." The history of the use of the term "large release frequency" is given in SECY-13-0029, "History of the Use and Consideration of the Large Release Frequency Metric by the U.S. Nuclear Regulatory Commission," dated March 22, 2013. Source: NUREG-2122.

g. Source: ABWR (GEH) data from NUREG-1503, "Final Safety Evaluation Report Related to the Certification of the Advanced Boiling Water Reactor Design, Main Report," issued July 1994.

h. Source: AP1000 data from NUREG-1793, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," issued September 2004.

i. Source: ESBWR data from NUREG-1966, "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design," issued April 2014.

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

- The analysis should explicitly define the class of affected plants and justify the use of specific PRAs to represent that class.

- The PRA should reflect the current state of PRA technology and include an analysis of uncertainties.

- The product of the analyses should be mean values and uncertainty estimates.

- The analysis should receive an independent review by staff knowledgeable and experienced in PRA, as well as reviews by the individual or group that identified the issue and the group that would be responsible for implementing the resolution.

- The analysis should be documented with sufficient detail to enable the analysis to be repeated. In addition, sufficient explanatory material should be provided to enable the reader to understand the significance of the calculations and to reconcile the various calculations with engineering judgment. Thus, the event or issue, its relationship to safety, the calculation approach, and all assumptions should be listed and justified, including, for example, choice of base PRA, choice of parameters, source of basic data, and any mathematical approximations used. The accident sequences affected should be described, and explanations of why they are affected should be provided.

The documentation should not present calculation results with more significant figures than are appropriate. If intermediate results are presented, a reader attempting to use these intermediate results in duplicating the calculation may not calculate the same final results because of rounding errors.

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 information is available and pertinent to the issue. However, the uncertainties associated with certain external event risk contributions can be relatively large. ~~Therefore, to supplement any available quantitative information, qualitative insights should be used for issues involving external events.~~

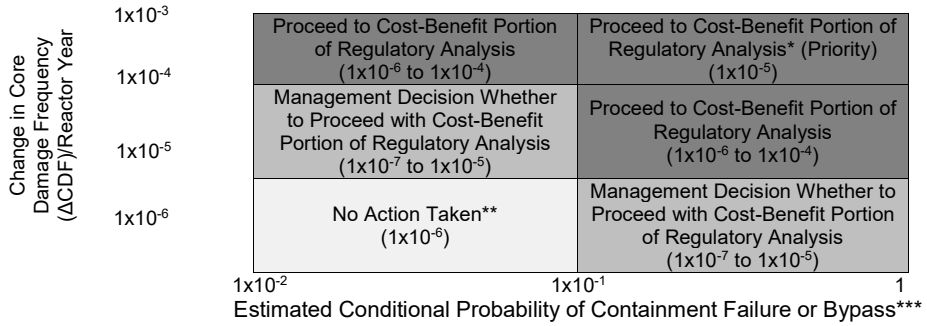
To evaluate regulatory initiatives against safety goals, the analysis should consider the magnitude of the change in CDF in concert with the determination of whether the substantial additional protection standard of the Backfit Rule is met. Specifically, a single common criterion is to be used for determining whether a regulatory initiative involving a reduction in CDF (1) meets the substantial additional protection standard identified in the Backfit Rule (10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities”) and (2) is appropriate, considering the subsidiary numerical objective of $1x10^{-4}$ in mean CDF per reactor year (NRC, 1990b). The staff has determined that this subsidiary numerical objective is a useful benchmark and an acceptable surrogate for the average individual latent cancer fatality risk quantitative health objective; however, it is not a Commission-approved safety goal.

In light of the inherent uncertainties of PRA analysis, a reduction in CDF should be considered to be clearly substantial if the reduction is equal to or greater than $1x10^{-4}$ per reactor year. If the reduction in CDF is between $1x10^{-4}$ and $1x10^{-5}$ mean CDF per reactor year (i.e., 10 percent or more of the subsidiary numerical objective of $1x10^{-4}$ in mean CDF per reactor year but less than $1x10^{-4}$), consideration should be given to the probability of containment failure before a conclusion is reached on whether the reduction in CDF constitutes substantial additional protection. As illustrated in Figure 2-2, this means that, with certain exceptions as discussed later in this guidance, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least $1x10^{-5}$ in the estimated mean value CDF (i.e., the CDF

before the proposed regulatory change should exceed the CDF after the change by at least $1x10^{-5}$) to support the decision to proceed 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 appropriate for implementation after more detailed cost-benefit assessments are performed in accordance with Section 2.5 of this guidance, or backfit or forward fit analyses are performed in accordance with NUREG-1409. 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 Division Director.
<$1x10^{-5}$/reactor year	Terminate further analysis unless the responsible Office Director decides otherwise~~, based on strong engineering or qualitative 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 indicates~~provides a calibration on~~ the significance of the proposed regulatory action. If the initiative results in a small change in CDF (less than $1x10^{-5}$ per reactor-year), the regulatory analysis should, in general, proceed only if an alternative 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.

In limited circumstances, ~~I~~if data is unavailable or it is not possible or practicable to develop adequate quantitative supporting information for the proposed new requirement, a qualitative analysis and associated perspectives ~~should~~ may 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 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 or forward fits).

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 large openings
- those for which containment is bypassed entirely and that have a high probability of causing core damage to occur, 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 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 decision 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 indicates taking no action, further activities and analyses should be terminated unless there is a qualitative basis for proceeding further.

~~*2.4.1.4 1.1.1.1 Regulatory Analysis*~~

~~If the safety goal evaluation of the proposed regulatory action results in a decision 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 indicates taking no action, further activities and analyses should be terminated unless there is a qualitative basis for proceeding further.~~

~~The Commission has directed that the NRC's regulatory actions affecting nuclear power plants be evaluated for conformity with the NRC's policy statement on safety goals for the operations of nuclear power plants (NRC, 1986). The policy statement sets out two qualitative safety goals and two quantitative objectives. Both the goals and the objectives apply only to the risks to the public from the accidental or routine release of radioactive materials from nuclear power plants.~~

~~The policy statement has the following qualitative safety goals:~~

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

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

~~The two quantitative objectives in the policy statement are to be used in determining achievement of the qualitative safety goals. The objectives are as follows:~~

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

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

~~This guidance contains specific information on implementing the quantitative objectives that the analyst should carefully follow. It states that a safety goal evaluation is needed for a proposed generic safety enhancement to nuclear power plants that is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). Thus, proposals for a facility specific backfit or for generic backfits within the exceptions at 10 CFR 50.109(a)(4)(i–iii) do not require a safety goal evaluation. Further, it states that a safety goal evaluation is not needed for a proposed relaxation of a requirement affecting nuclear power plants.~~

~~This guidance also states that a PRA should normally be used in performing a safety goal evaluation to quantify the risk reduction and corresponding values of a proposed new requirement. The NRC's final policy statement on the use of PRA methods in nuclear regulatory activities (NRC, 1995a) states the following:~~

~~The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments on the need for proposing and backfitting new generic requirements on nuclear power plant licensees.~~

~~If conducted, a safety goal evaluation should be included in Chapter 3 of the regulatory analysis document that covers "estimation and evaluation of cost benefit." The results of the safety goal evaluation should be included in Chapter 4 of the regulatory analysis document that covers "presentation of results."~~

2.4.2 New Power Reactors Under 10 CFR Part 52

When analyzing risks from severe accidents as part of the environmental review under 10 CFR Part 52 for an early site permit (ESP) or for a COL as provided in NUREG-1555, "Environmental Standard Review Plan: Standard Review Plans for Environmental Reviews for Nuclear Power Plants," the reviewer should compare the site-specific severe accident dose risks with the Commission's safety goals. New reactor designs submitted for standard certification must comply with the PRA requirements in 10 CFR Part 52.

2.5 Relationship to Other Procedural Requirements

This section discusses the relationship of regulatory analyses to other statutory requirements applicable to the NRC. The documentation required by the Regulatory Flexibility Act is typically included as an appendix to the regulatory analysis; documentation required by the Paperwork Reduction Act, though not appended to the regulatory analysis, must be developed. The remaining procedural requirements typically involve issues closely related to those examined in the regulatory analysis.

2.5.1 Paperwork Reduction Act

The Paperwork Reduction Act contains procedural requirements designed to minimize and control the recordkeeping and reporting burdens associated with collections of information by Federal agencies from individuals, businesses, and other private entities, and from State and local governments. MD 3.54, "NRC Information Collections Program," dated March 29, 2016, and the NRC Regulations Handbook contain the NRC's internal procedures for complying with the Paperwork Reduction Act and preparing justifications for OMB approval of information collections.

Whenever a proposed regulatory action involves information collections subject to OMB approval, an OMB clearance package must be prepared for the rulemaking. While the OMB clearance package need not be included as part of the rulemaking package that is submitted to the EDO or Commission for approval, the NRC Clearance Officer must approve the clearance package for submittal to the OMB before the rule can be submitted to the *Federal Register* for publication.

Agencies are required to obtain OMB approval for collections of information when (1) the information collection involves 10 or more persons by means of identical questions or reporting or recordkeeping requirements or (2) the collection is addressed to all or a substantial majority of an industry, even if that majority involves fewer than 10 persons (5 CFR Part 1320, "Controlling Paperwork Burdens on the Public").

The OMB's criteria for approval of information collections are in 5 CFR 1320.5(d)(1). The collection of information restrictions includes the voluntary participation of entities under the assumption that there is little or no difference between a Federally generated voluntary request and a requirement. To obtain OMB approval for information collections, an agency must demonstrate that the collection of information (1) is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives, (2) is not duplicative of information otherwise available to the agency, and (3) has practical utility. The agency should minimize its cost of collection, processing, and using the information but not by shifting disproportionate costs or burdens onto the public. Agencies should consult with interested agencies and members of the public 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 providing a reasonable basis 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 is appropriate in view of the potential safety significance of the issue. All 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 analysis is required and what the written statement should include.

MD 8.4 discusses facility-specific information requests directed at individual nuclear power reactor licensees and select materials licensees.

Written statements prepared according to the preceding requirements to provide a reasonable basis for the information requests are not regulatory analyses within the scope of this guidance. Nevertheless, the written 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. An information request analysis should 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

- a small organization that is a not-for-profit organization that is independently owned and operated and has annual gross receipts of $7.0 million or less

- a small governmental jurisdiction that is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000

- a small educational institution that is (1) supported by a qualifying small government jurisdiction or (2) is not State or publicly supported and has 500 or fewer employees

The NRC Regulations Handbook sets out procedural requirements for the preparation of regulatory flexibility analyses. The NRC public Web site provides a summary of these procedures. If a proposed rule would likely have a significant economic impact on a substantial number of small entities, an initial screening analysis must be prepared consistent with the NRC procedural requirements. After revisions are made to the rule package in response to public comments, a final regulatory flexibility analysis must be prepared to update information contained therein and to explain what was done to minimize the adverse economic impact of the rule on small entities. In addition, a small entity compliance guide would be issued along with the rule. The regulatory flexibility analysis may be included as an appendix to the regulatory analysis document or as an insert to the proposed rule. The regulatory flexibility analysis need not repeat information discussed in the body of the regulatory analysis; such information may be incorporated by reference. If the NRC determines that a rule would not have a significant economic impact on a substantial number of small entities, a certification to this effect must be included in the proposed rule and repeated in the final rule. The regulatory analysis must contain sufficient information about the potential impact of the proposed rule on small entities to support this certification.

2.5.4 National Environmental Policy Act

As previously discussed in Section 1.2.3, NEPA requires Federal agencies to prepare a "detailed statement for major Federal actions significantly affecting the quality of the human environment." This detailed statement, known as an environmental impact statement (EIS), is prepared 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). As previous noted, while NEPA 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.

As part of its obligations under NEPA, the NRC must assess the environmental impact of each rulemaking action and include a statement about the environmental impact in the supplementary information section of the preamble to each rulemaking. When an EIS or EA has been prepared under NEPA (see Section 4), ~~a brief summary of information from the EIS or EA is an acceptable substitute for the information required in Sections 2.3.1– through 2.3.3 of this~~

~~guidance. T~~the EIS or EA may be referenced ~~at other points~~ in the regulatory analysis as appropriate to avoid duplication.[7]

The regulatory analysis should conform with the environmental determinations of the EIS or EA. For example, the alternatives evaluated in the regulatory analysis should be the same as the alternatives evaluated in the EIS or EA.

2.5.5 Environmental Justice Reviews

Environmental justice reviews are conducted for rulemaking activities and provide a clear basis for the conclusion that minority and low-income populations would not experience disproportionately high and adverse human health and environmental effects. The environmental justice review for regulatory analyses in rulemaking activities follows the procedure below:

- The staff responsible for rulemaking should address environmental justice in the preamble to any proposed and final rule that requires an EIS, a supplement to an EIS, or generic EIS, or if warranted by a special case or circumstance an EA and Finding of No Significant Impact (FONSI).

- If it is known in advance that a rulemaking might disproportionately affect a minority or low-income population or community, the staff should ensure that the population knows about the rulemaking and are given the opportunity to participate. Such actions may include translating the *Federal Register* notice into a language other than English for publication in a local newspaper and holding public outreach meetings in the potentially affected community.

- The staff should consider using the template in the NRC Regulations Handbook to seek and welcome public comments on environmental justice. To perform the environmental justice review, the staff should follow the appropriate procedures for the action being analyzed. See e.g., "Procedures for Licensing Actions," steps 2 through 5 in Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-203, Revision 3, "Procedural Guidance for Preparing Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues," dated July 1, 2013 and steps IV.A through IV. E of Appendix C, "Environmental Justice Procedures," to NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," issued August 2003.

- Public comments on the environmental justice review should be addressed in the statements of consideration to the final rule when it is published in the *Federal Register*. Comments on the environmental justice review should be addressed at the same level of detail and in the same location as comments received on other parts of the rule.

- When a rule is being modified or developed that contains siting evaluation factors or criteria for siting a new facility, the staff may consider including specific language in the rule or supporting regulatory guidance to state that an environmental justice review will be performed as part of the licensing process.

[7] Where the action at issue is categorically excluded from the requirement for a NEPA review, the analyst will still need to prepare the information required in sections 2.3.1 through 2.3.3 of this guidance for the regulatory analysis. See 10 CFR 51.22 for a list of categories of actions that are categorical exclusions.

3 BACKFITTING, FORWARD FITTING, AND ISSUE FINALITY

3.1 General

Backfitting ~~is expected to~~may occur as part of the regulatory process to ensure the safety of power reactors and radioactive materials. ~~However, i~~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 justified and suitably defined. For additional information on backfitting, see MD 8.4 and NUREG-1409.

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.

The term “backfit” is not normally used in discussions relevant to new power reactors; instead, the concept of “issue finality” is used. 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 issue finality under 10 CFR Part 52.

A forward fit is defined in MD 8.4 as “the imposition of a new or modified requirement or regulatory staff interpretation of a requirement that results in the modification of or addition to systems, structures, components, or 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 as a condition of approval by the NRC of a licensee-initiated request for a licensing action when the underlying request did not propose to comply with the new or revised requirement or interpretation.” Such licensing actions may include a license amendment or a license renewal, although the process in 10 CFR Part 54, does not generally constitute forward fitting. Forward fits generally do not include instances when an applicant files an initial licensing action for a new facility.

3.2 Relationship of Regulatory Analysis to Backfitting, Forward Fitting, and Issue Finality

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

A regulatory analysis must be performed if the staff issues a new or modified regulatory position (e.g., a revision to regulatory guidance) and the existing regulatory position is no longer available for use by current licensees. A site-specific regulatory analysis should be performed if the staff imposes a new or modified regulatory position as part of the approval of a licensing action for a current licensee, and the existing regulatory position also is available for use by current licensees and applicable to the licensing action under review.

For all matters of potential backfitting, the staff first must consider whether the issue is one of adequate protection,[8] as discussed in NUREG-1409. If a backfitting action is determined to be necessary for adequate protection, a backfit analysis is not required and costs cannot be considered (unless the NRC staff identifies more than one means for implementing the new requirement, in which case costs could be considered in deciding which approach is appropriate).

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 from 10 CFR 50.109(c), 10 CFR 70.76(b), or 10 CFR 76.76(b), as appropriate, 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
- the potential ~~for~~ change in the risk to the public from the accidental offsite release of radioactive material
- the potential effect on~~f~~ radiological exposure of~~n~~ facility employees
- the installation and continuing costs associated with the backfitting action, including the cost of facility downtime or the cost of construction delay
- the potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements
- the estimated resource ~~costs~~ burden ~~for~~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 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 may not be considered in cases of ensuring continued adequate protection of public health and safety or common defense and security, or defining~~,~~ or redefining the level of ~~adequate~~ protection of public health and safety or common defense and security that would be regarded as adequate unless there are two or more ways to achieve a level of protection which is adequate. Should it be

[8] Like backfitting, for matters of potential forward fitting, the staff must first consider whether the issue is one of adequate protection. As discussed in MD 8.4, instances of adequate protection forward fitting should be rare.

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 an action from the options, provided that the objective of adequate protection is met.

Averted onsite costs can 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 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 directly tied to a safety enhancement, such as an estimated decrease in accident frequency or severity.

The Backfit Rule establishes a more difficult standard for imposing new regulations and positions than the cost benefit 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" per 10 CFR 50.109(a)(3). ~~Many~~In limited cases, it may not be possible or practical to quantify some of the factors to be addressed in the analysis ~~may not be easily quantified~~, and the Backfit Rule permits the judicious and disciplined consideration of other relevant and material factors, including qualitative factors (see Appendix A).

For backfits and issue finality, the CRGR Charter provides guidance on what cost and benefit information is needed for CRGR review. Guidance for performing this activity is provided in NUREG-1409.

4 COST-BENEFIT ANALYSIS FOR NATIONAL ENVIRONMENTAL POLICY ACT REVIEWS

4.1 General

This section provides guidance for assessing costs and benefits as part of NEPA analyses to support NRC rulemaking and licensing actions. NEPA established a national policy for considering environmental values through the preparation of a detailed statement for major Federal actions significantly affecting the quality of the human environment. NEPA's essential purpose is to ensure each Federal agency considers, along with other factors, the environmental impacts of its actions on the environment and the health and welfare of the public.

A cost-benefit analysis is one component of the analytical requirements of NEPA. As the Commission has explained, "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." (*Louisiana Energy Services* (Claiborne Enrichment Center), CLI-98-03, 47 NRC 77 (1998), quoting 10 CFR 51.71(d)). ~~This s~~Section 4 of this NUREG discusses the different approaches to NEPA-related cost-benefit analyses that NRC has developed for different licensing actions. ~~More detailed NEPA-related cost-benefit guidance for specific NRC applications will be provided in Appendix I, "NEPA Cost-Benefit Analysis," to this NUREG.~~

Commented [A2]: Deleted by Correction Notice dated March 17, 2020.

The intent of this section is to provide guidance to a cost-benefit analyst in support of NRC's NEPA obligations under the following licensing actions:

- Construction permit and operating license under 10 CFR Part 50,
- Early site permit, combined license, standard design certification, and manufacturing license under 10 CFR Part 52
- License renewal under 10 CFR Part 54, and,
- Material licenses under 10 CFR Parts 30, 40, 70, and 72.

The NRC's regulations implementing NEPA are in 10 CFR Part 51.

The section is organized into the following sections: (1) general guidance for costs and benefits in NEPA reviews for NRC licensing actions; (2) specific guidance for new reactors; (3) costs and benefits guidance for new reactor and material licensing actions; (4) environmental justice; and (5) public and occupational health impact analyses.

4.2 ~~Comparison of~~ Cost-Benefit Requirements in NEPA Reviews for NRC Licensing Actions

The need for a cost-benefit analysis to provide some input for environmental analysis varies across NRC's licensing actions ~~and, when prepared, may provide some input for environmental analysis~~. In some cases, a cost-benefit analysis is either not needed or prohibited. In cases where a cost-benefit analysis is prepared, the depth and relevance of the analysis to the NEPA review also varies across the types of actions taken. The regulations in 10 CFR Part 51 outline procedures for conducting NEPA reviews for NRC licensing actions. Licensing actions requiring

an EIS are listed in 10 CFR 51.20. ~~Similarly, licensing actions requiring an EA are listed in 10 CFR 51.21.~~ Licensing actions eligible for "categorical exclusion" and therefore not requiring preparation of an EA or EIS, are listed in 10 CFR 51.22. Under 10 CFR 51.21, all licensing and regulatory actions subject to 10 CFR Part 51, Subpart A, "National Environmental Policy Act-Regulations Implementing Section 102(2)," require an EA except for those identified in 10 CFR 51.20 as requiring an EIS and those identified in 10 CFR 51.22 as either eligible for categorical exclusion from the requirement for an environmental assessment or environmental impact statement or not requiring environmental review.

In support of NEPA reviews for NRC licensing actions, regulations in 10 CFR 51.45 require each applicant to submit an ER as part of its application. As presented in 10 CFR 51.45(c), except for an ER prepared at the early site permit stage or an ER prepared at the license renewal stage under 10 CFR 51.53(c), the analysis in the ER should include "consideration of the economic, technical, and other benefits and costs of the proposed action and its alternatives." The staff will independently evaluate the information provided in the ER and be responsible for the reliability of all information used in a NEPA review (10 CFR 51.41 and 10 CFR 51.70(b)).

For license renewal, 10 CFR 51.53(c)(3)(ii)(L) requires a consideration of the costs and benefits of SAMAs in an applicant's ER if the staff have not previously considered SAMAs in an EIS, related supplement, or in an EA. Conversely, a license renewal applicant for a plant that has already had a SAMA analysis considered by the NRC as part of an EIS, supplement to an EIS, or EA, does not need to provide another SAMA analysis in the ~~subsequent or second~~ license renewal ER. However, under 10 CFR 51.53(c)(3)(iv) the applicant's ER must also provide any new and significant information regarding the environmental impacts of license renewal of which the applicant is aware, including any cost-benefit information with respect to a prior SAMA analysis.

The regulations in 10 CFR 51.71 require an EIS to include the "consideration of the economic, technical, and other benefits and costs of the proposed action and alternatives." Supplemental EISs prepared at the license renewal stage under 10 CFR 51.95(c) need not discuss these considerations unless special circumstances exist. The EIS includes staff recommendations regarding the proposed action, which are based on information collected and independent analyses, as appropriate. These recommendations are also based on the environmental effects of the proposed action, the consideration of reasonable alternatives, and weighing the costs and benefits of the proposed action. ~~Under 10 CFR 51.75(b), early site permit EISs must not include an assessment of the economic, technical, or other benefits and costs of the proposed action unless the applicant chooses to address this information in the early site permit ER.~~

Commented [A3]: Addressed in section 4.3.

~~Under 10 CFR 51.55, design certification applicants must address the costs and benefits of severe accident mitigation design alternatives (SAMDAs), and the bases for not incorporating SAMDAs in the design. The regulations in 10 CFR 51.30(d) require the staff to consider the costs and benefits of SAMDAs in a design certification EA and the bases for not incorporating SAMDAs in the design certification.~~

~~Under 10 CFR 51.54, a manufacturing applicant must address the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs in the design. As for standard design certification, the staff conducts a cost-benefit analysis in an EA in accordance with 10 CFR 51.30(e) for a manufacturing license under Subpart F of 10 CFR Part 52, "Manufacturing Licenses."~~

Commented [A4]: Moved to section 4.3.

4.3 Specific Costs and Benefits Requirements for New Reactors

Under 10 CFR 51.55, design certification applicants must address the costs and benefits of severe accident mitigation design alternatives (SAMDAs), and the bases for not incorporating SAMDAs in the design. The regulations in 10 CFR 51.30(d) require the staff to consider the costs and benefits of SAMDAs in a design certification EA and the bases for not incorporating SAMDAs in the design certification.

Under 10 CFR 51.54, a manufacturing license applicant must address the costs and benefits of SAMDAs and the bases for not incorporating SAMDAs in the design. As for standard design certification, the staff conducts a cost-benefit analysis in an EA under 10 CFR 51.30(e) for a manufacturing license under Subpart F of 10 CFR Part 52, "Manufacturing Licenses."

For ESPs under 10 CFR Part 52, the draft EIS ~~need~~ must not include an assessment of the economic, technical, or other benefits (for example, need for power), costs of the proposed action, or an evaluation of alternative energy sources unless these matters are addressed in the ESP ER (10 CFR 51.75(b)). When consideration of costs and benefits is required, the staff should, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that 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 appropriate. 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.

[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.

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
- 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. For NEPA analyses, ~~T~~the cost-benefit analysis is not simply a mathematical formula 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~~using 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 Categorical Exclusions, Environmental Assessments and Considering Environmental Issues," dated July 1, 2013
- NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs: Final Report," issued August 2003
- "Environmental Standard Review Plan: Standard Review Plans for Environmental Reviews for Nuclear Power Plants," NUREG-1555
- "Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal: Final Report," NUREG-1555, Supplement 1, Revision 1, issued June 2013 (refer to the NRC Regulations Handbook)

4.6 Public and Occupational Health Impact Analyses

The EIS for a licensing action should include information on current background levels, historical exposure levels for the proposed action, and a summary of any public health studies performed in the region sufficient to establish baseline information on which to analyze impacts on public and worker health.

The analysis should consider potential pathways for the transfer of radioactive and nonradioactive materials from the proposed action and alternatives to the environment and ultimately to living organisms. The analysis should identify all pathways necessary to calculate public and occupational exposure.

The applicant's ER should present the following information, as applicable. It may not be necessary for the evaluation of potential impacts from the proposed action to require all the information requested below:

- major sources and levels of annual background radiation, including natural and man-made sources; express these doses in units of mrem (millisieverts)
- current sources and levels of exposure to radioactive materials

- major sources and levels of chemical exposure
- historical exposures to radioactive materials
- occupational injury rates and occupational fatality rates
- summary of health effects studies

4.6.1 Reactors—SAMA/SAMDA Analyses

Severe nuclear accidents are those that could result in substantial damage to the reactor core, whether or not there are serious offsite consequences. In the license renewal GEIS and in COL EISs, the staff assesses the impacts of severe accidents, using the results of existing analyses and site-specific information to conservatively predict the environmental impacts of severe accidents ~~for each nuclear power plant~~. In addition, an evaluation of SAMA for ~~the~~ each plant is required. SAMDA are a subset of the SAMA review that are specific to potential design changes; these are also evaluated as part of a new reactor DC or COL application. The purpose of the evaluation of SAMA is to determine whether there are SAMDAs, procedural modifications, and training activities that are appropriate to further reduce the risks of severe accidents.

4.6.1.1 Severe Accident Mitigation Alternatives

~~In accordance with~~Under 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).

4.6.1.2 Severe Accident Mitigation Design Alternatives

In 10 CFR 52.79(a)(38), the NRC requires that applicants for COLs for light-water reactors include "a description and analysis of design features for the prevention and mitigation of severe accidents" in the FSAR. In 10 CFR 52.47(a)(23), the NRC requires that applications for a light-water reactor DC include "a description and analysis of design features for the prevention and mitigation of severe accidents." In addition, 10 CFR 52.47(a)(27) requires a description of "the design-specific PRA and its results~~,~~" for all reactor DCs, and in 10 CFR 52.47(b)(2), the NRC requires an applicant-prepared ER that contains the information required by 10 CFR 51.55, "Environmental Report—Standard Design Certification."

In an ER submitted as part of a DC application under 10 CFR 51.55(a) or submitted as part of a COL application under 10 CFR 51.50(c), an applicant should identify candidate SAMDA based on a review of alternatives for other plant designs, including those considered in license renewal ERs, and on consideration of facility-specific enhancements. The alternatives are then screened to identify candidates for detailed evaluation.

After screening, the applicant for a DC or a COL would calculate the maximum attainable benefit associated with eliminating all risk for the design under review. This methodology involves determining the net value for a SAMDA by comparing the averted costs of the postulated accident to the cost of the enhancement ~~according to~~using the following formula:

Net Value = (APE + AOC + AOE + AOSC) – COE

where

APE = present value of averted public exposure (dollars)
AOC = present value of averted offsite property damage costs (dollars)
AOE = present value of averted occupational exposure costs (dollars)
AOSC = present value of averted onsite costs (dollars); this includes cleanup, decontamination, and long-term replacement power costs
COE = cost of enhancement (dollars)

If the net value of a SAMDA is negative, the cost of implementing the SAMDA is larger than the benefit associated with the SAMDA, and it is not considered to be cost beneficial. To assess the risk-reduction potential for SAMDAs, the applicant assumes that each design alternative would work perfectly to eliminate all severe accident risk from the events that are evaluated.

This assumption is conservative, because it maximizes the benefit of each design alternative. The applicant estimates the public exposure benefits for the design alternative on the basis of the reduction of risk expressed in terms of whole body person-rem per year received by the total population within an 80.5 km (50-mile) radius of the generic reactor site.

In 10 CFR 52.47(a)(27) and 10 CFR 52.79(a)(46), the NRC requires an applicant for a DC, or a COL, respectively, to perform either a design-specific or a plant-specific PRA. The aim of this PRA is to ~~seek~~ allow the identification of improvements in the reliability of core and containment heat removal systems that are significant and practicable. The set of potential design improvements to be considered for ~~the~~ a proposed DC would include~~s~~ those from generic, technology-appropriate, reactor SAMA reports.

The staff should evaluate the risk-reduction potential of design improvements for proposed designs based on risk-reduction estimates for screened design alternatives, in conjunction with an assessment of the potential impact of uncertainties on the results. The staff should perform averted cost estimates using two sets of parameters (best estimate and high estimate) when calculating the occupational dose after an accident and during decontamination and cleanup, and for the replacement power costs. The staff's maximum estimate is based on the use of "high or upper bound" estimated parameters and the proposed design's power rating.

4.6.2 Materials

The applicant or licensee should describe existing public and occupational health issues, as appropriate. The ER should present the following information, although it may not be necessary for the evaluation of potential impacts from the proposed action to require all of it:

- physical layout of the site, including the location and orientation of radioactive materials that are expected to be present
- location and characteristics of radiation sources and liquid and gaseous radioactive effluent
- measured radiation dose rates, airborne radioactivity concentrations, and waterborne radioactivity concentrations at specific locations where environmental radiological monitoring data exist
- calculated radiation dose rates, airborne radioactivity concentrations, and waterborne radioactivity concentrations at specific locations important to dose calculations where environmental radiological monitoring data are not available, including a description of the methodology
- calculated total effective dose equivalent to an average member of the critical group or calculated average annual concentration of radioactive material in gaseous and liquid effluent, including all models, assumptions, and input data to determine compliance with 10 CFR Part 20, "Standards for Protection against Radiation," and 40 CFR Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations"
- calculated dose to the workforce, including all models, assumptions, and input data to determine compliance with 10 CFR Part 20

The analyst should identify the list of credible accidents that have the potential for releases to the environment and analyze the dose consequences from these accidents. For example, these accidents are termed design-basis events for licenses under 10 CFR Part 72 and credible consequence events for licenses under 10 CFR Part 70.

5 DETAILS OF A COST-BENEFIT ANALYSIS

5.1 General

The discussions in this chapter apply to both reactor and materials licensing and regulatory actions.

A cost-benefit analysis can do the following:

- Help the analyst and decisionmaker define the problem.
- Provide a logical structure for the combination of issues contributing to a decision.
- Describe beneficial and detrimental aspects of a decision.
- Record the decision rationale to provide documentation, defensibility, and reproducibility.
- Focus discussions on the specific issues of contention to assist in resolution.
- Provide a framework for the sensitivity testing of data and assumptions.
- Consider all factors affecting an issue.
- Clarify results even with closely valued alternatives and large uncertainties.

5.1.1 Methods

As stated earlier, the regulatory analysis process comprises 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

(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

The cost-benefit portion of a regulatory analysis encompasses the third and fourth elements of the process. Cost-benefit analysis identifies and estimates the relevant costs and benefits likely to result from a proposed NRC action. The methodology is a systematic definition and evaluation of those costs and benefits.

The attributes affected by any given proposed action will vary and the analyst will have to determine the appropriateness of each attribute. Attributes, whether costs or benefits, can have either positive or negative algebraic signs, depending on whether the proposed action has a favorable or adverse effect. The sign conventions are as follows: favorable results are positive; adverse results are negative. Each attribute measures the change from the existing condition resulting from the proposed action. Sections 5.2 and 5.3 discuss attributes in detail.

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. 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 operations (i.e., nonaccident situations) that result from the proposed regulatory action. When used, this attribute would employ a~~n 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~~ an accident) as a result of changes in accident frequency or accident mitigation. External workers assisting in response to ~~the~~ an 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 an 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 operations (i.e., nonaccident situations). For many types of proposed actions, there will be an increase in worker exposures; ~~sometimes~~ for some elements of the actions this will be a one-time effect (e.g., installation or modification of equipment in a hot area), while for other~~s~~ elements there will be 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 during normal operations, 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 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 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 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 such as the testing of evacuation sirens.

This 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 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 analysis may also identify unique attributes 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.

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. 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 cannot be ~~addressed~~ resolved 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), then the incremental benefits attributable to ~~the~~ a proposed regulation ~~are~~ would be diminished. Alternatively, if "no credit" is given (i.e., it is assumed that complementary industry initiatives will cease and licensees will depart from the practices in place under the initiatives), then the incremental benefits ~~assigned~~ attributable to ~~the~~a proposed ~~rule~~ regulation could~~are~~ increase~~d~~.

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 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. Consideration of whether an initiative is likely to continue may take into account individual utilities' characterizations of the costs of the initiative as prudent investments.

- 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~~ appropriate credit for the industry initiative reflecting the degree to which the staff expects it to remain in place and a sensitivity analysis reflecting full and no 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.

To the degree to which the considerations associated with qualitative 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 this NUREG).

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, 1992b) 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 that adopting the proposed air-gap rule would be cost effective if 347 person-rem per year were saved. At the estimated average savings 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 only have to reduce the incident rate 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. The Commission, however, ultimately directed the staff to terminate this rulemaking effort in favor of performing a comprehensive risk review of the licensing and inspection programs, including licensees' activities. The results of the review were to be used to develop new risk-based licensing and inspection programs approved by the Commission as well as to determine whether a similar rulemaking should be developed. The withdrawal of this proposed rulemaking was noticed in the *Federal Register* on January 20, 1999 (64 FR 3052).

Example 2: In 1992, the NRC responded to a petition from General Electric (GE) and Westinghouse for a rulemaking to allow self-guarantee as an additional means for compliance with decommissioning regulations. An NRC contractor estimated the default risks of various types of financial assurance mechanisms, including the proposed self-guarantee. The contractor had to collect data on failure rates of firms of different sizes and of banks, savings and loans, and other suppliers of financial assurance mechanisms. The contractor estimated a default risk of 0.13 percent annually for the GE-Westinghouse proposal, with a maximum default risk of only 0.055 percent annually for third-party guarantors, specifically, a small savings and loan issuing a letter of credit. Based on these findings, the NRC initiated a proposed rulemaking that would allow self-guarantee for certain licensees. The final rule was issued December 29, 1993 (NRC, 1993b).

5.3.2.1 Public Health (Accident)

Evaluating the effect on public health from a change in accident frequency resulting from proposed regulatory actions is a multistep process. For each affected facility, the analyst first estimates the change in the public health (accident) risk associated with the action and reports this as person-rem avoided exposure. Reduction in public risk is algebraically positive; increase is negative (viewed as a negative reduction). Next, the analyst converts person-rem to their monetary equivalent (dollars) and discounts to present value. Finally, the analyst totals the change in public health (accident) as expressed in discounted dollars over all affected facilities.

The steps are as follows:

(1) Estimate the reduction in accident frequency per facility.

(2) Estimate the reduction in public health (accident) risk per facility.

(3) Convert the value of public health (accident) risk avoided (person-rem) per facility to the monetary equivalent (dollars) via the monetary valuation of health effects.

$$Z_{PHA} = RD_{PA}$$

where

Z_{PHA} = monetary value of public health (accident) risk avoided per facility-year before discounting (dollars/facility-year)
D_{PA} = avoided public dose per facility-year (person-rem/facility-year)
R = monetary equivalent of unit dose (dollars/person-rem)

(4) Discount to present value per facility (dollars).

(5) Total over all affected facilities (dollars).

$$V_{PHA} = NW_{PHA}$$

where

V_{PHA} = discounted monetary value of public health (accident) risk avoided for all affected facilities (dollars)
W_{PHA} = monetary value of public health (accident) risk avoided per facility after discounting (dollars/facility)
N = number affected facilities

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

$$V_{PHA} = \sum_{i} N_i W_{PHA_i}$$

where

i = facility (or group of facilities) index

5.3.2.1.1 Estimation of Accident-Related Health Effects

For the standard analysis, the analyst would employ data developed in existing risk studies that include offsite effects. Such studies provide population dose factors that can be applied to accident-release categories to yield dose estimates as follows:

$$\textit{Avoided Public Dose [DPA] (person-rem/facility-year)} = \sum_{\substack{\textit{Release} \\ \textit{Category}}} \left[\begin{matrix}\textit{Reduction in Release} \\ \textit{Category Frequency} \\ \left(\frac{events}{facility-year}\right)\end{matrix}\right] \times \left[\begin{matrix}\textit{Population Dose} \\ \textit{Factor for Release} \\ \textit{Category} \\ \left(\frac{person-rem}{event}\right)\end{matrix}\right]$$

If the risk assessment being used by the analyst to estimate public health (accident) employs its own unique accident-release categories with corresponding population dose factors, then these should be used.

Should the nature of the issue require that the reduction in accident frequency be expressed as a single number, a single population dose factor, preferably one that had been probabilistically weighted to reflect those for all accident-release categories, is generally needed. For this approach, the calculation of avoided public dose becomes the following:

$$\textit{Avoided Public Dose [DPA] (person-rem/facility-year)} = \left[\begin{matrix}\textit{Reduction in} \\ \textit{Accident Frequency} \\ \left(\frac{events}{facility-year}\right)\end{matrix}\right] \times \left[\begin{matrix}\textit{Population Dose} \\ \textit{Factor} \\ \left(\frac{person-rem}{event}\right)\end{matrix}\right]$$

It is possible that the proposed action will affect public health (accident) through a mitigation of consequences instead of (or as well as) through a reduction in accident frequency. Should this be the case, the previous general formulations are replaced with the following:

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

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 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. Offsite property consequences are separately valued and are not part of this conversion factor. 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 theoretically preferred approach to valuing morbidity effects. From WTP estimates, the value of

statistical illness (VSI) for cancer could be derived and combined with the nonfatal portion of the total cancer risk coefficient (i.e., cancer incidence minus fatality) to provide a comparable dollar-per-person-rem value for morbidity. However, many of the illnesses of concern have been the subject of few or no valuation studies and, therefore, lack existing WTP and VSI estimates (EPA, 2010). Some methods that may be used to estimate these values include cost-of-illness, averting behavior, and contingent valuation.

Several other methods to value morbidity do not estimate WTP but may be used to inform the analysis, such as risk-risk tradeoffs and health-state indexes. One such method, the quality-adjusted life-year (QALY), is a measure of the value of health outcomes that considers both life years saved and the quality of the life years when a person experiences disease. It is a type of health-state index most commonly applied in cost-effectiveness or cost-utility analyses to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived and the quality of those years. An Institute of Medicine panel commissioned by the U.S. Environmental Protection Agency (EPA) with support from the OMB discouraged the practice of monetizing QALYs because WTP and health-related quality of life indexes have been developed out of two differing, and not entirely compatible, frameworks (Institute of Medicine, 2006). As such, they should not be used for deriving monetary estimates for use in cost-benefit analyses, although there is evidence that components of these indices may still be useful in a benefit-transfer context (Van Houtven et al., 2006).

Psychosocial Effects

Psychosocial health effects are defined as post-accident stress and potential long-term psychological consequences (e.g., mental anguish, depression, post-traumatic stress) provoked by an accident or by population evacuation and emergency phase relocation, the fear of contracting diseases, or general stress on a sector of a society or on the society as a whole. This psychosocial effect may depend on the perceived quality of the emergency response or competence of the authorities, or feelings of powerlessness. Psychosocial effects may require medical treatment and may cause direct and indirect (e.g., workdays lost) costs to the society. If these ~~effects~~ costs are causally related to the accident and not included in another attribute, the analysis should consider these costs.

Following the accident at Three Mile Island, Unit 2 (TMI-2), psychosocial effects appear to have comprised the main health effect of the accident on the people living in the region of Three Mile Island (TMI) and on the workers at TMI. Mental stress (short-lived mental distress) resulting from the accident was found to be the primary effect, especially among those living within 5 miles of TMI and in families with preschool children or in families who left the area. Also, workers at TMI experienced more distress than workers at another plant studied for comparison purposes. This distress was higher among the nonsupervisory employees and continued in the months following the accident (Kemeny et al., 1979). Even 10 years after the 1979 TMI-2 accident, worries about personal and children's health were still elevated among residents who had lived within 10 miles of the plant before the accident (Bromet and Litcher-Kelly, 2002), even though radioactive releases from that accident were small. These effects were reported even though the TMI-2 accident caused no injuries, and numerous epidemiological studies conducted since 1981 have found no discernible direct health effects to the population near the plant.

Psychosocial effects were documented in populations affected by the 1986 Chernobyl accident. Danzer and Danzer (2014) analyzed a population sample consisting of adults who were not

relocated out of the areas contaminated by the accident. They used survey and economic data to estimate the increase in national income that would be needed to compensate the affected population for the impact of the accident on life satisfaction. The International Atomic Energy Agency (IAEA) Chernobyl Forum (2006) concluded that many people were traumatized by the relocation, the breakdown in social contacts, fear, and anxiety about what health effects might result. As a result, affected people reported high levels of anxiety and stress-related symptoms and were more subject to unexplained physical symptoms and subjective poor health. Masunaga et al. (2014) found that even well-educated people born after the Chernobyl accident in areas that were only modestly contaminated had anxiety about their radiation exposures, which has affected their mental health.

The Fukushima Dai-ichi nuclear power plant accident has produced considerable psychosocial stresses within populations in the Fukushima Prefecture over the past 4 years, even in areas where radiation levels are deemed by regulators to be acceptable for habitation. A study found that radiation anxiety, insomnia, and alcohol misuse were significantly elevated 3 years after the accident (Karz et al., 2014). Increased incidences of mental health problems and suicidal thoughts were also observed among residents forced to live in long-term shelters after the accident (Amagai et al., 2014). Complex psychosocial effects were also observed, including discordance within families over perceptions of radiation risk, between families over unequal compensatory treatments, and between evacuees and their host communities (Hasegawa et al., 2015). The National Academy of Science review of the Fukushima Dai-ichi nuclear power plant accident also highlighted the psychosocial effects of the accident on society (National Research Council Committee, 2008).

Commented [A5]: Staff should correct this reference, which is dated prior to the Fukushima Dai-ichi accident that it is listed as being a review of, or delete this sentence.

Psychosocial health effects from nuclear accidents involving land contamination may result in large attendant costs. These impacts are not readily monetized but should be considered within cost-benefit analyses, but not in NEPA analyses.

5.3.2.1.3 Discounting Monetized Value of Accident-Related Health Effects

The present value for accident-related health effects in their monetized form can be calculated as follows:

$$W_{PHA} = C \; x \; Z_{PHA}$$

where

W_{PHA} = monetary value of public health (accident) risk avoided per facility after discounting (dollars/facility)
C = $[\exp(-rt_i) - \exp(-rt_f)]/r$
r = real discount rate expressed as a fraction, not a percent
t_f = years remaining until end of facility life
t_i = years before facility begins operating
Z_{PHA} = monetary value of public health (accident) risk avoided per facility-year before discounting (dollars/facility-year)

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

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

Should public health (accident) risk not be discounted in an analysis, r effectively becomes zero in the preceding equations. In the limit as r approaches zero, $C = t_f - t_i$ (or $C = t_f$ when $t_i = 0$). This new value of C should be used to evaluate W_{PHA} in the undiscounted case.

The quantity W_{PHA} should be interpreted carefully to avoid misunderstandings. It does not represent the expected reduction in public health (accident) risk 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 (1) the expected annual loss resulting from a single accident (this is given by the quantity Z_{PHA}); (2) the possibility that such an accident could occur, with some small probability, at any time over the remaining facility life; and (3) the effects of discounting these potential future losses to present value. Because the quantity Z_{PHA} only accounts for the risk of an accident in a representative year, the result is the expected loss over the facility life, discounted to present value.

5.3.2.2 Public Health (Routine)

As with public health (accident), the evaluation of the effect on public health from a change in routine exposure resulting from proposed regulatory actions is a multistep process. Reduction in exposure is algebraically positive; increase is negative (viewed as a negative reduction).

The steps are as follows:

(1) Estimate reductions in public health (routine) risk per facility for implementation (D_{PRI}) and operation (D_{PRO}).

(2) Convert each reduction in public health (routine) risk per facility from person-rem to dollars via monetary evaluation of health effects.

$$G_{PRI} = RD_{PRI} \qquad G_{PRO} = RD_{PRO}$$

where

- G_{PRI} = monetary value of per-facility reduction in routine public dose required to implement the proposed action, before discounting (dollars/facility)
- G_{PRO} = monetary value of annual per-facility reduction in routine public dose to operate following implementation of the proposed action, before discounting (dollars/facility-year)
- D_{PRI} = per-facility reduction in routine public dose required to implement the proposed action (person-rem/facility)
- D_{RPO} = annual per-facility reduction in routine public dose to operate following implementation of the proposed action (person-rem/facility-year)
- R = monetary equivalent of unit dose (dollars/person-rem)

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

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

$$V_{PHR} = N\ (H_{PRI} + H_{PRO})$$

where

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

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

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

$$V_{PHR} = \sum_i N_i\ (H_{PRI} + H_{PRO})$$

where

i = facility (or group of facilities) index

5.3.2.2.1 Estimation of Change in Routine Exposure

A proposed NRC action can affect routine public 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 an increase or a decrease) in the recurring routine exposures after the action is implemented. The equations included in this revision apply a discounting term to doses associated with both implementation and operational impacts. In practice, the implementation dose may be of such short duration that discounting is not necessary. The staff includes it here in recognition that, in some cases, implementation may extend over a longer period than one year.

For the standard analysis, the analyst may attempt to make exposure estimates or obtain at least a sample of industry or community data for a validation of the estimates developed. NUREG/CR-2850, "Dose Commitments Due to Radioactive Releases from Nuclear Power Plant Sites in 1992," provides estimates of population and individual dose commitments for reported radionuclide releases from commercial power reactors operated during 1992. NUREG/CR-2907, "Radioactive Effluents from Nuclear Power Plants: Annual Report 2014," contains compiled and reported releases of radioactive materials in airborne and liquid effluents from commercial light water reactors (LWRs). Data on solid waste shipments are also included. This report is updated annually.

5.3.2.2.2 Monetary Valuation of Routine Exposure

As with public health (accident), monetary valuation for public health (routine) employs the monetary conversion factor from NUREG-1530.

5.3.2.3 Occupational Health (Accident)

Evaluating the effect on occupational health from a change in accident frequency resulting from proposed regulatory actions is a multistep process. A reduction in occupational risk is algebraically positive; an increase is negative (i.e., viewed as a negative reduction).

The steps are as follows:

(1) Estimate the reduction in accident frequency per facility.

(2) Estimate the reduction in occupational health (accident) risk per facility resulting from the following:

- "immediate" doses
- long-term doses

(3) Per facility, convert the value of occupational health (accident) risk avoided (person-rem) to the monetary equivalent (dollars) through monetary evaluation of health effects resulting from the following (see Section 5.2.3) (NRC, 2015):

- "immediate" doses $Z_{IO} = RY_{IO}$
- long-term doses $Z_{LTO} = RY_{LTO}$

where

Z_{IO} = monetary value of occupational health (accident) risk avoided per facility-year resulting from "immediate" doses, before discounting (dollars/facility-year)
Z_{LTO} = monetary value of occupational health (accident) risk avoided per facility-year resulting from long-term doses, before discounting (dollars/facility-year)
Y_{IO} = avoided occupational "immediate" dose per facility-year (person-rem/facility-year)
Y_{LTO} = avoided occupational long-term dose per facility-year (person-rem/facility-year)
R = monetary equivalent of unit dose (dollars/person-rem)

(4) Discount to present value per facility (dollars).

(5) Total overall affected facilities (dollars) using the following:

$$V_{OHA} = N\ (W_{IO} + W_{LTO})$$

where

V_{OHA} = discounted monetary value of occupational health (accident) risk avoided for all affected facilities
W_{IO} = monetary value of occupational health (accident) risk avoided per facility resulting from "immediate" doses, after discounting (dollars/facility)
W_{LTO} = monetary value of occupational health (accident) risk avoided per facility resulting from long-term doses, after discounting (dollars/facility)
N = number of affected facilities

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

$$V_{OHA} = \sum_{i} N\,(W_{IO_i} + W_{LTO_i})$$

where

i = facility (or group of facilities) index

5.3.2.4 Occupational Health (Routine)

As with occupational health (accident), the evaluation of the effect on occupational health from a change in routine exposure resulting from proposed regulatory actions is a multistep process. A reduction in exposure is algebraically positive; an increase is negative (i.e., viewed as a negative reduction).

The steps are as follows:

(1) Estimate reductions in occupational health (routine) risk per facility for implementation (D_{0R1}) and operation (D_{ORO}).

(2) Convert each reduction in occupational health (routine) risk per facility from person-rem to dollars through monetary evaluation of health effects as follows:

$$G_{ORI} = RD_{ORI} \qquad G_{ORO} = RD_{ORO}$$

where

G_{ORI} = monetary value of per-facility reduction in routine occupational dose to implement the proposed action before discounting (dollars/facility)
G_{ORO} = monetary value of annual per-facility reduction in routine occupational dose to operate after implementing the proposed action before discounting (dollars/facility-year)
D_{ORI} = per-facility reduction in routine occupational dose to implement the proposed action (person-rem/facility)
D_{ORO} = annual per-facility reduction in routine occupational dose to operate after implementing the proposed action (person-rem/facility year)
R = monetary equivalent of unit dose (dollars/person-rem)

(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 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 several sources. For power reactors, FSAR Chapter 12 for the plant will include a partitioning of the power plant into estimated

radiation zones. FSARs usually include both summary tables and plant layout drawings. Some FSARs provide exposure estimates for specific operational activities. The analyst should note that the FSAR values are calculated, not measured. Actual data from operating facilities like those that might be obtained from facility surveys would have greater accuracy. NUREG/CR-5035, "Data Base of System-Average Dose Rates at Nuclear Power Plants," provided generic estimates of dose rates for work on specific PWR and BWR systems and components. NUREG/CR-4627, "Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses," issued February 1992, used these estimates along with labor hours and occupational exposure estimates for specific repair and modification activities.

Work in a radiation zone requires extra labor because of radiation exposure limits and lower worker efficiency. Such inefficiencies arise from wearing restrictive clothing and rubber gloves, breathing through filtered respirators, standing on ladders or scaffolding, or crawling into inaccessible areas. In addition, the analyst should account for paid breaks during a job. Basically, five types of adjustment factors are identified for work on activated or contaminated systems. LaGuardia et al. (1986) identify the following five time-duration multipliers:

(1) Height (i.e., work conducted at elevations such as on ladders or scaffolds) equals 10 to 20 percent of the basic time duration.

(2) Respiratory protection equals 25 to 50 percent of the basic time duration.

(3) Radiation protection equals 10 to 40 percent of the basic time duration.

(4) Protective clothing equals 30 percent of the adjusted time duration.

(5) Work breaks equal 8.33 percent of the total adjusted time duration.

NUREG/CR-4627 provides information for estimating relevant labor productivity factors whose values can vary with the status of the plant and work environment at the time of the action.

Keeping these factors in mind, the analyst can estimate the implementation and operational doses. The implementation dose would be as follows:

$$D_{ORI} = -F_R \, x \, W_I$$

where

D_{ORI} = per-facility reduction in the routine occupational dose required to implement the proposed action (person-rem/facility-year)
F_R = radiation field in the area of activity (rem/hour)
W_I = work force required for implementation (labor-hours/facility)

As mentioned earlier, implementation dose normally involves an increase (hence the negative sign in the equation).

The operational dose is the change from the current level. Its formulation is as follows:

$$D_{ORO} = (F_R \, W_O \, A_F)_S - (F_R \, W_O \, A_F)_A$$

where

D_{ORO} = annual per-facility reduction in the routine occupational dose necessary to operate after implementing the proposed action (person-rem/facility-year)
F_R = radiation field in the area of activity (rem/hour)
W_o = work force required for the activity (labor-hours/facility-activity)
A_F = number of activities (e.g., maintenance, tests, inspections) per year (activities/year)
S = status quo (current conditions)
A = after implementation of the proposed action

Again, note the algebraic sign for D_{ORO} as mentioned earlier; an operational dose reduction is positive, and an increase is negative.

If the issue does not lend itself to the estimation procedure just presented, the analyst may use the approximation method for reactor facilities.

For a major effort beyond the standard analysis, a thorough survey of health physicists at the affected facilities would provide the best source of data to estimate both the implementation and operational exposures. A knowledgeable third party could screen the survey for bias and inflated values.

5.3.2.3.2 Monetary Valuation of Routine Exposure

Mortality Effects

The analyst should use the dollar-per-person-rem conversion factor discussed in NUREG-1530 for the monetary valuation of the cancer mortality risk resulting from routine exposures to radiation.

Morbidity Effects

As with the valuation of accident-related health effects, the use of WTP estimates to derive the VSI values for the illnesses of concern would be the preferred method for valuing morbidity effects. These values could then be combined with the nonfatal portion of the total cancer risk coefficient to provide a dollar-per-person-rem conversion factor for morbidity. In the absence of suitable WTP data, the OMB allows for consideration of alternative approaches that make use of health-related quality-of-life indices. However, as previously stated, the Institute of Medicine discourages reliance on monetized quality-of-life indices.

Psychosocial Effects

Psychosocial health effects consist of mental anguish, depression, and stress provoked by the fear of accidents or the fear of contracting diseases or general stress on a sector of a society or on the society as a whole. The psychosocial impact may also depend on the perceived competence of the authorities or feelings of powerlessness. Psychosocial effects may require medical treatment and may cause direct and indirect (e.g., workdays lost) costs to the society. If these effects are not included in another attribute, the analysis should consider these costs.

The NRC analyzed public perceptions of nuclear power (aesthetic effects) for the 1996 GEIS for the license renewal of nuclear plants (NRC, 2013a). The analysis consisted of seven case studies on the public perception of nuclear power, a survey of academic literature, and a review of newspaper and magazine articles. Based on the analysis, the staff found that license renewal would not likely alter existing perceptions of nuclear power. It is well understood that some people perceive the use of nuclear power and nuclear material negatively. Most of these negative perceptions are based on environmental and safety concerns, fear of accidents and acts of terrorism, or an antinuclear orientation.

Psychosocial health effects from routine exposure may result in attendant costs. These impacts are not readily monetized but should be considered within cost-benefit analyses. Psychosocial health effects may not be considered in NEPA analyses.

Although the NRC acknowledges the existence of psychosocial health effects arising from nuclear facility operations, this attribute is unlikely to influence the results of most cost-benefit analyses that it performs. Most regulatory analyses involve regulatory actions that could result in incremental changes to the risk attributed to a nuclear facility or class of nuclear facilities. For these cases, the alternatives evaluated as part of a cost-benefit analysis are not expected to differ significantly from the regulatory baseline with respect to the psychosocial health effects attribute. Therefore, the NRC anticipates that, although psychosocial health effects arising from changes to nuclear facilities are important to acknowledge, their existence may not significantly influence the results of the cost-benefit analysis. For this reason, psychosocial health effects may not be explicitly characterized as part of the incremental estimates prepared for each regulatory analysis.

5.3.2.3.3 Nonradiological Occupational Costs

In some cases, it will be possible to identify nonradiological occupational costs associated with a proposed action. When possible, the analyst should identify and include these costs in the regulatory analysis. One source of data on the incidence of occupational injuries for various industries is the "Injuries, Illnesses, and Fatalities" program Web site maintained by the U.S. Department of Labor's Bureau of Labor Statistics (BLS) (see the BLS Web site at https://www.bls.gov).

Occupational injury data should be converted to a dollar valuation. The value of an injury should include medical costs and the value of lost production (Regulatory Working Group, 1996 [Section 5]). The value of lost production is normally estimated using employee wage rates. Pain and suffering costs attributable to occupational injury can be identified qualitatively, but these costs would not normally be quantified in dollar terms. The National Center for Health Statistics (http://www.cdc.gov/nchs/index.htm) and the National Safety Council's annual publication, "Injury Facts: The Source for Safety Data" (http://www.nsc.org/learn/safety-knowledge/Pages/injury-facts.aspx), are potential sources for occupational injury valuation data.

5.3.2.4 Offsite Property

Estimating the effect of the proposed action upon offsite property involves the following three steps:

(1) Estimate the reduction in accident frequency.
(2) Estimate the level of property damage.
(3) Calculate the reduction in risk to offsite property as follows:

$$V_{FP} = N\Delta FD$$

where

V_{FP} = monetary value of avoided offsite property damage (dollars)
N = number of affected facilities
ΔF = reduction in accident frequency (events/facility-year)
D = present value of property damage occurring with frequency F (dollars-year)

The proposed action may possibly mitigate the consequences of an accident instead of reducing the accident frequency or may mitigate the consequences of an accident and reduce the accident frequency. In that event, the value of the action is as follows:

$$V_{FP} = (NFD)_S - (NFD)_A$$

where

F = accident frequency (events/facility-year)
S = status quo (current conditions)
A = after implementation of proposed action

A reduction in offsite property damage costs (i.e., cost savings) is algebraically positive; an increase (cost accruals) is negative (i.e., viewed as negative cost savings).

The MELCOR Accident Consequence Code System (MACCS) computer code has been developed to estimate power reactor accident consequences using currently available information. The consequence analyses in NUREG-1150 (NRC, 1990c) used the MACCS code.

The regulatory analysis must use cost values within 80.5 km (50 miles) of the plant. Sensitivity analyses or special cases may use alternative values that reflect shorter and longer distances from the plant.

The present value for offsite property damage can be calculated as follows:

$$D = C \times B$$

where

D = present value of offsite property damage (dollars-year)
C = $[\exp(-rt_i) - \exp(-rt_f)]/r$
t_f = years remaining until the end of the facility life
t_i = years before the facility begins operating
r = real discount rate (as fraction not percent)
B = undiscounted cost of offsite property damage

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, 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 in NUREG/CR-2723, “Estimates of the Financial Risks of Nuclear Power Reactor Accidents.” 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.

NUREG/CR-3673, “Economic Risks of Nuclear Power Reactor Accidents,” 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

- health effects, including the two basic approaches (human capital and willingness to pay)

5.3.2.5 Onsite Property

Onsite property damage cost savings (i.e., averted onsite costs) need to be included in the cost-benefit analysis. In the net-value formulation, it is a positive attribute.

Estimating the effect of the proposed action on onsite property involves three steps:

(1) Estimate the reduction in accident frequency.
(2) Estimate onsite property damage.
(3) Calculate the reduction in risk to onsite property as follows:

$$V_{OP} = N\Delta FU$$

where

V_{OP} = monetary value of avoided onsite property damage (dollars)
N = number of affected facilities
ΔF = reduction in accident frequency (events/facility-year)
U = present value of property damage occurring with frequency F (dollars-year).

A reduction in onsite property damage costs (i.e., cost savings) is algebraically positive; an increase (cost accruals) is negative (i.e., viewed as negative cost savings).

For the standard analysis, it is convenient to treat onsite property costs under three categories: (1) cleanup and decontamination, (2) long-term replacement power, and (3) repair and refurbishment.

Cleanup and Decontamination

Cleanup and decontamination of a nuclear facility, especially a power reactor, following a severe accident can be extremely expensive. Decontamination of the damaged unit requires several years of extended planning and analysis to allow for selection of the most appropriate equipment for the cleanup. The TMI-2 accident was the first commercial nuclear power plant accident, and many tools had to be specifically designed and manufactured to perform the work. This affected the time needed and the relative costs for decontamination and for fuel removal and transportation. Radioactive material, rubble, and melted core debris are stored at Idaho National Laboratory. The final decommissioning of TMI-2 will be undertaken at the time of decommissioning of the other nuclear unit at the TMI site (TMI-1).

According to official figures, the cleanup of the damaged TMI-2 nuclear reactor started in 1979 and officially ended in 1993, with a publicly announced cost of about $975 million. However, these costs do not consider some aspects of decommissioning and nuclear waste management that will make the total cost higher. The migration of cesium present in the cooling water into the concrete walls made the decommissioning of TMI-2 more complex and therefore more expensive. In addition, the melted core and other highly radioactive debris are currently stored

at Idaho National Laboratory and should continue to be properly managed and eventually disposed.

Long-Term Replacement Power

Section 5.3.2.7.1 discusses replaced power for short-term reactor outages (only electrical generating facilities need to consider replacement power). Following a severe power reactor accident, replacement power costs should be considered for the remaining reactor lifetime. Accidents at nonreactor nuclear facilities could also require replacement services of the same type provided by the facility where the accident occurred.

In the event of a permanent shutdown of a reactor, the analyst should assume that one or more existing generating units in the affected power pool will provide the replacement power. The incremental cost would be the difference in clearing price between the power price with and without the accident unit operating.

Repair and Refurbishment

In the event of an accident in which the facility is recoverable (e.g., a reactor event in which plant safety systems function as intended, some fuel cladding ruptures, but no fuel melts; the containment building is moderately contaminated, but there is minimal physical damage), the licensee will incur costs to repair or replace damaged components before the damaged facility can be returned to operation. For these events, NUREG/CR-3673 proposed a method for estimating equipment repair costs based on outage duration. Using this approximation method and data from outages of varying durations at reactors, ~~the authors suggest that~~ an upper bound estimate of these repair and refurbishment costs are roughly 20 percent of the long-term replacement power costs for a single event. The analyst may use this method when a quick estimate is necessary, when few details are available, or cost data are unavailable, when the cost estimate will be used to support “what if” analyses, or when the cost for a noncontroversial amendment to an existing rule or regulation is being approximated.

In general, a more detailed and complete accounting would be expected, and the analyst would prepare the repair and refurbishment cost estimates using the standard quantification techniques presented in Appendix B.

Onsite Property Damage Costs Following a Severe Accident

Any severe facility accident is expected to cause such extensive damage that resuming operations at that unit may be impossible. The facility involved may have to be permanently shut down and dismantled. However, depending on the onsite contamination levels and on decisions of Government agencies and the licensee following the accident, other undamaged facilities onsite could be temporarily or permanently shut down because of the accident. For example, if an accident occurs at a nuclear power plant site hosting multiple units, three possible outcomes could result in regard to the undamaged units: (1) continue operation of the undamaged units throughout the accident or restart of the units shortly after the accident, (2) resume operation of nonaffected units after a certain time, or (3) permanently shut down all the units at the site.

In the case of the TMI and the Chernobyl accidents, the undamaged onsite units resumed operations either immediately or sometime after the accident. The NRC suspended the license for the TMI-1 reactor, which was shut down for refueling at the time of the TMI-2 accident. The

NRC permitted the TMI-1 reactor to restart in October 1985, 5.5 years after the accident and after the plant had undergone some modifications. At Chernobyl, the three undamaged units continued operation after the accident given energy shortages in the country. The Chernobyl units were permanently shut down in 1991, 1996, and 2000, respectively. On the other hand, all six units at the Fukushima Dai-ichi site, including the undamaged Units 5 and 6, were permanently shut down following the nuclear accident.

The total costs are assumed to consist of cleanup and decontamination costs and replacement power costs. Repair and refurbishment costs are not applicable for a nonrepairable unit. The total onsite property costs are a risk-based cost: the discounted net present value of the risk over the remaining life of the plant, which is proportional to the accident frequency.

The risk-based costs should be interpreted carefully to avoid misunderstandings. The risk-based costs do not represent the expected onsite property damage resulting from a single accident; instead, the risk-based costs represent the present value of a stream of potential losses extending over the remaining lifetime of the facility. Therefore, the risk-based costs reflect the expected loss resulting from a single accident (given by present-value cleanup and decontamination and present-value replacement power quantities); the possibility that such an accident could occur, with some small probability, at any time over the remaining facility life; and the effects of discounting those potential future losses to the present value. When the quantity U is multiplied by the annual accident frequency, the result is the expected loss over the facility life discounted to the present value.

Power Reactor Severe Accident Example

Table 5-1 shows an example for a hypothetical 910 megawatt electrical (MWe) reactor that is assumed to have a remaining lifetime of 24 years. Table 5-1 lists the estimates for total risk-based costs attributed to regulatory actions that occur in 1993, assuming a 7-percent annual discount rate.

Table 5-1 Onsite Property Cost Estimate Following a Severe Accident at a Hypothetical 910-MWe Reactor

Variable	Cost Component	Risk-Based Cost (1993 dollars)
U_{RP}	Replacement Power	$\$1.0 \times 10^{10} \times F$
U_{CD}	Cleanup and Decontamination	$\$1.3 \times 10^{10} \times F$
U	Total	$\$2.3 \times 10^{10} \times F$

This method may be used to evaluate averted onsite property damage resulting from a proposed regulation. For example, assume that the proposed regulation, if implemented, would reduce the severe accident frequency by 1×10^{-6} per reactor-year and that the number of reactor units affected (N) is 100. The total averted onsite damage costs would be as follows:

$$V_{OP} = N\Delta FU = (100)(1\ x\ 10^{-6})(\$2.3x10^{10}) = \$2.3\ x10^{6}$$

The value of this reduction in accident frequency is $2.3 million net present value in 1993 dollars for 100 generic 910-MWe reactor units. This provides a generic estimate of the benefits for the proposed regulatory requirement that became effective in 1993 and that affects severe accident probabilities in that year.

5.3.2.6 Industry Implementation

This section provides procedures for computing estimates of the industry's incremental costs to implement the proposed action. Section 5.3.2.8 discusses estimating incremental costs during the operational phase that follows the implementation phase. Incremental implementation costs measure the additional costs to industry imposed by the regulation; they are costs that would not have been incurred in the absence of that regulation. 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 the industry's implementation costs:

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

(2) Estimate the costs associated with implementation.

(3) If appropriate, discount the implementation costs and then sum.

In preparing an estimate of industry implementation costs, the analyst should also carefully consider all cost categories that implementation of the action may affect. Example categories include the following:

- land and land use rights
- structures
- hydraulic, pneumatic, and electrical equipment
- radioactive waste disposal
- health physics
- monitoring equipment
- personnel construction facilities, equipment, and services
- engineering services
- recordkeeping
- procedural changes
- license modifications
- staff training/retraining
- administration
- facility shutdown and restart
- replacement power (power reactors only)
- reactor fuel and fuel services (power reactors only)
- items for averting illness or injury (e.g., bottled water or job safety equipment)

Note that transfer payments should not be included.

For the standard analysis, the analyst should use consolidated information to estimate the cost to industry for implementing the action and proceed as follows:

(1) Estimate the amounts and types of equipment, materials, and labor that will be affected by the proposed action, including not only physical equipment and craft labor, but also

professional staff labor for design, engineering, quality assurance, and licensing 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 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 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:

(1) Estimate the amount and types of equipment, materials, and labor that the proposed regulation will affect, including professional staff time associated with reporting requirements and compliance activities. The analyst should consider possible costs on a facility's capacity factor. The analyst may consult with engineering and costing experts, as needed. The analyst could seek guidance from NRC contractors, architect-engineering firms, or utilities.

(2) Estimate the associated operation and maintenance costs. The analyst should consider direct and indirect effects of the action (e.g., the action could have an impact on labor, which, in turn, could affect administrative costs).

(3) Discount the total costs over the remaining lifetime of the affected facilities.

Much of the discussion on industry implementation costs for nonreactor facilities applies here for operation costs. Again, the analyst will generally not find consolidated cost information comparable to that for power reactor facilities. However, the analyst may again need to rely on "engineering judgment," although specific data may be available through direct contact with cognizant industry or contractor personnel.

For a major effort beyond the standard analysis, the analyst should seek specific guidance from contractor or industry sources experienced in this area. The user may wish to use contractors that have developed explicit methodologies for estimating operating and maintenance costs. Budwani (1969); Carlson et al. (1977); Eisenhauer et al. (1982); NRC (1979, 1980, 1981); NUS Corporation (1969); Phung (1978); and United Engineers and Constructors, Inc. (1986, 1988a, 1988b), and Capital Cost Estimates (2016) can provide useful information for industry operation costs.

5.3.2.8 NRC Implementation

Once a proposed action is defined and the Commission endorses its application, the NRC will incur costs to implement the action. Implementation costs refer to those "front-end" costs necessary for the proposed action. The NRC views all costs associated with its activities in making the regulatory decision as "sunk" costs and excludes these costs from its implementation costs. However, any NRC activities that occur after the regulatory decision being modelled would be included in the analysis. 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).

Implementation costs to the NRC may arise from developing procedures, preparing guidance, and taking other actions to assist in or ensure compliance with the proposed action.

The analyst should determine whether the proposed action will be implemented entirely by the NRC or in cooperation with one or more Agreement States. Implementation costs shared by Agreement States may reduce those of the NRC.

NRC implementation costs include only the incremental costs resulting from adoption of the proposed action. The following are examples of these costs:

- developing guidelines for interpreting the proposed action and developing enforcement procedures

- 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

NUREG/CR-4627 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 several 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 reasonable y 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 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.

A major effort beyond the standard analysis would proceed along the lines described above, except that greater detail would be provided to account for acquisitions of special equipment and materials.

5.3.2.10 Other Government Entities

This attribute measures costs to the Federal Government (other than the NRC) and State (including Agreement States) and local governments. The discussion parallels that for NRC implementation and operation. A reduction in the net cost (i.e., cost savings or an averted cost) is algebraically positive; an increase (cost accrual) is negative (i.e., viewed as negative cost savings).

Implementation costs to the Federal (non-NRC) Government and to State and local governments may arise from developing procedures, preparing aids, supporting license amendments, and taking action to ensure compliance with the proposed action. For example, placing roadside evacuation route signs for the possibility of a radioactive release from a nearby power reactor would require expenditures from selected Government agencies. As another example, requiring criminal investigation checks for nuclear reactor personnel may require resources of the Federal Bureau of Investigation. When estimating the implementation costs, the analyst should be aware that these costs may differ between Agreement and non-Agreement States and should take such differences into account in preparing cost estimates.

The analyst should perform three steps to estimate the other government implementation costs:

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

(2) Determine the requirements for government 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 several government branches and offices. In developing estimates for the implementation costs, the analyst is encouraged to contact all the government components likely to be affected by the proposed action.

For the standard analysis, the analyst should identify the major tasks that should be performed to get the proposed rule implemented, 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 labor rate and then summed over all of the tasks.

Similarly, the analyst also needs to estimate the costs to complete tasks that would be contracted out. To obtain a reasonably good approximation of in-house and contractor costs, the analyst should contact the government agencies that would be responsible for carrying out or contracting for the tasks. Finally, the costs of major pieces of equipment and quantities of materials are added to the labor and contract costs.

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 provide a reasonable basis for the effort and indicate its effect. If necessary, this 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 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 efficiency, a proper evaluation of these effects may require a level of effort commensurate with

their magnitude. This may mean expending resources to obtain the judgments of experts outside the NRC if the necessary expertise is not available in-house.

Whether a panel of experts or the analyst performs the assessment, the following questions might be considered:

- Does this action conflict with any other NRC, Federal, or State directives?
- Are there any nuclear facilities for which (or conditions under which) this action might have unexpected or undesirable consequences?
- Do you foresee any major enforcement problems with this action or regulation?
- What sort of adjustments might industry undertake to avoid the intended effects of the regulation?
- How will the regulation affect productivity in the nuclear and electric utility industries?
- How will this action affect facility licensing times?
- How will this action affect the regulatory process within the NRC (and within other regulatory agencies)?

5.3.2.14 Safeguards and Security Considerations

Safeguards and security considerations include protecting the common defense and security and safeguarding restricted data and national security information. In more practical terms, this means providing adequate physical security and safeguards systems to prevent the diversion of certain types of fissionable and radioactive materials, the perpetration of acts of radiological sabotage, and the theft of restricted data or national security information by unauthorized individuals.

The NRC has a legislative mandate in the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011), to ensure the objectives mentioned above. Through its regulations and regulatory guidance, the NRC has established a level of protection deemed to satisfy the legislative mandate. As is the case for adequate protection of public health and safety, this level of protection should be maintained without consideration of cost.

Although quantification of safeguards and security changes may be difficult, the analyst should attempt quantification when feasible. If this process is not possible, the analyst may proceed with a qualitative analysis under this attribute.

5.3.2.15 Environmental Considerations

Environmental impacts can have monetary effects (e.g., environmental degradation, mitigation measures, environmental enhancements) that could render potential alternative actions unacceptable or less desirable than others. Therefore, the cost-benefit analysis should summarize the results of the environmental analysis.

For purposes of the regulatory analysis document, the analyst should use the results from the EIS or EA and FONSI, if applicable, and generally identify anticipated environmental consequences and potential mitigation measures. The results of this preliminary analysis should be quantified under the appropriate quantitative attributes, if possible, or addressed qualitatively under this attribute if they are not quantified.

Where a categorical exclusion applies, there will not be an environmental analysis to summarize, and the analyst many need to prepare additional material to support the regulatory analysis.[10] However, categorial exclusions reflect those actions which the Commission has found do not "individually or cumulatively have a significant effect on the human environment."[11]

5.3.2.16 Other Considerations

Other considerations may be associated with a proposed action that the preceding descriptions have not captured. If quantifiable, the effect should be included in essentially the same way as in the quantitative attributes. Because the NRC expects such considerations to be unusual, the regulatory analysis document should include some additional discussion.

The analyst needs to consider the possible effects of the proposed action. Some of the effects may not be immediately obvious. The analyst may wish to consult with other knowledgeable individuals to help identify all significant effects. The analyst needs to present these considerations clearly to facilitate the reader's understanding of the issues.

When quantification of effects is not feasible, the analyst should describe the magnitude of each effect to facilitate comparison among alternatives. Comparative language (e.g., greater than, less than, about equal to) can be helpful in achieving this objective because the analyst can make the necessary judgments. Consultation with experts or other knowledgeable individuals may be required.

5.4 Labor Rates

When determining the appropriate industry labor rates, the analyst should use data from the National Wage Data available on the BLS Web site (https://www.bls.gov/bls/blswage.htm). Depending on the industry and the occupation (e.g., manufacturing, health, and safety), the analyst should select an appropriate mean hourly labor rate and increase the labor rate using a multiplier in the range of 1.5 to 2.4 to account for benefits (e.g., pension, insurance premiums, and legally-required benefits). Because exact hourly rates may be difficult to obtain and may not be sufficiently recent, the analyst should use nationwide mean hourly rates including the 25th percentile, the mean, and the 75th percentile available on the BLS Web site.

The analyst should use the methodology in Abstract 5.2 of NUREG/CR-4627 to determine the NRC's labor rates. This methodology considers only variable costs (including salary and benefits) that are directly related to the implementation, operation, and maintenance of the amendments. The NRC distributes its labor rates annually for use in cost-benefit analyses.

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[10] The NRC's licensing, regulatory, and administrative actions subject to categorical exclusion are found at 10 CFR 51.22, "Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review."

[11] 10 C.F.R. § 51.22(a).

5.5 Economic Discounting and Calculation of Present Value

To evaluate the economic consequences of proposed regulatory actions, the costs incurred or saved over a period of years should be summed.

This summation cannot be done directly because an amount of money available today has greater value than the same amount at a future date. There are several reasons for this difference in value:

- The present amount of money can be invested, and the total amount can be increased through accumulated interest.
- Certain consumption today is considered superior to contingent consumption in the future.
- The option of present or future consumption is considered superior to future consumption alone.

A method known as "discounting" is used to compare amounts of money expended at different times. The result of discounting is called the "present value," which is the amount of money that should be invested today to achieve a specified sum in the future. To perform the discounting procedure, the analyst should know three parameters:

- the discount rate
- the time period over which discounting is to be performed
- the amount of money or value that is to be discounted

5.6 Discount Rate

The discount rates specified in the most recent version of OMB Circular A-4 are to be used in preparing regulatory analyses. Circular A-4 currently specifies the use of a real discount rate (r) of 7 percent per year. A discount rate of 3 percent should be used for a sensitivity analysis to indicate the robustness of the results to the choice of discount rate.

When the time horizon associated with a regulatory action exceeds 100 years, the 7-percent real discount rate should not be used; instead, the net value should be calculated using the 3-percent real discount rate. In addition, each year's values should also be displayed showing the costs and benefits at the time they are incurred with no discounting (OMB, 2003).

OMB Circular A-94 defines the term "discount rate" as the interest rate used in calculating the present value of expected yearly benefits and costs. When a real discount rate is used, yearly benefits and costs should be in real or constant dollars. Circular A-94 defines "real or constant dollar values" as economic units measured in terms of constant purchasing power. General price inflation does not affect real value. Real values can be estimated by deflating nominal values with a general price index, usually the gross domestic product deflator.

5.7 Discrete Discounting

The following formula is used to determine the present value (PV) of an amount (FV) at the end of a future time period:

$$PV = \frac{FV}{(1+r)^{t_f}}$$

where

r = the real annual discount rate (as a fraction, not percent)
t = the number of years in the future in which the costs occur

For example, to determine how much $750 to be received 25 years (t) hence is worth today, using a 7-percent real discount rate (r), the formula yields the following:

$$PV = \frac{\$750}{(1+\ .07)^{25}} = \$750\ x\ 0.184 = \$138$$

To find the present value of a stream of costs and revenues, the analyst should record the costs and revenues occurring in each year. For each year, the net cost is then determined by simply adding algebraically the costs and revenues for that year. After this has been done for each year, the net cost in each year is discounted to the present. The sum of these present values is the present value of the entire stream of costs and revenues. A sample use of this formula in a cost-benefit analysis would be to determine the present value of implementation costs for industry and the NRC that occur in the future.

The above formula is used for discounting single amounts backwards in time. However, some of the costs encountered in a cost-benefit analysis recur on an annual basis. These include not only industry and NRC operating costs, but also the monetized values of the annual per-facility reductions in routine public and occupational dose resulting from operations (see Sections 5.2.2 and 5.2.4). Such costs can be discounted using the following annuity formula (but only if they are the same amount for each time period):

$$PV = \frac{C_A\ x\ [(1+r)^t - 1]}{r\ x\ (1+r)^t}$$

where

C_A = identical annual costs
r = the real discount rate (as a fraction, not percent)
t = the number of years over which the costs recur

For example, if the increase in annual industry costs is $1,000 (because of increased maintenance expenses) for a 20-year period at a 7-percent real discount rate, starting at the present time, the present value of these costs is as follows:

$$PV = (\$1{,}000)x\ \frac{(1+.07)^{20} - 1]}{.07\ (1+.07)^{20}} = \$10{,}600$$

In most cases, a facility will start to incur operating costs at some date in the future after which the real costs will be constant on an annual basis for the remaining life of the facility. To discount the costs in this situation, a combination of the above two methods or formulas is needed. For example, given the same $1,000 annual cost for a 20-year period at a 7-percent

real discount rate but starting 5 years in the future, the formula to calculate the present value is as follows:

$$PV = (\$1{,}000)x\ \frac{(1+r)^{t_2}-1]}{r\ (1+r)^{t_1}\ (1+r)^{t_2}}$$

where

r = 7-percent discount rate (i.e., 0.07 per year)
t_1 = 5 years
t_2 = 20 years for the annuity period

Therefore, the following applies:

$$PV = (\$1{,}000)x\ \frac{(1+.07)^{20}-1]}{.07\ (1+.07)^{5}\ (1+.07)^{20}} = \$7{,}560$$

EPRI-P-4463-SR, "Technical Assessment Guide," issued 1986; U.S. Department of Energy (DOE)/MA-0063, "Cost Guide, Volume 2: Standard Procedures for Determining Revenue Requirements (Product Cost)," Volume 2, issued 1982; and Wright (1973) provide additional background on discrete discounting.

5.8 Continuous Discounting

Discrete discounting, as discussed above, deals with costs and revenues that occur at discrete instances over a period of time. Most regulatory analyses can use discrete discounting and present value factors. Technically, discrete discounting does not correctly account for consequences that occur constantly, but the difference is viewed as minimal, and the additional effort is generally not warranted in a standard regulatory analysis.

Continuous discounting should be used in regulatory analyses beyond the standard analysis when costs and revenues occur continuously over a period of time, such as those that should be weighed by an accident frequency over the remaining life of a facility. The accident frequency is a continuous variable, although the real cost of the accident consequences is constant.

The formula for continuous discounting is derived from the discrete discounting formula as shown below. Assume that, in one period (t), the time will be subdivided into n intervals. The formula for discrete discounting, with a real discount rate of r, is $1/(1 + r/n)^n$. As the time period is subdivided into an infinite number of intervals in the limit, discrete intervals would be abandoned altogether and so set the limit as follows:

$$\lim_{n\to\infty} \frac{1}{(1+\frac{r}{n})^n} = e^{-r}$$

For t periods, instead of one period as above, the formula becomes e^{-rt}, where r and t are defined over the same time period.

The monetized values for the reductions in public and occupational dose resulting from accidents and the avoided onsite and offsite property damage costs require continuous discounting. To calculate the present value for the public health (accident) and offsite property attributes, when the monetary value or cost C_o can occur with a frequency f, NUREG/CR-2723 provides the following formula:

$$\int_{t_i}^{t_f} C_0 f e^{-rt} dt = C_0 f [e^{-rt_i} - e^{-rt_f}]/r$$

where

t_i = time of onset of accident risk
t_f = time of end of accident risk

For public (accident) risk, the product $C_o f$ is replaced by Z_{PHA}, which represents the monetary value of avoided risk before discounting (dollars/facility-year (see Section 5.3.2.1.3)). As an example, assume the monetary value of avoided public risk resulting from an accident is $\$1.0 \times 10^4$ per facility-year ($C_o f = \$1.0 \times 10^4$). The facility is operational ($t_i = 0$) with a remaining lifetime of 25 years ($t_f = 25$). For an annual discount rate of 7 percent (r = 0.07 per year), the present value of avoided risk (monetized) becomes:

$$PV = \frac{\left(\frac{\$10{,}000}{yr}\right) x \, [e^{-(0.07)(0)} - e^{-(0.07)(25)}]}{0.07/yr} = \$118{,}000 \, per \, facility$$

To determine the present value of a reduction in offsite property risk, the frequency (f in the general equation above) is replaced with the frequency reduction (Δf). As an example, let the frequency reduction (Δf) be 1.0×10^{-5} per facility-year and the cost (C_o) be $\$1.0 \times 10^9$. The annual discount rate is 7 percent (r = .07 per year), and the reduction in accident frequency takes place 5 years in the future ($t_i = 5$) and will remain in place for 20 years ($t_f = 5 + 20 = 25$). The present value of the avoided offsite property damage becomes:

$$PV = \frac{(\$1.0 \, x \, 10^9)\left(\frac{1.0 \, x \, 10^{-5}}{yr}\right) x \, [e^{-(0.07)(5)} - e^{-(0.07)(25)}]}{0.07/yr} = \$75{,}800 \, per \, facility$$

To calculate present values for the occupational health (accident) and onsite property attributes, the continuous discounting formula should be modified. The modifications account for two items. First, constant annual charges do not represent some components of severe accident costs, as noted in Section 5.7 . Secondly, the single-event present values should be reintegrated because the accident costs and risks would be spread over a period of time (e.g., over the remaining plant lifetime for replacement power costs and over the estimated 10 years for cleanup and decontamination following a severe accident for onsite property damage). Section 5.3.2.6, “Onsite Property,” addresses these modifications and provides estimation guidelines for regulatory initiatives that affect accident frequencies in current and future years.

6 CONCLUSION

Revision 5 to NUREG/BR-0058 consolidates the NRC cost-benefit analysis guidance of NUREG/BR-0058, Revision 4, and NUREG/BR-0184 into one document, which allows the NRC to efficiently obtain the guidance necessary to support its regulatory analysis reviews. Second, this revision incorporates improvements in methods for assessing factors that are difficult to quantify and includes the relevant best practices identified in GAO-09-3SP and recommendations from GAO-15-98. Finally, this revision incorporates the NRC's experience and improvements in uncertainty analysis and the Commission's direction on cost-benefit analysis since the last revision of these documents.

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KLS Edits

APPENDIX A
QUALITATIVE FACTORS ASSESSMENT TOOLS

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
~~AHP~~	~~analytic hierarchy process~~
h	hour
~~MAUT~~	~~multiattribute utility theory~~
NUREG	NRC technical report designation
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget
~~SMART~~	~~simple multiattribute rating technique~~
SRM	staff requirements memorandum
WTP	willingness to pay

QUALITATIVE FACTORS ASSESSMENT TOOLS

A.1 PURPOSE

The purpose of this appendix is to provide guidance and best practices for use in considering qualitative factors (i.e., intangible costs and benefits) to improve the clarity, transparency, and consistency of the U.S. Nuclear Regulatory Commission's (NRC's) regulatory, backfit, forward fit, issue finality, and environmental review 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 approved plans to update guidance regarding the use of qualitative factors, directed the NRC staff to "ensure that qualitative factors are used in a judicious and disciplined manner," and stated that "the revised guidance should continue 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 attributes that cannot be readily quantified. These attributes are termed "qualitative~~,~~ factors" and this appendix captures best practices for their consideration ~~of such qualitative factors~~ by providing methods that can be used to support the NRC's evidence-based~~,~~ analytical approach to decisionmaking. This guidance provides a toolkit to enable analysts to clearly present analyses of qualitative ~~results~~ factors in a transparent way for decisionmakers, stakeholders, and the general public. The methods described in this appendix should be used when quantification is not ~~practical or~~ possible or practical.

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 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~~may 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. 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 may 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~~
- ~~operational readiness~~

~~[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.~~

- ~~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, in some limited circumstances, they can also be too important to ignore. In these situations, the analysts should use accurate information to develop realistic estimates to quantify parameters and then use the methods in this appendix to inform decisionmaking when quantitative analyses are difficult or would provide an incomplete analysis if presented alone.

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 each method. The use of consistent methods enables analysts to present qualitative results in a transparent way for decisionmakers, stakeholders, and the general public.

Several tools are available 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. For example, the WTP methodology underlies the Value of a Statistical Life component of the person-rem-dose conversion factor in NUREG-1530.

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~~for the decisionmaker ~~can~~ to determine whether the benefits for ~~the~~ an alternative outweigh the costs. This section briefly describes some methods and references for qualitative analyses. 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, the analyst can ensure consistency with prior regulatory analyses performed by the staff.~~ The analyst should articulate the proposed rationale for the selection of qualitative factors and describe with specificity how these factors were used in the analysis, including the use of sensitivity analyses~~sophistication of the method selected should be commensurate with the complexity of the issue and 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 ~~are~~ do not have the same ~~as cost-benefit analyses in their~~ ability to identify an economically ~~-~~efficient policy as cost-benefit analyses. 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 as well as the strengths and limitations of the information. This discussion should ~~also~~ include 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 unverified assumptions, a postulated consequence may result in an 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 rangedistribution 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 shwould need to be analyzed qualitatively.

A.3.2 Cost-Effectiveness Analysis

Cost-effectiveness analysis can 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 limited cases with substantial uncertainties or with important values that are difficult to quantifywhen quantitative analyses are not possible or practical. 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 attempts to find the leastcost 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 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. 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 A1 and A2 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

Commented [A2]: This table should be deleted.

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 costbenefit index to arrive at a recommendation. To achieve this cost, multiply the benefit score by the cost-benefit index. Table A2 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 costeffectiveness 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, costeffectiveness 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 costeffectiveness of each option compared with the baseline, as well as its incremental costeffectiveness compared with successively more stringent requirements. The analysts should prepare an array of costeffectiveness 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 several years. To compare alternative options, both the costs and benefits should be discounted to a common time period.

Shortcomings are inherent in the cost-effectiveness approach. It is a poor measure of the consumers' WTP principle, because no monetary value is placed on the benefits. WTP is defined as the amount of money that, if taken away from income, would make an individual exactly indifferent to experiencing the specified outcome or not experiencing either the improvement or any change in income.

Moreover, in the calculation of cost-effectiveness, the cost numerator does account for the scale of alternative options. Nevertheless, the cost-effectiveness ratio is a useful criterion for selecting alternative regulatory options when the benefits cannot be monetized.

~~The~~ OMB does not require agencies to use any specific measure of effectiveness. In fact, ~~the~~ OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. According to OMB Circular A-4, the regulatory analysis should explain which measures were selected and why and how they were implemented.

A.3.3 Threshold Analysis

A break-even analysis is one alternative that can be used when either risk data or valuation data are lacking. Analysts who have per-unit estimates of economic value but lack risk estimates cannot quantify net benefits. They can, however, estimate the number of cases (each valued at the per-unit value estimate) at which overall net benefits become positive, or where the regulatory action will break even. In its discussion of sensitivity analysis, OMB Circular A-4 refers to these values as a "switch point."

Consider a proposed regulatory action that is expected to reduce the number of cases resulting in outcome X with an associated cost estimate of $1 million. Further, suppose that the analysts estimate that the WTP to avoid a case resulting in outcome X is $200, but because of limitations in data, it is difficult to estimate the reduction in the number of cases of this outcome that would result from this regulatory action. In this case, the proposed regulatory action must reduce the number of cases by 5,000 to "break even." This estimate then can be assessed for plausibility quantitatively. Decisionmakers should determine if the breakeven value is acceptable or plausible.

Similar analyses are possible when analysts lack valuation estimates that produce a break-even value requiring assessment for credibility and plausibility. Continuing with the example above, suppose the analyst estimates that the proposed policy would reduce the number of cases of endpoint X by 5,000 but does not have an estimate of WTP to avoid a case of this outcome. In this case, the policy can be considered to break even if WTP is at least $200.

One way to assess the credibility of economic break-even values is to compare them to effects that are more or less severe than the outcome being evaluated. For the break-even value to be plausible, it should fall between the estimates for these more and less severe effects. For the example above, if the estimate of WTP to avoid a case of a more serious effect were only $100, the above break-even point may not be considered plausible.

A break-even analysis is most effective when there is only one missing value (i.e., unknown) in the analysis. ~~For example, a~~Analysts missing estimates for two different unknowns (but having valuation estimates for both) should consider a "break-even frontier" that allows the values of both unknowns to vary. This approach makes it possible to construct such a frontier, although it is difficult to determine which points on the frontier are relevant for regulatory analysis.

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 (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 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~~ then used by ~~these~~ such 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. The Commission, however, ultimately directed the staff to terminate this rulemaking effort in favor of performing a comprehensive risk review of the licensing and inspection programs, including licensees' activities. The results of the review were to be used to develop new risk-based licensing and inspection programs approved by the Commission as well as to determine whether a similar rulemaking should be developed. The withdrawal of this proposed rulemaking was noticed in the *Federal Register* on January 20, 1999 (64 FR 3052).

The analyst should provide a recommendation on the likelihood that a switch point, or combination of switch points, would be reached and a narrative explanation for the basis for that conclusion.

A.3.4 Bounding Analysis

A bounding analysis is designed to limit or provide a specified 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 drawback to this method is that there is no objective 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~~ strategies used in decision theory ~~where~~ to select between 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 is the better loss of all other alternatives, given the circumstances). This decisionmaking strategy is based on pessimistic loss, in which the analyst assumes that the worst that can happen will happen and then chooses the alternative with the best worst-case scenario. In the maximax analysis, the analyst looks at the best that can happen in each alternative for a given outcome and then chooses the alternative that is the best of the best (i.e., the alternative where the gain is the best of the best of all other alternatives, given the circumstances). This decisionmaking strategy is based on optimistic gain, in which the analyst assumes that the best that can happen will happen and then chooses the alternative with the best-case scenario.

~~An example of a maximin and maximax analysis is its application to the modification of drug testing for fitness for duty. This~~To illustrate the use of maximin and maximax analyses, assume that a hypothetical regulatory action has three alternatives for drug testing, with the first alternative representing the status quo. These alternatives involve modifying the procedures and cutoff levels for drug testing to reduce false positives. The exception is the first alternative (the status quo), which represents the current procedures for conducting drug testing. The following are the three possible ~~alternative~~ frequencies for drug testing across all three alternatives:

(1) Test 10 times a year.
(2) Test 15 times a year.
(3) Test 20 times a year.

For each alternative, Table A-3 gives the expected number of false positives for each outcome of drug testing as determined by a panel of medical experts.

Table A-1 Expected Number of False Positives for Each Outcome of Drug Testing

Alternatives	Frequency of Drug Tests Per Year		
	10	15	20
Alternative 1	3	4	5
Alternative 2	1	2	5
Alternative 3	2	3	4

In ~~the~~ a maximin analysis with this data, the analyst would look~~s~~ at the highest number of false positives (worst gain) for each alternative over all possible outcomes and choose~~s~~ the alternative with the lowest number of false positives (best of the worst) for some outcome. Examination of the results of each alternative shows the following:

(1) For alternative 1, the highest number of false positives is five for testing 20 times a year.

(2) For alternative 2, the highest number of false positives is five for testing 20 times a year.
(3) For alternative 3, the highest number of false positives is four for testing 20 times a year.

~~According to the~~Using a maximin analysis examining only the potential for false positive results, the analyst would choose alternative 3 for testing 20 times a year, because this alternative has the lowest number of false positives (i.e., four is less than five).

In ~~the~~ a maximax analysis with this data, the analyst would look~~s~~ at the lowest number of false positives (best gain) for each alternative over all possible outcomes and choose~~s~~ the alternative with the lowest number 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~~Using a maximax analysis examining only the potential for false positive results, the analyst would choose alternative 2 for testing 10 times a year, because it has the lowest number of false positives.

The choice between a ~~(~~maximin or maximax~~)~~ analysis, when appropriate, would depend~~s~~ on the preference of the decisionmaker. The maximin ~~criterion~~ strategy involves selecting the alternative that maximizes the minimum payoff achievable, and so a decisionmaker who prefers a guaranteed minimum at the risk of losing the opportunity to make big gains would opt for the maximin result. The maximax ~~criterion~~ strategy involves selecting the alternative that maximizes the greatest payoff available, so this approach would be more suitable for a "riskseeking" investor, who 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~~ Other Techniques

A variety of other techniques have been developed that may be useful. (See, e.g., Fülöp (2005).) The analyst should document the costs and benefits of applying these increasing complexity methods and seek management direction on the approach to be used.

~~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 would 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 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 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 quantifiable; nonmonetized criteria are 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 qualitative evaluation to the monetized 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 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 A1, 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 analyst should clearly state the assumptions and limitations used to determine the subjective weighting factors. To the greatest extent possible, the analyst should avoid using numeric values, which may inappropriately suggest that the weighting factors reflect a quantitative analysis, and instead use a short qualitative description such as "poor," "fair," "good," or "best" to describe the attribute.

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. To the extent alternatives have qualitative descriptions for specific attributes, the analyst could provide a numeric ranking among alternatives for the attribute and then sum the value of those rankings in the final ranking.

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 NUREG1530, 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 important role: they convert the raw performance values so that a 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_i reflects the relative importance of criteria $\mathbf{a}_i$ to the decision)
x_j = ranking value of alternative A_j

In addition to the above additive model, another method is to assess weights for each of the criteria to reflect their relative importance to the decision. First, the criteria are ranked in order of importance, and 10 points are assigned to the least important criterion. Then, the next-least-important criterion is chosen, more points are assigned to it, and so on, to reflect their relative importance. The final weights are obtained by normalizing the sum of the points to 1. However, comparing the importance of the decision criteria is meaningless if it does not also reflect the range of the utility values of the alternatives.

A.3.9.3 Generalized Means Technique

In a decision problem, the vector $x = (x_1, \ldots, x_n)$ plays a role of aggregation, accounting for the performance scores for every criterion with the given weight. This means that the vector **x** should fit into the rows of the decision matrix as well as possible. Mészáros and Rapcsák (1996) showed that the optimal solution is a positive multiple of the vector of the weighted geometric means of the columns; consequently:

$$w = \sum_{i=1}^{m} w_i$$

with the values

$$x_j = \prod_{i=1}^{m} a_{ij}^{w_i/w}, i = 1, \ldots, n$$

where:
a_{ij} = the alternative listed in the i^{th} row and j^{th} column
w = total of all weighting factors, w_i
x_i = ranking value of alternative a_i

A.3.9.4 Analytic Hierarchy Process

The basic idea of the analytic hierarchy process (AHP) is to convert subjective assessments of relative importance to a set of overall scores or weights. The AHP is one of the more widely applied multiattribute decisionmaking methods.

The AHP methodology is based on pairwise comparisons of the following type: "How important is criterion C_i relative to criterion C_j?" Questions of this type are used to establish the weights for criteria, and similar questions are answered to assess the performance scores for alternatives on the subjective (judgmental) criteria.

To derive the weights of each criteria, the analyst should respond to a pairwise comparison question asking the relative importance of the two criteria. The analyst's responses use the following nine-point scale to express the intensity of the preference for one criterion versus another:

1 = equal importance or preference
3 = moderate importance or preference of one over another
5 = strong or essential importance or preference
7 = very strong or demonstrated importance or preference
9 = extreme importance or preference

If the analyst judges that criterion C_j is more important than criterion C_i, then the reciprocal of the relevant index value is assigned.

Let c_{ij} denote the value obtained by comparing criterion C_i to criterion C_j. Because the analyst is assumed to be consistent in making judgments about any one pair of criteria and since all criteria will always rank equally when compared to themselves, then:

$$c_{ji} = \frac{1}{c_{ij}} \; and \; c_{ii} = 1$$

This means that it is only necessary to make ½ m (m-1) comparisons to establish the full set of pairwise judgments for m criteria. The entries c_{ij}, $i,j = 1,\ldots,m$ can be arranged in a pairwise comparison matrix C of size m x m. Therefore, the analyst should make 15 pairwise judgments to establish the full set of pairwise judgments for six criteria.

The next step is to estimate the set of weights that are most consistent with the relativities expressed in the comparison matrix. Note that, while there is complete consistency in the (reciprocal) judgments made about any one pair, consistency of judgments between pairs (i.e., $c_{ij}c_{jk} = c_{ik}$) for all i,j,k, is not guaranteed. Thus, the task is to search for an m-vector of the weights such that the m x m matrix W of entries w_i/w_j will provide the best fit to the judgments recorded in the pairwise comparison matrix C. The weighting method is one of the simplest multiobjective optimizations that has been widely applied to find the noninferior optimum solution.

This method may not be capable of generating the efficient solutions of the efficient frontier. Also, the optimal solution of a weighting problem should not be used as the best compromise solution, if the weights do not reflect the Commission's preferences or if the Commission does not accept the assumption of a linear utility function.

As in calculating the weights for the criteria, AHP uses the same technique based on pairwise comparisons to determine the relative performance scores of the decision table for each of the alternatives on each subjective (judgmental) criterion. Now, the pairwise questions to be answered ask about the relative importance of the performances of pairs of alternatives relating to the considered criterion. Responses use the same set of nine index assessments as before, and the same techniques can be used as when computing the weights of criteria.

With the weights and performance scores determined by the pairwise comparison technique above, and after further possible normalization, analysts can evaluate alternatives using any of the decision table aggregation techniques of the MAUT methods. The so-called additive AHP uses the same weighted algebraic means as SMART, and the multiplicative AHP is essentially based on the computation of the weighted geometric means.

A.3.10 Outranking Methods Technique

The outranking method is based on evaluating each pair of alternatives by considering two conditions as follows. Alternative A_k outranks A_j if, generally, the criterion A_k performs at least as well as A_j (concordance condition), while worse performance is still acceptable on the other criterion (nondiscordance condition). After having determined for each pair of alternatives whether one alternative outranks another, these pairwise outranking assessments are combined into a partial or complete ranking. Contrary to the MAUT methods, where the alternative with the best value of the aggregated function can be obtained and considered as the best one, a partial ranking of an outranking method may not directly render the best alternative. A subset of alternatives can be determined such that any alternative not in the subset is outranked by at least one member of the subset. The aim is to make this subset as small as possible. This subset of alternatives can be used to screen a long list of alternatives into a short list, within which the use of other methods could find a good compromise alternative.

The principal outranking methods assume data availability broadly similar to that required for the MAUT methods. This method requires that alternatives and criteria be specified and uses the same data as the decision table (i.e., the values represented by a_{ij} and w_i).

The ELECTRE I Method

The ELECTRE I methodology is based on the concordance and discordance indices defined as follows. The analyst starts with the decision matrix data and normalizes the weighting so that the sum of the weights of all criteria equals 1. For an ordered pair of alternatives (A_j, A_k), the concordance index c_{jk} is the sum of all the weights for those criteria where the performance score of A_j is at least as high as that of A_k. This is shown mathematically as follows:

$$c_{jk} = \sum_{i:\, a_{ij} \geq a_{ik}} w_i, \quad j,k = 1,\ldots,n \; where \; j \neq k$$

where the concordance index lies between 0 and 1.

The computation of the discordance index d_{jk} is a bit more complicated. The discordance index is zero if A_j performs better than A_k on all criteria. Otherwise, for each criterion where A_k outperforms A_j, the ratio is calculated between the difference in performance level between A_k and A_j and the maximum difference in score on the criterion concerned between any pair of alternatives. This is shown mathematically as follows:

$$d_{jk} = 0 \; if \; a_{ij} > a_{ik}, \quad i = 1, \ldots, m$$

or

$$d_{jk} = \max_{i=1,\ldots,m} \frac{a_{ik} - a_{ij}}{\max_{j=1,\ldots,n} a_{ij} - \min_{j=1,\ldots,n} a_{ij}}, \quad j, k = 1, \ldots, n, \; j \neq k$$

The maximum of these ratios is the discordance index, which has a value between 0 and 1.

A concordance threshold c^* and discordance threshold d^* are defined such that $0 < d^* < c^* < 1$. Then, A_j outranks A_k if the $c_{ij} > c^*$ and $d_{ik} < d^*$ (i.e., the concordance index is above its threshold and the discordance index is below its threshold, respectively).

This outranking defines a partial ranking on the set of alternatives by identifying the set of alternatives that outrank at least one other alternative and are themselves not outranked. By using this method, the analyst identifies the most promising alternatives. By interactively changing the level thresholds, the analyst can also change the size of this set.

As shown, the ELECTRE I method may be used to construct a partial ranking and choose a set of promising alternatives. (Figueira et al. (2004) gives more details about the ELECTRE methods.)

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APPENDIX B
COST ESTIMATING AND BEST PRACTICES

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ABBREVIATIONS AND ACRONYMS

AACEI	Association for the Advancement of Cost Engineering International
CER	cost estimating relationship
CFR	*Code of Federal Regulations*
DOE	U.S. Department of Energy
EEDB	Energy Economic Data Base
EO	Executive Order
EVM	earned-value management
GAO	Government Accountability Office
ICE	independent cost estimate
ICR	independent cost review
LCC	life-cycle cost
LCCE	life-cycle cost estimate
LOE	level of effort
NRC	U.S. Nuclear Regulatory Commission
PERT	program evaluation and review technique
RP	recommended practices
WBS	work breakdown structure

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. The appendix describes practices for~~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, from authorization through end-of-life-cycle operations.

Before following this guidance and beginning a cost estimating process, the NRC staff must 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 inappropriately consider~~s~~ costs in accordance with NUREG-1409, "Backfitting Guidelines."

This appendix does not impose new requirements, establish NRC policy, or direct the actions of NRC staff. 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. In GAO-15-98, "NRC Needs to Improve Its Cost Estimates by Incorporating More Best Practices," issued December 2014, the GAO specifically recommended that NRC cost estimating guidance be aligned with relevant cost estimating best practices identified by GAO to ensure that future cost estimates are prepared in accordance with relevant cost estimating best practices. This appendix includes other recommendations from GAO.

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 to improve the quality of cost estimates that 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 (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.
- **Well-documented**—The supporting documentation for the estimate is thoroughly documented, including source data and significance, clearly detailed calculations and results, and explanations.
- **Accurate**—The 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.

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 steps to estimating (GAO, 2009) and the tasks related to implementing 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, backfit analyses, environmental analyses), which, in turn, determines 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 to the extent practical.
- Proposed actions subject to the Backfit Rule 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

Cost estimates are produced by gathering input, developing the cost estimate, 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 inform decisions. Table B-1 lists the 12 steps, extracted from GAO-09-3SP.

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. • Determine who will do the independent cost estimate. • Outline the cost estimating approach. • Develop the timeline for the estimate.
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., full-time equivalent or contract work, training) and security needs and risk items. • Determine system quantities for development, test, and production. • Develop deployment and maintenance plans.
4	Determine the estimating structure.	• Define a work breakdown structure (WBS) and describe each element in a WBS dictionary (a major automated information system may have only a cost-element structure). • Choose the best estimating method for each WBS element. • Identify potential cross-checks for likely cost and schedule drivers. • Develop a cost estimating checklist.
5	Identify ground rules and assumptions.	• Clearly define the scope of the estimate (i.e., what it includes and excludes). • Identify global and program-specific assumptions, such as the estimate's base year, including time-phasing and life cycle. • Identify program schedule information by phase and program acquisition strategy. • Identify any schedule or budget constraints, inflation assumptions, and travel costs. • Specify equipment the government is to furnish, as well as the use of existing facilities or new modification or development. • Identify prime contractor and major subcontractors.

Step	Description	Associated Tasks
		• Determine technology refresh cycles, technology assumptions, and new technology to be developed. • Define commonality with legacy systems and assumed heritage savings. • Describe effects of new ways of doing business.
6	Obtain data.	• Create a data collection plan with emphasis on collecting current and relevant technical, programmatic, cost, and risk data. • Investigate possible data sources. • Collect data and normalize them for cost accounting, inflation, learning, and quantity adjustments. • Analyze the data for cost drivers, trends, and outliers and compare results against rules of thumb and standard factors derived from historical data. • Interview data sources and document all pertinent information, including an assessment of data reliability and accuracy. • Store data for future estimates.
7	Develop a point estimate and compare it to an independent cost estimate.	• Develop the cost model, estimating each WBS element, using the best methodology from the data collected,[a] and including all estimating assumptions. • Express costs in constant year dollars. • Time-phase the results by spreading costs in the years they are expected to occur, based on the program schedule. • Sum the WBS elements to develop the overall point estimate. • Validate the estimate by looking for errors like double counting and omitted costs. • Compare the estimate against the independent cost estimate and examine where and why there are differences. • Perform cross-checks on cost drivers to see if the results are similar. • Update the model as more data become available or as changes occur and compare results against previous estimates.
8	Conduct a sensitivity analysis.	• Test the sensitivity of cost elements to changes in estimating input values and key assumptions. • Identify effects on the overall estimate of changing the program schedule or quantities. • Determine which assumptions are key cost drivers and which cost elements are most affected by changes.
9	Conduct a risk and uncertainty analysis.	• Determine and discuss with technical experts the level of cost, schedule, and technical risk associated with each WBS element. • Analyze each risk for its severity and probability. • Develop minimum, most likely, and maximum ranges for each risk element to account for uncertainties and cost variations. • Determine the type of risk distributions and reason for their use. • Ensure that risks are correlated. • Use an acceptable statistical analysis method (e.g., Monte Carlo simulation) to develop a confidence interval around the point estimate. • Identify the confidence level of the point estimate. • Recommend that the project or program office develop a risk-management plan to track and mitigate risks.
10	Document the estimate.	• Document all steps used to develop the estimate so that a cost analyst unfamiliar with the program can recreate it quickly and produce the same result.

Step	Description	Associated Tasks
		• Document the purpose of the estimate, the team that prepared it, and who approved the estimate and on what date. • Describe the program, its schedule, and the technical baseline used to create the estimate. • Present the program's time-phased life-cycle cost. • Discuss all ground rules and assumptions. • Include auditable and traceable data sources for each cost element and document for all data sources how the data were normalized. • Describe in detail the estimating methodology and rationale used to derive each WBS element's cost (prefer more detail over less). • Describe the results of the risk, uncertainty, and sensitivity analyses. • Document how the estimate compares to the funding profile. • Track how this estimate compares to any previous estimates.
11	Present the estimate to management for approval.	• Develop a briefing that presents the documented life-cycle cost estimate (LCCE). • Include an explanation of the technical and programmatic baseline and any uncertainties. • Compare the estimate to an independent cost estimate (ICE) and explain any differences. • Compare the LCCE or ICE to the budget with enough detail to easily defend it by showing how it is accurate, complete, and high in quality. • Focus in a logical manner on the largest cost elements and cost drivers. • Make the content clear and complete, so that those who are unfamiliar with it can easily comprehend the basis for the estimate results. • Make backup slides available for more probing questions. • Act on and document feedback from management. • Seek acceptance of the estimate.
12	Update the estimate to reflect actual costs and changes.	• Update the estimate to reflect changes in technical or program assumptions to keep it current as the program passes through new phases and milestones. • Replace estimates with earned value management (EVM) and independent estimate at completion from the integrated EVM system. • Report progress on meeting cost and schedule estimates. • Perform a post mortem and document lessons learned for those elements where actual costs or schedules differ from the estimate. • Document all changes to the program and how they affect the cost estimate.

[a] In a data-rich environment, the estimating approach should precede the investigation of data sources; in reality, a lack of data often determines the approach.

Source: GAO-09-3SP, Table 2.

B.3 COST ESTIMATING INPUTS

Cost estimate development is initiated by inputs to the process. These inputs are 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 must 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 appropriately considers costs in accordance with NUREG-1409, “Backfitting Guidelines.”

B.3.1 Project Requirements

Cost estimates are performed for regulatory, backfit, forward fit, issue finality, and environmental review 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.

B.4.2 Cost Estimate Classifications

Cost estimates have common characteristics, such as 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.

As a project evolves, it typically becomes more defined. Likewise, cost estimates depicting evolving projects or work also become more defined over time. Determinations of cost estimate classifications help ensure that the cost estimate quality is appropriately considered. Classifications may also help determine the appropriate application of, for example, use of direct and indirect costs (as determined by cost estimate techniques).

Widely accepted cost estimate classifications are found in the Association for Advancement of Cost Engineering International (AACEI) 2011 Recommended Practices (RP) No. 17R-97 and 2011 RP No. 18R-97. Table B-3 lists the five suggested cost estimate classifications, along with their primary and secondary characteristics, and the estimate uncertainty range, as a function of the estimate class.

Table B-3 Cost Estimate Classification

	Primary Characteristic	**Secondary Characteristic**		
ESTIMATE CLASS	DEGREE OF PROJECT DEFINITION Expressed as % of complete definition	END USAGE Purpose of estimate	METHODOLOGY Typical estimating methodology	EXPECTED ACCURACY RANGE Typical variation in low and high ranges [a,b]
Class 5	0% to 2%	Concept	Capacity factored, parametric models, judgment, or analogy	Low: -20% to -50% High: +30% to +100%
Class 4	1% to 15%	Study or feasibility	Equipment factored, parametric models, judgment, or analogy	Low: -15% to -30% High: +20% to +50%
Class 3	10% to 40%	Budget authorization	Semi detailed unit costs	Low: -10% to -20% High: +10% to +30%
Class 2	30% to 70%	Bid/tender	Detailed unit costs with forced detailed take-off	Low: -5% to -15% High: +5% to +20%
Class 1	70% to 100%	Check estimate or bid/tender	Detailed unit costs with forced detailed take-off	Low: -3% to -10% High: +3% to +15%

[a] The state of scope and requirements definition and the availability of applicable reference cost data can significantly affect the expected accuracy range.

[b] The expected accuracy range of low and high values represents the typical percentage variation of actual costs from the mean estimate.

Source: Based on U.S. Department of Energy (DOE), "Cost Estimating Guide," Table 4.3.

Table B-3 is intended only as an illustration of the general relationship between estimate accuracy and the level of specificity defined (e.g., level of project definition or level of engineering complete). As described in AACEI RP No. 17R-97, there is no absolute standard range on any estimate or class of estimates. The common plus or minus percent measure associated with an estimate is a useful simplification, given that each individual estimate is associated with a different level of uncertainty.

Although the level of project definition is an important determinant of estimate accuracy, other affecting factors include the quality of reference cost estimating data (i.e., material pricing, labor hours, labor wage rates), the quality of the assumptions used in preparing the estimate, the state of new technology in the project, the experience and skill level of the cost analyst, the specific 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 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.

For managing contracts, 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.

The NRC does not use either of these types of contingency reserves in its regulatory analysis cost estimates (GAO, 2009).

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 not include contingencies when performing a sensitivity analysis for a regulatory analysis (i.e., a high estimate). Appendix C, “Treatment of Uncertainty,” to this NUREG discusses the concept of sensitivity analysis as a subset of uncertainty 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 develop work 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 activity-based, detailed, or unit-cost estimating methods include the following:

- a greater level of confidence

- more detail that can be used, for example, for better monitoring and change control
- enhanced scope and individual activity definition
- detailed quantities to establish more accurate metrics
- better resource basis for the schedule

The disadvantages of using activity-based, detailed, or unit-cost estimating methods include the following:

- more time needed to develop the estimate
- more costly to develop than relationship estimating

B.5.2 Parametric-Estimating Techniques

A parametric model is a useful tool for preparing early conceptual estimates when there is little technical data or engineering deliverables to provide a basis for using more detailed estimating methods. A parametric estimate comprises cost estimating relationships (CERs) and other cost estimating functions that provide logical and repeatable relationships between independent variables, such as design parameters or physical characteristics, and the dependent variable, cost. Capacity factor and equipment factor are simple examples of parametric estimates; however, sophisticated parametric models typically involve several independent variables or cost drivers. Parametric estimating relies on the collection and analysis of previous project cost data to develop the CERs.

B.5.2.1 Cost Estimating Relationships

CERs, also known as cost models, composites, or assemblies and subassemblies, are developed from historical data for similar systems or subsystems. Analysts use a CER to estimate a cost or price by using an established relationship with an independent variable. For example, a CER of design hours per drawing may be applied to the estimated number of drawings to determine total design hours. Identifying an independent variable (driver) that demonstrates a measurable relationship with contract cost or price develops a CER. That CER may be mathematically simple (e.g., a simple ratio), or it may involve a complex equation.

Parametric estimates are commonly used in conceptual and check estimates. For a CER to be most effective, the cost analyst should understand how the CER was developed and where and how indirect costs, overhead costs, and escalation are applicable. The parametric-estimating technique is most appropriate for Class 5, 4, and 3 cost estimates. The parametric technique is best used when the design basis has evolved little, but the overall parameters have been established.

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 consider 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.5.2.3 Physical-Dimension Method

The physical-dimension method is used when enough historical data are available from similar work, based on the area or volume of that work. The method uses the relationship of the physical dimensions of existing work data to that of the physical dimensions of similar new work. The method does not consider any economies of scale or the location or timing of the work. For example, the total cost of a previous project was $150,000 for a 1,000-square-foot foundation. A new foundation is to be 3,000 square feet. Using the dollar-per-square-foot value from the previous

project yields a value of $150 per square foot (i.e., $150,000 divided by 1,000 square feet). The estimated cost of the new foundation is $450,000 (i.e., $150 per square foot x 3,000 square feet).

B.5.2.4 Capacity-Factored Method

The capacity-factored method is used during the feasibility stage of a project, when enough historical data are available from similar work, based on the capacity of that work. The method uses the relationship of the capacity of existing work data to that of the capacity of similar new work. It accounts for economies of scale but not the location or timing of the work and provides a sufficiently accurate means of determining whether a proposed project, regulatory action, or alternative should be continued. The screening method (Class 5 estimate) is most often used. While the capacity-factored method is most often used to estimate the cost of entire facilities, it may also be applied at the system or equipment level.

When estimating using the capacity-factored method, the cost of a new plant is derived from the cost of a similar plant of a known capacity, with similar operational characteristics (e.g., batch processing, base load) but not necessarily the same end products. Although the end products do not need to be the same, the products should be relatively similar.

The method uses a nonlinear relationship between capacity and cost, as shown in the following equation:

$$\frac{\$B}{\$A} = \left[\frac{Capacity_B}{Capacity_A}\right]^e$$

where

$A and $B = costs of the two similar plants
$Capacity_A$ and $Capacity_B$ = capacities of the two plants
e = exponent or proration factor

The exponent *e* used in the capacity-factor equation is the slope of the log curve that is drawn to reflect the change in the cost of a plant as it is made larger or smaller. These curves are typically drawn from the data points of the known costs of completed plants. With an exponent of less than 1, economies of scale are achieved such that as plant capacity increases by a percentage (e.g., by 20 percent), the costs to build the larger plant increase by less than 20 percent. This methodology of using capacity factors is sometimes referred to as the scale-of-operations method or the six-tenths-factor method because of the reliance on an exponent of 0.6 if no other information is available.

The value of the exponent *e* typically lies between 0.5 and 0.85, depending on the type of plant, and should be analyzed carefully for its applicability to each estimating situation. As plant capacity increases to the limits of existing technology, the exponent approaches a value of 1. At this point, it becomes as economical to build two plants of a smaller size as it is to build one large plant.

Companies may not make proration factor data available, and recent studies are sparse. However, if the proration factor used in the estimating algorithm is relatively close to the actual value, and if the plant being estimated is relatively close in size to the similar plant of known cost, then the potential error is certainly well within the level of accuracy that would be expected from a stochastic method. A purely stochastic method is one where the state is randomly determined, with a random probability distribution or pattern that may be analyzed statistically but may not be

predicted precisely. In this regard, it can be classified as nondeterministic (i.e., "random"), so that the subsequent state of the system is determined probabilistically.

B.5.2.5 Ratio or Factor Method

The ratio or factor method is used when historical building and component data are available from similar work. Scaling relationships of existing component costs are used to predict the cost of similar new work. This method is also known as "equipment-factor" estimating. The method does not account for any economies of scale or the location or timing of the work.

For example, if a plant that cost $1,000,000 to construct has major equipment that costs of $250,000, then the plant cost-to-equipment cost factor would be 4.0, as illustrated below:

$$plant\ cost\ to\ equipment\ cost\ factor = \frac{plant\ cost}{equipment\ cost} = \frac{\$1{,}000{,}000}{\$250{,}000} = 4.0$$

If a proposed new plant will have $600,000 of major equipment, then the factor method would predict that the new plant is estimated to cost $2,400,000 ($600,000 x 4.0).

B.5.3 Other Estimating Methods

B.5.3.1 Level-of-Effort Method

A form of parametric estimating is based on level of effort (LOE). Historically, LOE is used to determine future repetitive costs based on past cost data (e.g., if two employees spent 1,000 person-hours to develop a guidance document last year, then similar documents may need a similar level of effort). Often, LOE estimates have few parameters or performance objectives from which to measure or estimate but are carried for several time periods at a similar rate (e.g., the number of workers for a specified amount of time). LOE estimates are normally based on hours and the number of full-time equivalents. Because they are perceived to have little objective basis, LOE estimates are often subject to scrutiny. The key to LOE estimates is that they should generally be based on a known scope of similar work.

Numerous cost elements may affect an LOE estimate. For example, using the LOE method to estimate the costs for installing a new pump may raise questions about the impacts of radiological contamination or security issues and related productivity adjustments. Other cost factors that need to be considered are indirect costs, overhead costs, profit and fee, and other assumptions.

B.5.3.2 Specific-Analogy Method

Specific analogies use the known cost or schedule of an item as an estimate for a similar item in a new system. Adjustments are made to known costs to account for differences in relative complexities of performance, design, and operational characteristics. The analogy method uses actual costs from a similar program, adjusted to account for the difference between the requirements of the existing and new systems. A cost analyst typically uses this method early in a program's life cycle, when insufficient actual cost data are available but the technical and program definition is good enough to make the necessary adjustments (e.g., regulatory basis and possibly during the proposed rule stage).

Adjustments should be made as objectively as possible, by using factors (sometimes scaling parameters) that represent differences in size, performance, technology, or complexity. The

cost analyst should identify the important cost drivers, determine how the old item relates to the new item, and decide how each cost driver affects the overall cost. All estimates based on the analogy method, however, should pass a reasonable person test. That is, the sources of the analogy and any adjustments should be logical, credible, and acceptable to a reasonable person. In addition, because analogies are one-to-one comparisons, the historical and new systems should have a strong parallel.

The specific-analogy method relies a great deal on expert opinion to modify the existing system data to approximate the new system. If possible, the adjustments should be quantitative rather than qualitative, avoiding subjective judgments. An analogy is often used to cross-check other methods. Even when an analyst is using a more detailed cost estimating technique, an analogy can provide a useful check. Table B-4 shows how the analogy method is used.

Table B-4 Example of the Analogy Cost Estimating Method

Parameter	Existing System	New System	Cost of New System (assumes a linear relationship)
Diesel-driven air compressor	F-100	F-200	
Cubic feet per minute	100	175	
Cost	$1,406	unknown	(175/100) x $1,406 = $2,461

The equation in Table B-4 assumes a linear relationship between the air compressor cost and its output. However, there should be a compelling scientific or engineering reason why the air compressor cost is directly proportional to its output. Without more data, it is hard to know what parameters are the true drivers of cost. Therefore, when using the analogy method, it is important that the cost analyst research and discuss with experts the reasonableness of technical program drivers to determine whether they are significant cost drivers.

The advantages of using the analogy method include the following:

- The method can be applied before detailed program requirements are known.
- If the analogy is strong, the estimate will be defensible.
- An analogy can be developed quickly and at minimal cost.
- The tie to historical data is simple enough to be readily understood.

The disadvantages of using the analogy method include the following:

- An analogy relies on a single data point.
- It is often difficult to find the detailed cost, technical, and programmatic data required for analogies.
- There is a tendency to be too subjective about the technical parameter adjustment factors.

The last disadvantage can be better explained with an example. If a cost analyst assumes that a new component will be 20 percent more complex but cannot explain why, this adjustment factor is unacceptable. The complexity should be related to the system's parameters (e.g., the new system will have 20 percent more data processing capacity or will weigh 20 percent more).

GAO Case Study 34 in GAO-09-3SP highlights what can happen when technical parameter assumptions are too optimistic.

B.5.3.3 Expert-Opinion Method

Expert opinion is an estimating technique in which analysts consult experts about the cost of a program, project, subproject, task, or activity. The expert opinion technique is most appropriate in the early stages of a project (i.e., regulatory bases or proposed rule cost estimates). The expert-opinion method is commonly used to fill gaps in a relatively detailed WBS when one or more experts are the only qualified source of information. Cost analysts should verify experts' credentials before relying on their opinions. Cost analysts should not ask experts to estimate costs outside their expertise.

One method for forecasting cost based on expert opinion is the Delphi method. For the Delphi method, a group (e.g., six or more experts) receives a specific, usually quantifiable, question. Each expert sees the estimates produced by others and the rationale supporting the estimates and then can modify previous estimates until a group consensus is reached. If, after multiple rounds, there is no consensus, the original question may be broken into smaller parts for further rounds of discussion, or a mediator may facilitate a final consensus, if feasible.

Such techniques may be used for portions of or entire estimates and activities for which there is no other defensible basis. The advantages of using an expert opinion include the following:

- Expert opinion can be used if no historical data are available.
- The approach takes minimal time and is easy to implement, once the experts are assembled.
- An expert may provide a different perspective or identify facets not previously considered, leading to a better understanding of the program.
- It can be useful as a cross-check for CERs that require data significantly beyond the data range.
- It can be blended with other estimation techniques within the same WBS element.
- It can be applied in all acquisition phases.

The disadvantages associated with an expert opinion include the following:

- Experts might lack objectivity.
- One expert might try to dominate the discussion and sway the group toward his or her opinion.
- There is a possibility of an impasse.
- This approach is not considered very accurate or valid as a primary estimating method.

Because of its subjectivity and lack of supporting documentation, expert opinion should be used sparingly, as a last resort. GAO Case Study 35 in GAO-09-3SP shows how relying on expert opinion as a main source for a cost estimate is unwise.

B.5.3.4 Learning-Curve Method

The learning curve is a way to understand the efficiency of producing or delivering large quantities. Studies have found that people engaged in repetitive tasks will improve their performance over time (i.e., for large quantities of time and units, labor costs will decrease per unit). This observation led to the formulation of the learning-curve equation $Y = AX^b$ and the concept of a constant learning curve slope b that captures the change in Y given a change in X. The constant slope b is given by the formula b = log (slope)/log 2.

The aircraft industry first recognized and named the learning curve and successfully used it in estimating. It can be used most effectively when new procedures are being fielded and where labor costs are a significant percentage of total unit cost. It is important to note that the learning curve applies only to direct labor input. Materials and overhead will not necessarily be affected by the learning curve. Figure B-1 illustrates a hypothetical learning curve.

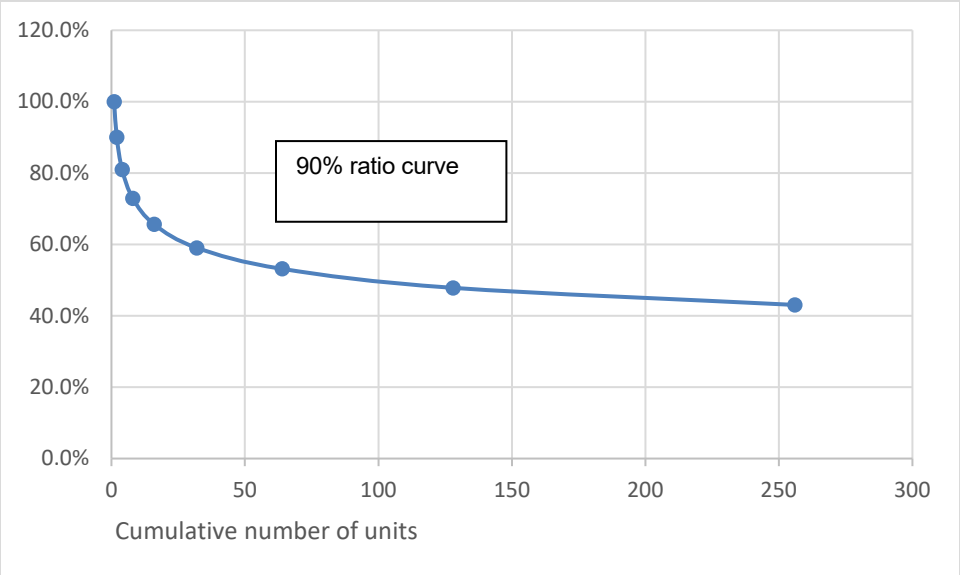

Figure B-1 A Learning Curve

Figure B-1 shows how an item's cost gets cheaper as its quantities increase. For example, if the learning curve slope is 90 percent and it takes 1,000 hours to produce the first unit, then it will take 900 hours to produce the second unit. Every time the quantity doubles—for example, from 2 to 4, 4 to 8, 8 to 16—the resource requirements will reduce according to the learning-curve slope.

Typical learning curves start with high labor costs (hours) that decrease rapidly on early production units and then flatten as production continues. This exponential relationship between labor productivity and cumulative production is expressed in terms of labor reduction resulting from production increases. For example, a 90-percent learning-curve function requires only 90 percent of the labor hours per unit each time production doubles. When a total of 200 units is produced, labor costs for the second 100 units will be only nine-tenths of the costs of the first 100.

Increased productivity allows for lower labor costs later in a project and should result in a lower overall project cost. Subsequent similar projects should have fewer labor hours for each unit of production also, which could result in both more contractor profit and lower government contract costs.

No standard reduction rate applies to all programs, and learning-curve benefits will vary across projects. When labor hour reductions of the first units are known, the analyst can calculate an accurate percentage reduction and extend it to subsequent units. If no data exist, it may be risky to assume that learning-curve savings will be experienced.

Both traditional and nontraditional projects can use the learning-curve estimating. The learning curve is most effective when applied to repetitive activities and can also be used to update labor hours calculated in earlier estimates.

B.6 METHODS OF ESTIMATING OTHER LIFE-CYCLE COSTS

Different methods may be used to estimate other project and program support costs (e.g., design, engineering, inspections, and regulatory review). This section describes some common methods.

B.6.1 Count-Deliverables Method

The cost analyst calculates the number of deliverables (e.g., drawings, specifications, procurements, license amendment requests, safety evaluations) for a specific project. The more complex the project is, the more deliverables it will require, and hence, the higher the associated costs.

B.6.2 Full-Time-Equivalent Method

The number of individuals anticipated to perform specific functions of a project forms the basis for this method. The analyst estimates the cost by calculating the labor-hour quantity and multiplying it by the cost per labor hour and the duration of the project function.

B.6.3 Percentage Method

The cost analyst calculates a certain percentage of the direct costs and assigns this amount to the other project functions (i.e., design, project management). Some possible benchmarks include the following:

- Total design percentages are usually 15 to 25 percent of the estimated construction costs. Nontraditional, first-of-a-kind projects may be higher, while simple construction, such as buildings, will be lower (on the order of 6 percent); the more safety and regulatory intervention involved, the higher the percentage.

- Project management costs range from 5 to 15 percent of the other estimated project costs, depending on the nature of the project and the scope of what is covered under project management. The work scope associated with this range should be defined.

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 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 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 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 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 a plan for deciding on the safety importance of a proposed regulatory change, regulatory alternatives available to address the issue, cost benefit attributes affected, estimating methodology or methodologies the analyst will use, and potential sources of data. The cost analyst completes this task when 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.

In many cases, only secondary data are available. Therefore, the cost analyst should seek to understand how the data were normalized, what the data represent, how old the data are, and whether the data are incomplete. If these questions can be answered, the secondary data should be useful for estimating and would certainly be helpful for cross-checking the estimate for reasonableness.

Some specific sources of data include the following:

- **Estimating Manuals**—The construction industry produces numerous costing manuals to assist in the pricing of work. Robert Snow Means Co. "Cost Data Books" and Richardson Construction Estimating Standards are two readily available estimating manuals. There are other estimating manuals that are available from other Federal agencies and should be used when appropriate.

- **NRC Technical Documents**—The NRC has sponsored several studies on generic costs associated with the construction activity at nuclear power plants. These generic studies are intended to provide tools and methods to assist cost analysts in the estimation of costs resulting from new and revised regulatory requirements. Table B-5 lists these documents.

Table B-5 List of NRC Cost Studies

Document No.	Title
Nuclear Power Plant Construction Costs	
NUREG/CR-5160	"Guidelines for the Use of the EEDB [Energy Economic Data Base] at the Sub-Component and Subsystem Level"
NUREG/CR-4546	"Labor Productivity Adjustment Factors: A Method for Estimating Labor Construction Costs Associated with Physical Modifications to Nuclear Power Plants"
SEA Report 84-116-05-A:1	"Generic Methodology for Estimating the Labor Cost Associated with the Removal of Hardware, Materials, and Structures from Nuclear Power Plants"
NUREG/CR-4921	"Engineering and Quality Assurance Cost Factors Associated with Nuclear Plant Modification"
NRC Cost Estimating Methods, Reference Assumptions, and Data	
DOE/NE-0044/3	"Nuclear Energy Cost Data Base: A Reference Data Base for Nuclear and Coal-fired Power Plant Power Generating Cost Analysis"
NUREG/CR-3971	"A Handbook for Cost Estimating: A Method for Developing Estimates of Cost for Generic Actions for Nuclear Power Plants"
NUREG/CR-4627	"Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses"
NUREG/CR-4568	"A Handbook for Quick Cost Estimates: A Method for Developing Quick Approximate Estimates of Costs for Generic Actions for Nuclear Power Plants"
NUREG/CR-4555	"Generic Cost Estimates for the Disposal of Radioactive Wastes"
NUREG/CR-3194	"Improved Cost-Benefit Techniques in the U.S. Nuclear Regulatory Commission"
Under contract NRC-33-84-407-006	"The Identification and Estimation of the Cost of Required Procedural Changes at Nuclear Power Plants"
NUREG/CR-5138	"Validation of Generic Cost Estimates for Construction-Related Activities at Nuclear Power Plants"

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 confidence of real-time accuracy. However, the cost analyst should use caution when using industry-supplied or secondary cost estimates. 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. 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 may involve interviewing the persons and applying their judgment to assist in the

development of the cost estimate. Because of its subjectivity and, usually, the lack of supporting documentation, team or individual judgment should be used sparingly.

- **Learning-Curve Data**—As described in Section B.5.3.4, learning-curve data are useful for understanding the efficiency of producing or delivering large quantities. Numerous sources are available from trade associations and governmental organizations. NUREG/CR-5138 (see Table B-5) provides guidance on learning-curve factors, based on nuclear power plant modification activities, and gives guidelines for selecting the appropriate factors and their use.

B.7.3.2 Cost Estimate Development Considerations

When assigned the task of developing a cost-benefit estimate, the cost analyst should gather general project information, including the following:

- project background
- project scope
- pertinent contract or subcontract information, if applicable
- estimate purpose, classification, how the estimate will be used, and techniques anticipated
- project schedule

If the assignment is for a regulatory analysis supporting the evaluation of a proposed regulatory action, such as for rulemaking, the cost analyst would collect the following specific inputs:

- draft *Federal Register* notice
- draft rule language
- statements of consideration
- applicable guidance documents
- WBS, if generated
- historical information and other sources of information, including previous regulatory analyses and cost estimates
- project assumptions
- industry cost estimates

The cost analyst will be able to use this information, whether provided by others or developed by the cost analyst as an assumption, to determine the appropriate estimating techniques to employ.

B.7.4 Cost Estimate Preparation

The principle step in the estimating process is producing the cost estimate and its corresponding schedule and basis of estimate. It is important that the analyst coordinate scope development, documentation, and control with the cost estimate production as key iterative processes. In general, the production of a cost estimate has several steps that should be based on requirements, purpose, use, classification, and technique, including the following:

- Identify the scope of work, activities, and tasks.
- Document all bases of such factors as the estimate, assumptions, allowances, and risks during the estimating process.
- For detailed engineering estimates, perform quantity takeoffs and field walkdowns, if applicable.
- Develop the detailed items or models that make up the activities.
- Assign measurable quantities to the detailed items or models.
- Obtain vendor information, conduct market research, or establish other pertinent sources of information.
- Establish productivity rates or perform task analyses.
- Calculate all applicable costs, including direct and indirect costs.
- Determine if (and to what extent) risks should be mitigated with activities (or assumptions) in the cost estimate.
- Consider other inputs, including peer reviews or independent cost estimates, as appropriate.

However, for cost estimates for proposed regulatory actions, the scope of the cost estimate is to compute the incremental costs to implement the proposed regulatory action. These incremental costs measure the additional costs imposed by regulation in that they are costs that would not have been incurred in the absence of that regulation. In general, the cost analyst should follow three steps to estimate these incremental costs:

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

(2) Estimate the costs associated with implementation and operation.

(3) If appropriate, discount the implementation costs, then sum.

In preparing an estimate of industry implementation costs, the analyst should also carefully consider all cost categories that may be affected by implementing the action. Examples of categories include the following:

- land and land-use rights

- structures
- hydraulic, pneumatic, and electrical equipment
- radioactive waste disposal
- health physics
- monitoring equipment
- personnel construction facilities, equipment, and services
- engineering services
- recordkeeping
- procedural changes
- license modifications
- staff training and retraining
- administration
- facility shutdown and restart
- replacement power (power reactors only)
- reactor fuel and fuel services (power reactors only)
- items for averting illness or injury (e.g., bottled water or job safety equipment)

Transfer payments should not be included.

For the standard analysis, the cost analyst should use consolidated information to estimate the cost for implementing the action, as follows:

Step 1— Estimate the amounts and types of equipment, materials, and labor that the proposed action will affect, including physical equipment, craft labor, and professional staff labor for design, engineering, quality assurance, and licensing associated with the action. If the action requires work in a radiation zone, the estimate should account for the extra labor required by radiation exposure limits and low worker efficiency from awkward radiation protection gear and tight quarters.

When performing a sensitivity analysis, but not for the best estimate, the analyst should include contingencies as discussed in Section B.5.1.

Step 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. The analyst should identify any significant secondary costs that may arise. One-time component replacement costs and associated labor costs should be accounted for as secondary costs. Additional information on cost categories, especially for reactor facilities, appears in NUREG-0248, "Commercial Electric Power Cost Studies, Part 8, Total Generating Costs: Coal and Nuclear Plants," and UCSD-CER-13-01 "ARIES Cost Account Documentation". Indirect costs are typically absorbed by society and not subject to accounting on the owner's financial statement. Indirect costs include environmental costs (e.g., lost wetlands and other habitats, soiling of property from pollution), societal costs (e.g., lost productivity, medical costs), and other intangible costs that may occur. Indirect costs tend to be harder to quantify and often involve significant effort from the analyst. However, many indirect cost categories have been the subject of economic study and values are available in the literature.

Step 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 the proposed action is adopted.

When performing cost-benefit analyses for nonreactor facilities, the analyst may encounter difficulty in finding consolidated information on industry costs comparable to that for power reactors. Comprehensive data sources, such as NUREG/CR-4627, "Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses," Revision 2, are generally unavailable for nonreactor facilities. The types of nonreactor facilities are quite diverse. Furthermore, within each type, the facility layouts typically lack the limited standardization of the reactor facilities. These combine to leave analysts making independent assumptions in developing industry implementation costs for nonreactor facilities. Specific data may be best obtained through direct contact with knowledgeable sources for the facility concerned, possibly even 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 cost data from NRC contractors or industry sources experienced in this area (e.g., architect-engineering firms). The incremental costs of the action should be defined at a finer level of detail. The analyst should refer to the code of accounts in the EEDB (NUREG/CR-5160) to prepare a detailed account of implementation costs.

B.7.4.1 Work-Breakdown Structure

The analyst should develop a WBS because it details the work necessary to accomplish the proposed regulatory action. Going through the process of WBS development helps to clearly identify the activities needed to be performed and ensure that they are appropriately sequenced. This then forms a basis for estimating the resources and costs needed to accomplish the regulatory action. That process, in turn, provides a basis for estimating activity durations and resource requirements. Establishing a product-oriented WBS is a best practice because it shows how elements relate to one another, as well as to the overall end product.

The 100-Percent Rule

The logic of a "100-percent rule" is that the next level of decomposition of a WBS element (child level) should represent 100 percent of the work applicable to the next higher (parent level)

element. This is considered a best practice by many experts in cost estimating because a product-oriented WBS following the 100-percent rule ensures that all costs for all deliverables are identified. Failing to include all work for all deliverables can lead to unrealistic cost estimates. To avoid this problem, standardizing the WBS is a best practice in organizations that have a set of program types that are standard and typical. This enables an organization to simplify the development of the top-level program WBSs by publishing the standard. It also facilitates an organization's ability to collect and share data from common WBS elements across many programs. The more data that are available for creating the cost estimate, the higher the confidence level. As this process indicates, and as described in this appendix, the development of a WBS and cost estimates is a highly iterative and interrelated process.

B.7.4.2 Collect, Validate, and Adjust Data

NRC cost estimates can use many possible sources of data. Regardless of the source, the validation of the data (relative to the purpose of its intended use) always remains the responsibility of the cost analyst. In some cases, the data will need to be adjusted or normalized. For example, in analogy estimates, the reference system cost should be adjusted to account for any differences—in system characteristics (technical, physical, complexity, or hardware cost), support concepts, or operating environment—between the reference system and the proposed system being estimated.

For most cost elements, historical cost data are available, as discussed in Section B.7.3.1. The cost analyst should always carefully examine data before using it in a cost estimate. The estimate should display historical data over a period of a few years (not just a single year) that are separated by organization or location. This should be done so that abnormal outliers in the data can be identified, investigated, and resolved as necessary. In some cases, it may also be necessary to ensure that the content of the data being used is consistent with the content of what is being estimated (to avoid any gaps in coverage).

For example, historical cost data may contain information based on the use of past technologies, so it is essential to make appropriate adjustments to account for differences between the new system and the existing system with respect to such things as design characteristics, manufacturing processes (automation versus hands-on labor), and types of material used. This is where statistical methods, like regression, that analyze cost against time and performance characteristics can reveal the appropriate technology-based adjustment.

Data that can be used for detailed bottoms-up engineering buildup estimates (described in Section B.7.4.3) often come from contractor databases. The cost analyst should validate these types of data before use, possibly on a sampling basis. This is especially important if the proposed regulatory action being estimated is not mature (i.e., incomplete design details). The validation should address the completeness of the estimate, the realism of component reliability and maintainability estimates, and the legitimacy of the component unit prices.

B.7.4.3 Select Cost Estimating Methods or Models

The analyst may use several techniques to estimate the costs of a proposed regulatory action. The suitability of a specific approach will depend to a large degree on the maturity of the proposed regulatory solution and the level of detail of the available data. Most regulatory analysis estimates are accomplished using a combination of five estimating techniques:

(1) **Parametric**—The parametric technique uses regression or other statistical methods to develop CERs (an equation or algorithm used to estimate a given cost element using an established relationship with one or more independent variables). The relationship may be mathematically simple, or it may involve a complex equation (often derived from regression analysis of historical systems or subsystems). The CERs should be current, applicable to the system or subsystem in question, and appropriate for the range of data being considered.

(2) **Analogy**—An analogy is a technique used to estimate a cost based on historical data for one or more analogous system(s) or to estimate a cost for a subsystem (such as an engineered containment filtered vent subsystem). This technique uses a currently fielded system, similar in design and operation to the proposed system, as a basis for the analogy. The cost of the proposed system is then estimated by adjusting the historical cost of the current system to account for differences (between the proposed and current systems). The cost analyst can make such adjustments using factors (sometimes called scaling parameters) that represent differences in size, performance, technology, reliability and maintainability, complexity, or other attributes. Adjustment factors based on quantitative data are usually preferable to adjustment factors based on judgments from subject matter experts.

(3) **Engineering Estimate**—This technique uses discrete estimates of labor and material costs for maintenance and other support functions. The cost analyst breaks down the system being estimated into lower-level subsystems and components, each of which is estimated separately. The analyst then aggregates the component costs, with additional factors for integration, using simple algebraic equations to estimate the cost of the entire system (hence the common name “bottoms-up” estimate). For example, system maintenance costs could be calculated for each system component using data inputs such as system operating tempo, component mean time between maintenance actions, component mean labor hours to repair, and component mean material cost per repair. Engineering estimates require extensive knowledge of a system’s (and its components’) characteristics and a significant amount of detailed data. These methods are normally employed for mature programs; regulated entities continue to use these methods after the regulation is promulgated.

(4) **Extrapolation of Actual Costs**—With this technique, analysts use actual cost experience or trends (from prototypes, engineering development models, and early production items) to project future costs for the same system at other facilities. Such projections may be made at various levels of detail, depending on the availability of data.

(5) **Cost Factors**—Cost factors are applicable to certain cost elements not related to the proposed system characteristics. Often, cost factors are simple per capita factors that are applied to direct (i.e., unit-level) labor to estimate indirect cost elements, such as general training and education, coordination, or quality assurance.

In many instances, it is a common practice to employ more than one cost estimating method so that a second method can serve as a cross-check to the preferred method. Analysts often use analogy estimates as cross-checks, even for mature systems.

B.7.4.4 Estimate Costs

With the completion of the steps described earlier in Section B.7.4, the actual computations of the cost estimate can begin. The time and energy in front-end planning for the estimate will help to minimize the amount of midcourse corrections and wasted effort. In actual practice, the planning process may be more iterative than the sequence of discrete steps described earlier. Nevertheless, the basic principles remain valid and important.

The selected cost estimation techniques typically depend on the stage of the proposed regulatory change (e.g., regulatory basis, proposed rule, or final rule) and the availability and specificity of the supporting regulatory guidance. In the earlier stages, cost estimates are commonly based on analogies and parametric CERs. In some cases, as the proposed regulatory change definition is refined, the use of analogies and CERs may be improved by increasing the level of detail of the cost estimate—for some cost elements, making distinct estimates for major subsystems and components.

B.7.4.5 Conduct Uncertainty Analysis

For any proposed regulatory action, estimates of future costs are subject to varying degrees of uncertainty. These uncertainties result from the use of different cost estimating methods, variability in facility design, and differing approaches that licensees take to implement changes to their facilities to comply with a new or revised regulation. Although these uncertainties cannot be eliminated, the cost estimate should address them. For each major concern, it is useful to quantify its degree of uncertainty and its effect on the cost estimate.

Typically, the cost analyst identifies the relevant cost elements and their associated cost drivers and then examines how costs vary with changes in the cost-driver values. For example, a sensitivity analysis might examine how the maintenance cost varies with different assumptions about system reliability and maintainability values. In good sensitivity analyses, the cost-driver values are not changed by arbitrary plus or minus percentages but rather by a careful assessment of the underlying uncertainties.

B.7.4.6 Cost Estimate Results

The cost analyst should formally document the cost estimate. The documentation serves as a permanent record of source data, methods, and results, and should be easy to read and well organized to allow any reviewer to understand the estimate. The key standard is that an outside professional cost analyst should be able to review the data and methods employed and understand the results.

The documentation should address all aspects of the cost estimate: the ground rules and assumptions, the description of the alternatives evaluated, the selection of cost estimating methods, the data sources, the actual estimate computations, and the results of the uncertainty analyses. The documentation may be provided within a regulatory analysis or similar report.

B.7.5 Cost Estimate Review

The cost analyst should ensure that the cost estimates are peer reviewed for quality and reasonableness before release. Reviews can be either objective, subjective, or a combination of both. As a minimum, NRC cost estimates should address the review criteria listed in Enclosure B-1.

NRC regulatory analyses, and the cost estimates that support them, should include an assessment of cost realism and reasonableness. To test the reasonableness and realism of a cost estimate, an NRC cost analyst will review the regulatory analysis, the cost estimate, and the supporting documentation to analyze whether the estimate is sufficient regarding the validity of cost assumptions, the rationale for the cost estimate methodology, and completeness.

This review should provide an unbiased check of the assumptions, productivity factors, and cost data used to develop the estimate. This is a vital step in providing consistent, professionally prepared cost estimates, as shown in step 7 of Table B-1.

The review should document the following:

- the name of the reviewer(s)—office, agency, contractor affiliation (as appropriate)
- the date of the review

B.7.6 Estimate Reconciliation

Reconciliation may be necessary to account for changes made in a proposed rulemaking or guidance documents or the availability of new data. Reconciliations should cover all aspects of the cost estimating documentation (i.e., cost estimate, basis of estimate, schedule, and risks). In general, reconciliation should recognize or focus on specific changes in scope, basis of estimate, schedule, and risks. There should be an understanding that, as time progresses, more and better information is expected to be available and used as cost estimate documentation.

B.7.7 Cost Estimate Documentation

Well-documented cost estimates are considered a best practice for high-quality cost estimates for several reasons:

- Complete and detailed documentation is essential for validating and defending a cost estimate.

- Documenting the estimate with a detailed, step-by-step process provides enough documentation so that someone unfamiliar with the estimate could recreate or update it.

- Good documentation helps with analyzing changes in costs and contributes to the collection of cost and technical data that can be used to support future cost estimates.

- A well-documented cost estimate is essential to ensure that an effective independent review is valid and credible. It also supports reconciling differences with an independent cost estimate and improving the understanding of the cost elements and their differences so that decisionmakers can be better informed.

Cost Estimate Package

All cost estimates should have an accompanying cost estimate package or report (e.g., a regulatory analysis). All cost estimate packages should contain the same categories of information and the same types of documentation; only the level of detail in the estimate package varies. GAO-09-3SP provides best practices for preparing cost estimates for developing and managing capital program costs. When documenting cost estimates for other purposes, the

analyst should use a graded approach to estimate packaging and reporting, keeping the scope limited to the intended function of the estimate.

The cost estimate should contain the following information:

- **Estimate Purpose Statement**—This provides the reason the estimate was prepared and includes the following steps:

  – Determine the estimate's purpose.
  – Determine the level of detail required.
  – Determine who will receive the estimate.
  – Identify the overall scope of the estimate.

- **Technical-Scope Summary**—This summarizes the technical scope of the project, including what is included in the project as well as what is not included.

- **Qualifications and Assumptions**—This lists the key estimate qualifications and cost assumptions that bound the estimate and scope. The qualifications and assumptions may describe the types of work expected, the amount of work expected, the source of various materials, conditions in which the work is to be performed (e.g., general access, confined space, contaminated building), and any other information that would significantly influence the estimate but is not clearly identified in the problem statement or alternative description(s). This information also describes the major assumptions and exclusions that affect the estimate or the accuracy of the estimate.

  Once the qualifications and assumptions are identified, the cost analyst should identify key information for reviewers or users of the estimates, those areas where scope descriptions have deficiencies, and areas where key information is missing and must be assumed. The analyst should describe and document the qualifications and assumptions to a level practicable and should clearly describe them so an individual not intimately involved with the estimate can understand the estimate's basis.

- **Method and Justification for Use of Labor Rates**—This explains how labor rates were selected and applied.

- **Method and Justification for Use of Contingencies**—This is an explanation of how contingencies were determined and applied.

- **Method and Justification for Use of Escalation**—This explains the escalation rates used, how they were obtained, why they were selected, and how they were applied.

- **Documentation of Review and Concurrence**—This shows evidence that the estimate was reviewed and received concurrence.

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 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 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 office should ensure that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC or by a petition to the NRC. These mechanisms include rules, bulletins, generic letters, regulatory guides, orders, standard review plans, branch technical positions, and standard technical specifications.

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, backfit, forward fit, issue finality, and environmental review 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, 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. Because 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 independent cost estimates to cross-check NRC cost-benefit analyses on a case-by-case basis.

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ENCLOSURE B-1: COST ESTIMATE REVIEW CRITERIA

When reviewing the U.S. Nuclear Regulatory Commission (NRC) cost estimates, at a minimum, reviewers should use the generic criteria described in this enclosure. To be considered complete, the estimates should address all criteria. If all criteria are reasonably addressed, then the estimates represented may be considered quality, reasonable, and as accurate as possible. The estimates should also have been prepared by following the U.S. Government Accountability Office (GAO) 12-step process for developing a cost estimate (GAO, 2009), as recommended in this appendix.

The generic review criteria include the following:

- **Work-Breakdown Structure (WBS)**—If a WBS is used, ensure that the technical definition, the cost estimate, and the implementation schedule are consistent. The use of a common WBS should be considered for consistency between cost estimates.

- **Scope of the Problem**—Ensure that the cost estimate discusses the scope of the problem in terms of the classes of licensees or facilities being affected, including the number and size of facilities in the affected classes. The estimate should note any difference between the NRC and Agreement State licensees and identify the implications of taking no action (i.e., maintaining the status quo). Verify that the planning phase size and cost estimating modeling are commensurate with the scope of the problem and the alternatives identified. The cost estimate should be activity based, to the extent practicable.

- **Costs**—Ensure that the estimate includes all costs appropriately and documents and references all unit rates. The quantification should employ monetary terms whenever possible. Verify that the dollar values use constant dollar values (i.e., dollars of constant purchasing power).

- **Cost Estimate Ranges**—Ensure that the range of estimated cost or benefit inputs consider the proposed alternative's stage of development, size, complexity, and other factors, which may influence its cost. The cost estimate inputs should have a documented basis.

ENCLOSURE B-2: DEFINITIONS

The following are definitions of terms used within this appendix.

Activity-based costing

- costing using a method to ensure that the budgeted amounts in an account truly represent all the resources consumed by the activity or item represented in the account

- cost estimating in which the project is divided into activities and an estimate is prepared for each activity; also used with detailed, unit cost, or activity-based cost estimating

Actual cost—the costs actually incurred and recorded in accomplishing work performed

Allowance—an amount included in a base-cost estimate to cover known but undefined requirements

Analysis—the separation of a whole (project) into parts; examination of a complex entity, its elements, and their relationships; a statement of such analysis

Assumptions—factors used for planning purposes that are considered true, real, or certain. Assumptions affect all aspects of the estimating process and the progression of the project activities. (Generally, the assumptions will contain an element of risk.)

Baseline—a quantitative definition of cost, schedule, and technical performance that serves as a standard for estimating incremental costs and benefits of alternatives

Basis (basis of estimate)—documentation that describes how an estimate was developed and defines the information used in support of its development

Benchmark—a standard by which performance may be measured

Bias—a repeated or systematic distortion of a statistic or value, imbalanced about its mean

Bounding assumption—identified risks that are totally outside the control of the project team and therefore cannot be managed (i.e., transferred, avoided, mitigated, or accepted)

Buried contingency—costs that may have been hidden in the details of an estimate. To reviewers, buried contingency often implies inappropriately inflated quantities, lowered productivity, or other means to increase estimated costs or benefits. Buried contingency should not be used in NRC cost-estimates

Code of accounts—systematic coding structure for organizing and managing asset, cost, resource, and schedule information; an index to facilitate finding, sorting, compiling, summarizing, and otherwise managing information to which the code is tied. A complete code of accounts includes definitions of the content of each account

Conceptual design—the concept that meets a regulatory need; requires a regulatory need as an input. Concepts for meeting a regulatory need are explored and alternatives considered before arriving at the set of alternatives that are technically viable, affordable, and sustainable

Confidence (confidence level)—the probability that a cost estimate can be achieved or bettered; typically determined from a cumulative probability profile (see *cumulative distribution function*) that is the output from a Monte Carlo simulation

Construction—a combination of engineering, procurement, erection, installation, assembly, demolition, or fabrication to create a new facility or to alter, add to, rehabilitate, dismantle, or remove an existing facility; includes alteration and repair (dredging, excavating, and painting) of buildings, structures, or other real property and construction, demolition, and excavation conducted as part of environmental restoration or remediation

Consequence—the outcome of an event

Construction management—a wide range of professional services relating to the management of a project during the predesign, design, and construction phases; includes development of project strategy, design review of cost and time consequences, value management, budgeting, cost estimating, scheduling, monitoring of cost and schedule trends, procurement, observation to ensure that workmanship and materials comply with plans and specifications, contract administration, labor relations, construction methodology and coordination, and other management of construction acquisition

Contingency or contingency reserve—an amount within a project budget estimate that is derived from a structured evaluation of identified risks, to cover a likely future event or condition, arising from presently known or unknown causes, within a defined project scope. Contingency is funding related and is not used in NRC regulatory analysis cost estimates.

Correlation—the relationship between variables such that changes in one (or more) variable(s) are generally associated with changes in another. Correlation is caused by one or more dependency relationships. It is the measure of a statistical or dependence relationship existing between two items estimated for accurate quantitative risk analysis

Cost account—the point at which budgets (resource plans) and actual costs are accumulated and compared to earned value for management control purposes; a natural management point for planning and control that represents work assigned to one responsible organization on one work breakdown structure element

Cost accounting—historical reporting of actual or committed disbursements (costs and expenditures) on a project. Costs are denoted and segregated within cost codes that are defined in a chart of accounts. In project control practice, cost accounting provides a measure of cost commitment and expenditure that can be compared to the measure of physical completion (earned value) of an account

Cost-benefit analysis—the systematic, quantitative method of assessing the desirability of proposed regulatory actions

Cost-effective analysis—one method to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practicable (i.e., from the lack of methodologies or data) to consider the dollar value of the benefits provided by the alternatives under consideration. Cost-effective analysis values policy consequences in monetary terms; the difference is that at least one policy consequence is not valued but, instead, is quantified in physical units. The analysis then quantifies the monetized value in terms of one physical unit. The alternative with the largest benefits per unit (or the smallest costs per unit) would normally be preferred

Cost estimate—a documented statement of costs to be incurred to complete a proposed regulatory action

Cumulative distribution function—a statistical function based on the accumulation of the probabilistic likelihood of occurrences. In the case of the cost estimate uncertainty analysis, it represents the likelihood that, at a given percentage, the project cost will be at or below a given value. As an example, the x-axis might represent the range of potential cost estimate values evaluated by the Monte Carlo simulation and the y-axis might represent the project's probability of the costs being less than or equal to that value

Decision analysis—the process for assisting decisionmakers in capturing judgments about risks as probability distributions, having a single value measure, and putting these together with expected value calculations

Delphi technique—the technique for gathering information used to reach consensus within a group of subject matter experts on a particular item. Generally, a questionnaire is used on an agreed set of items regarding the matter to be decided. Responses are summarized, and further comments elicited. The process is often repeated several times. The technique is used to reduce bias in the estimate

Discount rate—the interest rate used in calculating the present value of expected yearly benefits and costs (see definitions for *nominal interest rate* and *real interest rate*)

Escalation—the provision in actual or estimated costs for an increase in the cost of equipment, material, and labor, for example, from continuing price level changes over time; inflation may be a component of escalation, but nonmonetary policy influences, such as supply and demand, are often components

Estimate—the assessment of the most likely quantitative result (generally, it is applied to costs and durations with a confidence percentage indication of the likelihood of its accuracy)

Estimate uncertainty—the inherent accuracy of a cost-benefit estimate; it represents a function of the level of project definition that is available, the resources used (skill set and knowledge) and time spent to develop the cost estimate and the data (e.g., vendor quotes, catalogue pricing, historical databases) and methodologies used to develop the cost estimate

Expert interviews—the process of seeking opinions or assistance on the project from subject matter experts

Facilities—buildings and other structures; their functional systems and equipment; site development features such as landscaping, roads, walks, and parking areas; outside lighting and communications systems; central utility plants; utility supply and distribution systems; and other physical plant features

Historical cost information—a database of information from completed projects normalized to some standard (e.g., geographical, national average) and time-based (e.g., brought to current year data) using historical cost indices

Improvements to land—site clearing, grading, drainage, and facilities common to a project as a whole (such as roads, walks, paved areas, fences, guard towers, railroads, and port facilities) but

excluding buildings, structures, utilities, special equipment or process systems, and demolition, tunneling, and drilling that are a significant intermediate or end product of the project

Independent cost estimate—a cost estimate, prepared by an organization independent of the cost-benefit analysis preparation, using the same detailed technical and procurement information to make the project estimate; it can be used to validate the project estimate to determine whether it is accurate and reasonable

Independent cost review—an independent evaluation of a project's cost estimate that examines its quality and accuracy, with emphasis on specific costs and technical risks; it involves the analysis of the existing estimate's approach and assumptions

Inflation—the proportionate rate of change in general price, as opposed to the proportionate increase in a specific price

Influence diagram—a graphical aid to decisionmaking under uncertainty, it depicts what is known or unknown at the time of making a choice, and the degree of dependence or independence (influence) of each variable on other variables and choices

Key risk—a set of risks considered to be of interest to the project team; those risks estimated to have the most impact on costs and benefits and could include project, technical, internal, external, and other subcategories of risk

Lessons learned—a formal or informal set of "lessons" collected from project or program experience that can be applied to future projects or programs; lessons can be gathered at any point during the life of the project or program

Level of effort (LOE)—a form of parametric estimating. LOE is used to determine future repetitive costs based on past cost data (e.g., if two employees spent 1,000 person-hours to develop a guidance document last year, then similar documents may need a similar LOE). Often, LOE estimates have few parameters or performance objectives from which to measure or estimate but are carried for several time periods at a similar rate (e.g., the number of workers for a specified amount of time). LOE estimates are normally based on hours and the number of full-time equivalents

Life cycle—the length of time over which an alternative is analyzed

Management reserve— funds set aside 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. Management reserve is not used in the NRC regulatory analysis cost estimates

Monte Carlo analysis—a method of calculation that approximates solutions to a variety of mathematical problems by performing statistical sampling experiments using a computer

Net present value—the difference between the discounted present values of benefits and costs

Nominal interest rate—a rate that is not adjusted to remove the effects of actual or expected inflation; market interest rates are generally nominal interest rates

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)—a spectrum of estimated costs or benefits for a proposed regulatory alternative. Ranges may be established based on 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 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)

Risk assessment—identification and analysis of project and program risks, ensuring an understanding of each risk in terms of probability and consequences

S-curve (spending curve)

- a graphic display of cumulative costs, labor hours, or other quantities plotted against time; named from the S-shaped curve (flatter at the beginning and end, steeper in the middle) produced on a project that starts slowly, accelerates, and then slows again

- a representation of costs over the life of a project

Sensitivity analysis—an analysis that considers all activities associated with one cost estimate. If a cost estimate can be sorted by total activity cost, unit cost, or quantity, sensitivity analyses can determine which activities are cost drivers. A sensitivity analysis is used to determine what variables most affect the mean cost estimate

Simulation (Monte Carlo)—a process for modeling the behavior of a stochastic (probabilistic) system. A random sampling technique is used to obtain trial values for key uncertain model input variables; repeating the process for many trials allows creation of a frequency distribution that approximates the true probability distribution for the system's output

Triangle distribution—a subjective distribution of a population for which there is limited sample data. It is based on knowledge of the minimum and maximum and a best estimate as to what the modal value might be. It is also used as an alternative to the Beta distribution or PERT distribution

Uncertainty analysis—an analysis that considers all activities associated with one cost estimate and their associated risks. An uncertainty analysis may also be considered part of a risk analysis or risk assessment

Unidentified risks (or unknown unknowns)—risks that were not anticipated or foreseen. Unidentified risks might originally be unanticipated because the probability of the event is so small that its occurrence is virtually unimaginable. Alternatively, an unidentified risk might be one that falls into an unanticipated or uncontrolled risk-event category

Work-breakdown structure (WBS)—the product-oriented grouping of project elements that organizes and defines the total scope of the project; a multilevel framework that organizes and graphically displays elements representing work to be accomplished in logical relationships. Each descending level represents an increasingly detailed definition of a project component. Components may be products or services. The structure and code integrate and relate all project work (technical, schedule, and cost) and are used throughout the life cycle of a project to identify and track specific work scope. Note: The WBS should not be developed or organized along financial or organizational lines. It should be broken into organized blocks of work scope and scope-related activities. Financial or organizational identification needs should be attached as separate codes that relate to the WBS element

Work package—a task or set of tasks performed within a control account

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 (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.

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
  - current project status
  - major issues and problems

  - project organization
  - work-breakdown structure (WBS)

- Project schedule should include, but not be limited to, the following:
  - milestones
  - critical path

- Design and estimate documentation/backup should include, but not be limited to, the following:
  - project information, such as:
    - facilities descriptions
    - plot plans and layout drawings
    - piping and instrumentation drawings, process diagrams
    - electrical one-line drawings
    - system descriptions
  - design-basis documentation
    - cost estimate summary
    - cost estimate details
    - cost estimate backup data, such as:
  - vendor quotes
  - labor rates
  - productivity factors
  - estimate basis and assumptions
  - overhead and markup assumptions and calculations
  - labor estimates

- ICR/ICE results should include, but not be limited to, the following:
  - current estimate
  - estimate basis (all major components)
  - uncertainty analysis
  - escalation
  - major assumptions
  - resource availability and leveling analysis

Reconciliation of Independent Cost Review and Independent Cost Estimate and Project Estimate

- A draft of the ICE report is generated, representing the consensus of both the U.S. Nuclear Regulatory Commission (NRC) project manager and the ICE contractor, and includes the ICE contractor's report as support for the draft ICE report.

- The ICE report includes the team leader's programmatic observations and comments.

- The draft ICE report is transmitted to the project office for review and comments.

- The ICE team leader reviews the comments with the support contractor to determine whether the major differences between the project estimate and the ICE can be resolved in a teleconference or if a face-to-face meeting is required for reconciliation.

- Reconciliations include the following:
  - Concentrate on major cost differences or items of special interest.
  - Reconciliation does not necessarily mean consensus.
  - An attempt should be made to keep reconciliations nonadversarial.
  - If data are presented at the reconciliation that proves the ICE is in error, the ICE should be changed. The project team should adhere to this rule as well.
- A final draft ICE report will be developed to reflect any changes resulting from the reconciliation meeting.

Independent Cost Estimate Report Contents

The ICE report should contain the following:

- executive summary
- background (including project cost/baseline history)
- project status
- technical baseline description
- information available to the ICE team
- cost estimate methodology(s) used
- comparison of project estimate and the ICE by WBS
- variance analysis
- uncertainty analysis
- conclusions
- recommendations

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-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.

Table B-7 Twelve Steps of High-Quality Cost Estimating Mapped to the Characteristics of a High-Quality Cost-Benefit Analysis

Cost-benefit analysis characteristic	Cost estimating step [a]
Well documented. The analysis is thoroughly documented, including inputs, clearly detailed calculations and results, and explanations for choosing a particular method or reference. Well documented characteristics include: • Data are traced back to the source documentation • Includes a technical baseline description • Documents all steps in developing the estimates so that a cost analyst could recreate the analysis with the same result • Documents all data sources including how the data were normalized • Describes the estimating methodology and rationale used to estimate costs and benefits.	1. Define the estimate's purpose. 3. Define program characteristics. 5. Identify ground rules and assumptions. 6. Obtain data. 10. Document the estimate. 11. Present the estimate to management for approval.
Comprehensive. The analysis level of detail is sufficient to ensure that cost-benefit elements necessary to model the incremental changes are neither omitted nor double counted. This is demonstrated by ensuring that the analysis: • Details all cost-influencing ground rules and assumptions • Describes each cost-benefit element	2. Develop an estimating plan. 4. Determine the estimating structure.

Cost-benefit analysis characteristic	Cost estimating step [a]
Accurate. The analysis is unbiased, not overly conservative or overly optimistic, and based on an assessment of most likely costs and benefits. This is demonstrated by ensuring that the analysis: • Has few, if any, mathematical mistakes, and any mistakes are minor • Has been validated for errors like double counting and omitted costs • Identified and analyzed cost drivers • Is timely • Is updated to reflect changes in technical or regulatory assumptions and information from public outreach, feedback, or comments, and from phases or milestones	7. Develop a point estimate and compare it to an independent cost estimate. 12. Update the estimate to reflect actual costs and changes.
Credible. Discusses any limitations of the analysis from uncertainty or biases surrounding data or assumptions: • Major assumptions are realistic and varied, and other outcomes are recomputed to determine their sensitivity to changes in assumptions • Risk and uncertainty analysis is performed to determine the level of risk associated with the estimate • An independent cost estimate is developed to determine if other estimating methods produce similar results	7. Develop a point estimate and compare it to an independent cost estimate. 8. Conduct a sensitivity analysis. 9. Conduct a risk and uncertainty analysis.

[a] Cost estimating steps are from Table B-1 of this appendix.

Validating Cost-Benefit Analyses

If assumptions are optimistic, then the cost-benefit analysis could be unrealistic. As a result, the costs may be underestimated. One way to avoid this issue is to ensure that cost-benefit analyses are generated early in the process so that the analyses can benefit from internal review and public comment. This increases the confidence that the cost-benefit analysis is reasonable and as accurate as possible.

The following steps should be taken to verify the quality of a cost-benefit analysis:

1. Determine That the Cost-Benefit Analysis Is Well Documented

Cost-benefit analyses are considered valid if they are well documented, they can be reproduced or updated, and inputs can be traced to their original sources. Well-documented analyses increase its credibility and help support management's decisionmaking. The documentation should identify the primary methods, calculations, results, assumptions, and data sources used to generate the analysis.

Cost-benefit analysis documentation should be detailed sufficiently to provide an accurate assessment of the document's quality based on the following characteristics:

- Data sources are identified and cited
- Assumptions are identified and justified
- The estimating method(s) used are described and documented

These qualities should allow a qualified analyst to replicate or update the analysis.

2. Determine That the Cost-Benefit Analysis Is Comprehensive

Analysts should make sure that the cost-benefit analysis is complete and accounts for all costs and benefits that are likely to occur. The analyst should confirm the document's completeness, its consistency, and the realism of its inputs and results to ensure that all pertinent costs and benefits are included and that the results are technically reasonable. In addition, the cost-benefit analysis should be documented in sufficient detail to ensure that cost-benefit elements are neither omitted nor double counted.

To determine whether a cost-benefit analysis is comprehensive, the cost-benefit analysis review and concurrence process should ensure that the cost-benefit analysis meets its intended purpose. During the review and concurrence process, the reviewer verifies that the cost-benefit analysis adequately evaluates the proposed regulatory change, using a methodology that accounts for changes in costs and benefits resulting from the proposed regulatory changes over the time period in which cost and benefits would be incurred. In addition, the reviewers on concurrence should satisfy themselves that all assumptions, applicability statements, and scope exclusions are identified, explained, and reasonable.

3. Determine That the Cost-Benefit Analysis Is Accurate

Cost-benefit analyses are accurate when they are not overly conservative or too optimistic, when they are based on an assessment of most likely costs and benefits, when inputs are properly normalized to the base year, and when the analysis contains few, if any, mistakes. In addition, when inputs, alternatives, timing, or other assumptions change, the cost-benefit analysis is revised to reflect the current status.

Validating that a cost-benefit analysis is accurate requires thoroughly understanding and investigating how the cost-benefit analysis was prepared. For example, all cost-benefit elements should be checked to verify that the calculations are accurate and account for all costs and benefits, including indirect costs and benefits. Moreover, inputs should be normalized so that data are expressed consistently and accurately in constant, base year dollars. In addition, checking modelling calculations and data input is imperative to validate the cost-benefit model accuracy.

Besides these basic checks for accuracy, the estimating technique used and the distribution selected for each cost-benefit element should be reviewed to make sure it is appropriate. Depending on the methodology used in the cost-benefit analysis, several questions should be used to assess the cost-benefit analysis accuracy. Table B-8 provides typical questions that should be used to assess accuracy associated with various estimating techniques.

Table B-8 Questions for Checking the Accuracy of the Cost-Benefit Analysis

Technique	Questions
Analogy	• Are the analogous data from reliable sources? • Did technical experts validate the data applicability and the scaling factor, if used? • Can any unusual requirements invalidate the use of this analogous data for this application? • Are the parameters used to develop an analogous factor similar to the changes being estimated? • What adjustments are made to account for differences between how the data was originally used and how the data is used in this application? Are they logical, credible, and acceptable?
Data Collection	• How old are the data? Are the data still relevant for its intended use? • Is there enough knowledge about the data source to determine if it can be used to estimate accurate costs and benefits for the intended use? • Has a data scatter plot been developed to determine whether any outliers, relationships, correlations, or trends exist? • Were descriptive statistics generated to describe the data, such as the mean, standard deviation, and coefficient of variation? • If data outliers were removed, did the data fall outside three standard deviations? Was the removal of outlier data identified and justified? Were comparisons made to historical data to show the outliers were an anomaly? • Were the data properly normalized?
Engineering Buildup	• Was each work breakdown structure (WBS) cost element defined in enough detail to use this method correctly? • Are data adequate to accurately estimate the cost or benefit of each WBS cost-benefit element? • Did experts help determine or provide input for the estimates of each cost-benefit element? • Is each WBS cost-benefit element composition defined? • Were labor rates based on credible sources (e.g., national wage data, NRC payroll data)? Did the labor rates include only variable costs (e.g., salary, pension, insurance premiums, and legally required benefits), which is directly related to the implementation, operation, and maintenance of incremental changes resulting from proposed regulatory actions?[a] • Is a detailed and accurate materials and parts list available? Was it used?
Expert Opinion	• Do quantitative historical data support the estimates received from expert opinion? • Did the estimate account for the possibility that bias influenced the results or that the lower and upper bounds estimated by experts tend to represent the 15 percent and 85 percent level, respectively, of all possible outcomes?[b]
Extrapolate from actuals (e.g., averages, learning curves, or estimates at completion)	• Were cost reports (e.g., NRC dynamic web site) that were extracted from historical actuals validated as appropriate for use in this application? • Was the cost element at least 25% complete before using its data as an extrapolation? How was the data normalized? • Were functional experts consulted to validate the appropriateness of using this cost data in this application? • Are recurring and nonrecurring costs and benefits separated to avoid double counting? • How are first unit costs of the learning curve determined? What historical data are used to determine the learning curve slope? • Are recurring and nonrecurring costs separated when the learning curve was developed? • How are partial units treated in the learning curve equation, if applicable?

Technique	Questions
Parametric	• Was a valid cost estimating relationship (e.g., CER), between historical costs and the physical and performance characteristics established? • How logical is the relationship between key cost drivers and cost? • Was the CER used to develop the estimate validated and accepted? • How old are the data? Are the data still relevant for use in this intended application? • Do the independent variables fall within the CER data range? • What is the level of variation in the CER? How well does the CER explain the variation and how much of the variation does the model not explain? • Do any outliers affect the overall fit? • How significant is the relationship between cost and its independent variables? • How well does the CER predict costs?

[a] Labor rates are burdened consistent with the methodology in Abstract 5.2 of NUREG/CR-4627. Fully burdened labor rates are generally not used in these analyses.
[b] GAO-09-3SP, "Expert Opinion, pages 161 and 162.

Validating Parametric Cost Estimating Relationships and Cost-Benefit Models

Cost estimating relationships (CERs) and cost-benefit models are validated to demonstrate that they can predict costs and benefits within an acceptable range of accuracy. To do this, data from historical programs similar to the new program should be collected to determine whether the CER selected is a reliable predictor of costs and benefits. In performing this review, the analyst should review the technical parameters for the historical programs to determine whether they are similar to the cost-benefit analysis being performed. For the CER to be accurate, the new and historical programs should have similar functions, objectives, and program factors, like acquisition strategy, or results could be misleading.

Before a parametric model is used in a cost-benefit analysis, the model should be calibrated and validated to ensure that it is based on current, accurate, and complete data and is therefore a good predictor of cost and benefits. Validation with calibration gives confidence that the model is a reliable estimating technique. To evaluate a model's ability to predict costs and benefits, the analyst can perform a variety of assessment tests. One test is to compare calibrated values with independent data that were not included in the model's calibration. Comparing the model's results to the independent test data's known value provides a useful benchmark for how accurately the 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 this NUREG) 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.

ENCLOSURE B-5: CROSS-REFERENCE TO GAO-09-3SP

Table B-9 provides a cross-reference of the Government Accountability Office's (GAO's) 12-step process for developing a cost estimate and the implementing tasks[1] to the section of this appendix that contains guidance for accomplishing those steps.

Table B-9 Cross-Reference to GAO-09-3SP Best Practices

GAO Project Phase	GAO Best Practice	GAO Associated Task	Where Conformance to GAO Practice is Demonstrated
INITIATION AND RESEARCH—Your audience, what you are estimating, and why you are estimating it are of the utmost importance.	Step 1: *Define the estimate's purpose.*	Determine the estimate's purpose, required level of detail, and overall scope.	Guidance related to the purpose of the estimate can be found in Section B.2.1.
		Determine who will receive the estimate.	
	Step 2: *Develop an estimating plan.*	Determine the cost estimating team and develop its master schedule.	Guidance related to planning the estimate development can be found in Section B.4.1.
		Determine who will do the independent cost estimate.	
		Outline cost estimating approach.	
		Develop the estimating timeline.	
ASSESSMENT—Cost assessment steps are iterative and can be accomplished in varying order or concurrently.	*Step 3: Define the program characteristics*	In a technical baseline description document, identify the program's purpose and its system and performance characteristics and all system configurations.	Guidance related to program characteristics and requirements for cost estimates are discussed in Section B.3.
		Describe technology implications.	
		Describe acquisition schedule and strategy.	
		Describe relationship to other existing systems, including predecessor or similar legacy systems.	
		Define support (e.g., manpower, training) and security needs and risk items.	
		Develop system quantities for development, test, and production.	
		Develop system quantities for development, test, and production.	
		Define deployment and maintenance plans.	
	Step 4: *Determine the estimating structure.*	Define a work-breakdown structure (WBS) and describe each element in a WBS dictionary (a major automated information system may have only a cost-element structure).	Guidance relative to estimate structure is found in Sections B.2.2 and B.7.4.1.

[1] Figure 1, "The Cost Estimating Process," in the main document identifies the GAO project phase. Table 2, "The Twelve Steps of a High-Quality Cost Estimating Process," in the main text (and Table B-1) lists the GAO best practice and the GAO associated task from GAO-09-3SP, "GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs," issued 2009.

GAO Project Phase	GAO Best Practice	GAO Associated Task	Where Conformance to GAO Practice is Demonstrated
		Choose the best estimating method for each WBS element.	
		Identify potential cross-checks for likely cost and schedule drivers.	
		Develop a cost estimating checklist.	
	Step 5: *Identify ground rules and assumption*s.	Clearly define what the estimate includes and excludes.	The concepts related to ground rules and assumptions are discussed in Section B.7.4 and in Tables B-1, B-2, and B-5.
		Identify global and program-specific assumptions, such as the estimate's base year, including time phasing and life cycle.	
		Identify the estimate's base year, including time phasing and life cycle.	
		Identify program schedule information by phase and program acquisition strategy.	
		Identify any schedule or budget constraints, inflation assumptions, and travel costs.	
		Specify equipment the government is to furnish, as well as the use of existing facilities or new modifications or development.	
		Identify the prime contractor and major subcontractors. Determine technology refresh cycles, technology assumptions, and new technology to be developed.	
		Define the commonality with legacy systems and assumed heritage savings.	
		Describe the effects of new ways of doing business.	
	Step 6: *Obtain data.*	Create a data collection plan with emphasis on collecting current and relevant technical, programmatic, cost, and risk data.	Estimate data sources and associated guidance can be found in Sections B.4, B.7.3, and B.7.4 and in Table B-1.
		Investigate possible data sources.	
		Collect data and normalize them for cost accounting, inflation, learning, and quantity adjustments.	
		Analyze the data for cost drivers, trends, and outliers and compare results against rules of thumb and standard factors derived from historical data.	
		Interview data sources and document all pertinent information, including an assessment of data reliability and accuracy.	
		Store data for future estimates.	

GAO Project Phase	GAO Best Practice	GAO Associated Task	Where Conformance to GAO Practice is Demonstrated
	Step 7: *Develop a point estimate and compare it to an independent cost estimate.*	Develop the cost model, estimating each WBS element, using the best methodology from the data collected, and including all estimating assumptions.	The techniques available for estimate development are described in Section B.5 and the estimate development process itself is discussed extensively in Section B.7.4. Independent cost estimates are discussed in Sections B.7.4 and B.7.7 and more extensively in Section B.9.2.
		Express costs in constant-year dollars.	
		Time phase the results by spreading costs in the years they are expected to occur.	
		Sum the WBS elements to develop the overall point estimate.	
		Validate the estimate by looking for errors like double counting and omitted costs.	
		Compare the estimate against the independent cost estimate and examine where and why there are differences.	
		Perform cross-checks on cost drivers to see if results are similar.	
		Update the model as more data become available or as changes occur and compare results against previous estimates.	
ANALYSIS—The confidence in the point or range of the estimate is crucial to the decisionmaker.	Step 8: *Conduct a sensitivity analysis.*	Test the sensitivity of cost elements to changes in estimating input values and key assumptions.	The concept of a sensitivity analysis is discussed in Sections B.4.3 and B.7.4.5 as a subset of the uncertainty analysis. However, the requirements for such analyses can also be found throughout this guidance document.
		Identify effects on the overall estimate of changing the program schedule or quantities.	
		Determine which assumptions are key cost drivers and which cost elements are affected most by changes.	
	Step 9: *Conduct a risk and uncertainty analysis.*	Determine and discuss with technical experts the level of cost, schedule, and technical risk associated with each WBS element.	An explanation of the NRC's guidance relative to risk and uncertainty analysis can be found in Section B.7.4.5.
		Analyze each risk for its severity and probability.	
		Develop minimum, most likely, and maximum ranges for each risk element.	
		Determine type of risk distributions and reason for their use.	
		Ensure that risks are correlated.	
		Use an acceptable statistical analysis method (e.g., Monte Carlo simulation) to develop a confidence interval around the point estimate.	

GAO Project Phase	GAO Best Practice	GAO Associated Task	Where Conformance to GAO Practice is Demonstrated
		Identify the confidence level of the point estimate.	
		Recommend that the project or program office develop a risk management plan to track and mitigate risks.	
	Step 10: *Document the estimate.*	Document all steps used to develop the estimate so that a cost analyst unfamiliar with the program can recreate it quickly and produce the same result.	Estimate documentation is discussed in Section B.7.7.
		Document the purpose of the estimate, the team that prepared it, and who approved the estimate and on what date.	
		Describe the program, its schedule, and the technical baseline used to create the estimate.	
		Present the program's time-phased life-cycle cost.	
		Discuss all ground rules and assumptions.	
		Include auditable and traceable data sources for each cost element and document, for all data sources, how the data were normalized.	
		Describe in detail the estimating methodology and rationale used to derive each WBS element's cost (prefer more detail over less).	
		Describe the results of the risk, uncertainty, and sensitivity analyses.	
		Document how the estimate compares to the funding profile.	
		Track how this estimate compares to any previous estimates.	
PRESENTATION—Documentation and presentation make or break a cost estimating decision outcome.	*Step 11: Present the estimate to management for approval.*	Develop a briefing that presents the documented life-cycle cost estimate (LCCE).	Guidance related to the presentation of estimate results can be found in Sections B.7.4.6 and B.7.7.
		Include an explanation of the technical and programmatic baseline and any uncertainties	
		Compare the estimate to an independent cost estimate (ICE) and explain any differences.	
		Compare the LCCE or ICE to the budget with enough detail to easily defend it by showing how it is accurate, complete, and of high quality.	

GAO Project Phase	GAO Best Practice	GAO Associated Task	Where Conformance to GAO Practice is Demonstrated
		Focus in a logical manner on the largest cost elements and cost drivers.	
		Make the content clear and complete, so that those who are unfamiliar with it can easily comprehend the competence that underlies the estimate results.	
		Make backup slides available for more probing questions.	
		Act on and document feedback from management.	
		Request acceptance of the estimate.	
	Step 12: Update the estimate to reflect actual costs and changes.	Update the estimate to reflect changes in technical or program assumptions or keep it current as the program passes through new phases or milestones.	Estimate updates to reflect changes in assumptions or to incorporate new information is discussed in Sections B.2.2, B.4.1, and B.7.7.
		Replace estimates with earned value management (EVM) and ICE from the integrated EVM system.[a]	
		Report progress on meeting cost and schedule estimates.	
		Perform a post mortem and document lessons learned for elements where actual costs or schedules differ from the estimate.	
		Document all changes to the program and how they affect the cost estimate.	

[a] The shaded boxes are not applicable to regulatory analysis cost estimates used to evaluate proposed actions affecting entities that the U.S. Nuclear Regulatory Commission (NRC) regulates. The NRC regulatory analyses are not intended to be living documents to monitor or control project costs. Updates to regulatory analysis estimates end when the NRC either finalizes and issues or withdraws the regulatory action.

APPENDIX C
TREATMENT OF UNCERTAINTY

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
GAO	U.S. Government Accountability Office
NRC	U.S. Nuclear Regulatory Commission
PERT	program evaluation and review technique
PRA	probabilistic risk assessment

TREATMENT OF UNCERTAINTY

C.1 INTRODUCTION

Identifying and assessing uncertainties are important aspects of an ~~good~~ analysis. ~~When appropriately considered in an assessment,~~ Uncertainty analysis provides insight regarding the effects that uncertain~~varying~~ inputs ~~can~~ have on ~~a range of outcomes and~~ results. In this appendix, two categories of such an analysis are considered for cost estimation purposes: (1) sensitivity analysis and (2) uncertainty analysis.

A sensitivity analysis assesses the~~how~~ sensitivity~~e~~ of outcomes ~~are~~ to variations in inputs. Typically, a sensitivity analysis characterizes the effect of varying one input at a time, but the analysis can also be used to characterize the effect of multiple inputs ~~together~~ on results ~~a given outcome~~. A sensitivity analysis typically does not assess the relative likelihood of different outcomes. 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 uncertainties~~y~~ in model inputs.

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. Risk assessments for nonreactor facilities often identify best estimates only.

C.2 TREATMENT OF UNCERTAINTY IN COST-BENEFIT ANALYSES

Regulatory, backfit, forward fit, issue finality, and environmental review analyses 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 and~~, as well as the perceived~~ significance of the uncertainties to the overall finding and conclusion.

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 the uncertainty analysis. This appendix will provide guidance on the appropriate treatment of uncertainty in cost-benefit analyses.

C.3 AVAILABLE GUIDANCE

~~Knowledge about uncertainty is extensive.~~ This appendix focuses on the use of current NRC and~~documents, supplemented by~~ GAO guidance on~~, to~~ performing uncertainty and sensitivity analyses in cost-benefit analyses. Specifically, analysts should consider NUREG-1855, "Guidance on the Treatment of Uncertainties Associated with PRAs [probabilistic risk assessments] in Risk-Informed Decision Making," Revision 1, and GAO-09-3SP, "GAO Cost Estimating and Assessment Guide—Best Practices for Developing and Managing Capital Program Costs," issued March 2009.

GAO-09-3SP provides detailed guidance on best practices in developing cost estimates and also explains how to develop the sensitivity and uncertainty analyses in support of those estimates. Specifically, it provides details on the following:

- determining the program cost drivers and associated risks
- developing probability distributions to model various types of uncertainty (e.g., program, technical, external, organizational, and program management, including cost estimating and scheduling)
- accounting for the correlation between cost elements to properly capture risk
- performing the uncertainty analysis using a Monte Carlo simulation model
- identifying the probability level associated with the point estimate
- identifying high-risk elements to help in risk mitigation efforts

C.3.1 Methodology

Uncertainty analysis is a process, not a result. The analyst is using many variables, each with statistical distributions, to determine the merits of implementing a regulatory requirement in rulemaking, to justify a facility modification ~~to a site~~, or to analyze other issues that require weighing the cost against the benefit of a~~the~~ change. ~~To complicate matters, the analyst is not the decisionmaker.~~ The task of the analyst is to present ~~the~~ results to support decisionmaking. Therefore, when developing an uncertainty analysis~~the study~~, the analyst should understand the individual variables as well as the cumulative impacts of those variables on the analysis. ~~Individual variables require sensitivity analyses of each variable, and cumulative impacts requires a combined analysis, such as that accomplished by a Monte Carlo simulation. Further,~~ ~~t~~The results of the analysis should evaluate the confidence interval for the cost-benefits that are presented to support an informed decision.

C.3.2 Sensitivity Analysis

~~Credible cost estimates clearly identify limitations because of uncertainty or bias surrounding the data or assumptions. Major assumptions should be varied and other outcomes recomputed to determine how sensitive outcomes are to changes in the assumptions. In addition, an uncertainty analysis should be performed to determine the level of risk (i.e., cost estimate uncertainty) associated with the estimate.~~

Using sensitivity analysis, the analyst can determine the importance of variables to the regulatory analysis. Variables that significantly affect the overall cost-benefit analysis should be identified. Figure C-1 lists the variables that should be evaluated. For each issue, the significant cost or benefit drivers may be different. The sensitivity analysis is performed by changing each variable and evaluating the impact on the result. A tornado diagram (Figure C-2) can illustrate the results of a sensitivity analysis. The tornado diagram helps to graphically display the results and illustrates the impact of each cost variable on the overall analysis.

For a sensitivity analysis to be useful, the analyst should assess the underlying risks and supporting data. Additionally, the sources of the variation should be well documented. For a sensitivity analysis to reveal how a change in a single assumption can affect the cost estimate, the analyst should examine the effect of changing one assumption or cost driver at a time, while holding all other variables constant. This method facilitates a better understanding of which variable most affects the cost estimate. In some cases, such as for discount rates or for the dollar per person-rem conversion factor, a sensitivity analysis can examine the effect of multiple assumptions changing in relation to a specific scenario. Regardless of whether the analysis is performed on only one cost driver, or several within a single scenario, the difference between the sensitivity analysis and uncertainty analysis is that a sensitivity analysis tries to isolate the effects of changing one variable at a time, while an uncertainty analysis examines the effects of many variables changing all at once to determine the level of risk associated with the estimate. By examining the effects of varying the estimate's elements, a degree of uncertainty about the estimate can be expressed with a range of potential costs and benefits that are qualified by a factor of confidence.

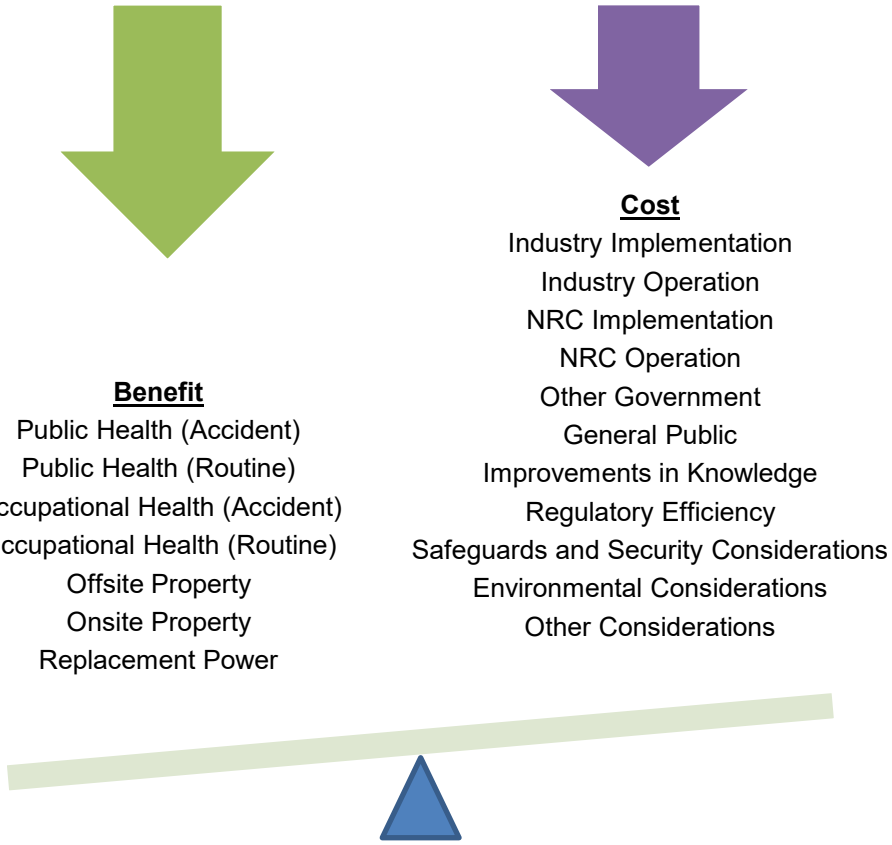

Figure C-1 Examples of Affected Variables that Support the Weighing of Costs and Benefits in a Regulatory Analysis

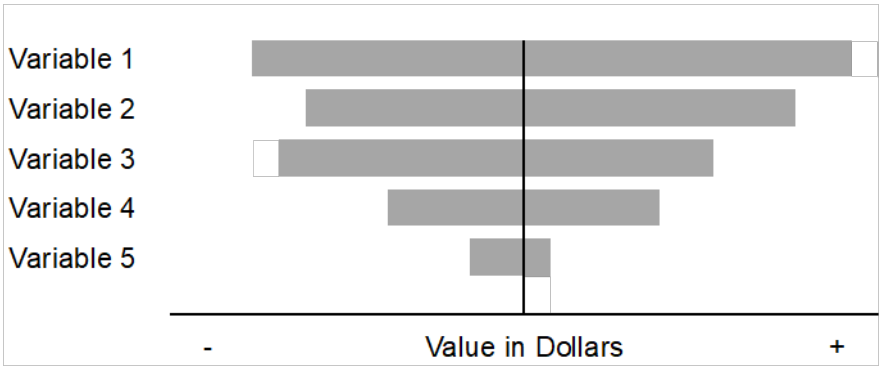

Figure C-2 Example of a Tornado Diagram

C.3.3 Monte Carlo Simulation

A sensitivity analysis typically changes one variable at a time to determine its impact. AThe Monte Carlo[1] simulation approximates the probability of results by performing multiple trials or simulations, each of which is based on randomly chosen input values from pre-defined distributionscombines all the variables statistically to determine the overall uncertainty in the results of the analysis. The availability of high-performance computers has facilitated numerical calculation using Monte Carlo simulation. However, the efficacy of the analysis depends on the pre-defined distributions of input data supporting the overall variables to determine the individual distributions for those elements. Since the NRC issued NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," in January 1997, a number of regulatory analyses and severe accident mitigation alternative analyses have been performed. These analyses provide data to help inform the overall benefit distributions for the regulatory analysis.

If input data are available, then the analyst should attempt to fit them into the appropriate distribution using a goodness-of-fit technique[2] for probability distributions. Table C-1 illustrates nine of the distributions that could be used in support of the regulatory analysis and shows when they would typically be used. For cost parameters, the program evaluation and review technique (PERT), represented as a beta distribution, is commonly used, which consists of low, best, and high estimates to evaluate the uncertainty. The PERT distribution is 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.

Once the distribution is obtained for each variable, the analyst can use a sensitivity analysis to determine which variables are more important to the analysis and then run the Monte Carlo simulation on that limited set. The analyst can run the simulation on all the variables by running a holistic simulation of both the benefit and the cost.

Table C-1 Nine Common Probability Distributions

Distribution	Description	Typical Application
Bernoulli	Assigns probabilities of "p" for success and "1 – p" for failure; mean = "p"; variance = "1 – p".	With likelihood and consequence risk cube models; good for representing the probability of a risk occurring but not for showing the impact on the program.
Beta	Similar to normal distribution but does not allow for negative cost or duration; this continuous distribution can be symmetric or skewed.	To capture outcomes biased toward the tail ends of a range; often used with engineering data or analogy estimates; the shape parameters usually cannot be collected from interviewees.
Lognormal	A continuous distribution positively skewed with a limitless upper bound and known lower bound; skewed to the right to reflect the tendency toward higher cost.	To characterize uncertainty in nonlinear cost estimating relationships; it is important to know how to scale the standard deviation, which is needed for this distribution.

[1] A Monte Carlo simulation is a computer-based method of analysis that uses statistical sampling techniques to obtain a probabilistic approximation to the solution of a mathematical equation or model.

[2] Goodness-of-fit techniques include formal statistical tests as well as graphical methods to measure how well predicted values match a set of observations.

Distribution	Description	Typical Application
Normal	Used for outcomes likely to occur on either side of the average value; symmetric and continuous, allowing for negative costs and durations. In a normal distribution, about 68% of the values fall within 1 standard deviation of the mean.	To assess uncertainty with cost estimating methods; standard deviation or standard error of the estimate is used to determine dispersion. Because data should be symmetrical, it is not as useful for defining risk, which is usually asymmetrical, but can be useful for scaling estimating error.
Program Evaluation and Review Technique (PERT)	The PERT distribution is similar to a triangular distribution, in that it has the same set of three parameters. Technically, it is a special case of a scaled beta distribution.	To express technical uncertainty, because it works for any system architecture or design; also used to determine schedule uncertainty. It is considered superior to the triangular distribution when the parameters result in a skewed distribution, as the smooth shape places less emphasis in the direction of the skew.
Poisson	Peaks early and has a long tail compared to other distributions.	To predict all kinds of outcomes, like the number of software defects or test failures.
Triangular	Characterized by three points (most likely, pessimistic, and optimistic values); can be skewed or symmetric and is easy to understand because it is intuitive. One drawback is the absoluteness of the end points, although this is not a limitation in practice because it is used in a simulation.	To express technical uncertainty, because it works for any system architecture or design; also used to determine schedule uncertainty.
Uniform	Has no peaks because all values, including highest and lowest possible values, are equally likely.	With engineering data or analogy estimates.
Weibull	Versatile as it can take on the characteristics of other distributions, based on the value of the shape parameter “b”—e.g., Rayleigh and exponential distributions can be derived from it.*	In life data and reliability analysis because it can mimic other distributions and has an objective relationship to reliability modeling.

* The Rayleigh and exponential distributions are a class of continuous probability distribution.

C.3.4 Results

Using the results from the Monte Carlo analysis, the analyst can then develop the cumulative distribution function illustrated in Figure C-3. This is an important tool to support the decisionmaking process. The distribution illustrates the confidence interval for the analysis and the cost associated with achieving a higher confidence interval. In this case, decisionmakers can evaluate the benefit of approving the change and also understand that the cost can vary considerably.

Any change in cost as the issue progresses from the conceptual stage to later stages in the development of regulatory requirements is important to communicate. Figure 15 in GAO-09-3SP illustrates this concept (shown here as Figure C-4). Issuing the implementation

guidance with the proposed rule ensures that the costs associated with the regulatory action accurately reflect the costs associated with implementing the change. As additional cost information is gained, the uncertainty band typically narrows, because of the availability of more accurate information and a better understanding of details of the requirement.

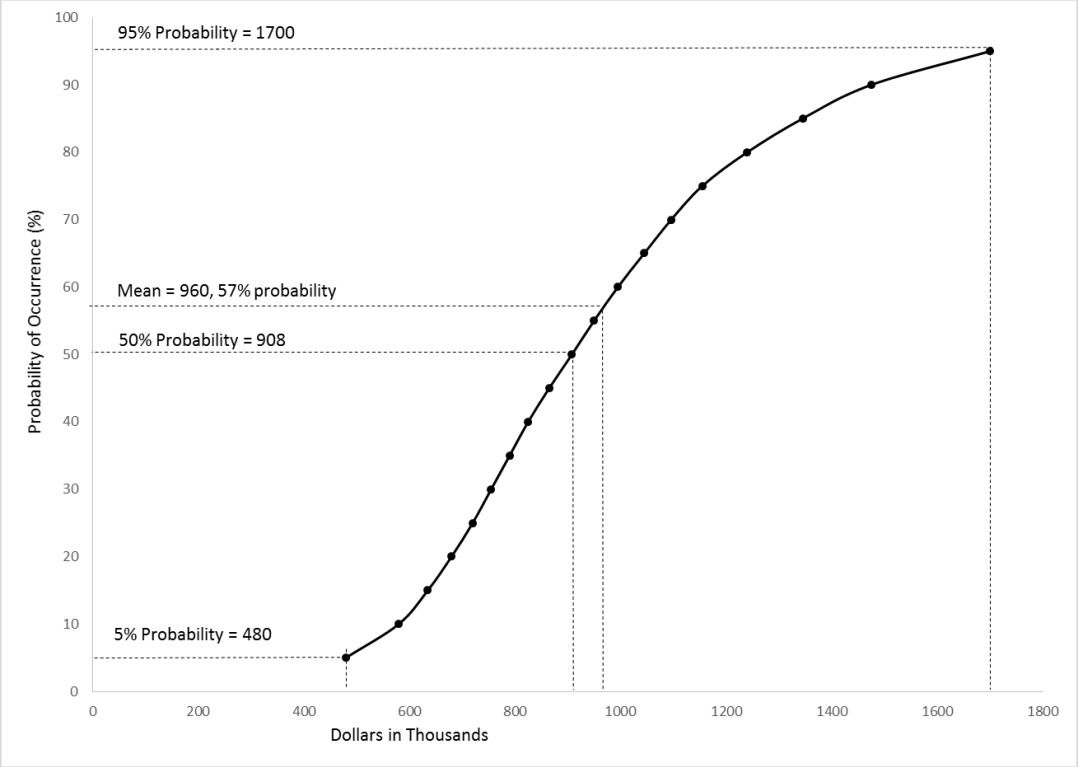

Figure C-3 Example of a Cumulative Distribution Function

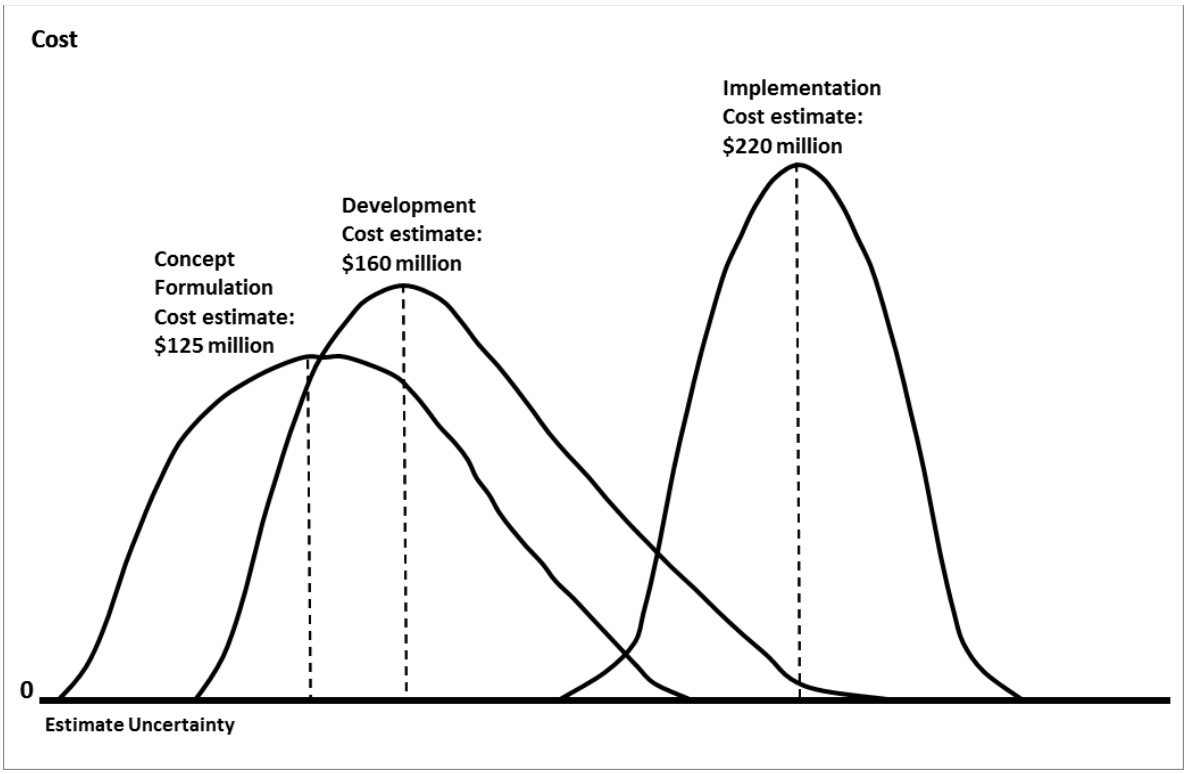

Figure C-4 Example of Change in Cost-Estimate Uncertainty

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

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

ASME	American Society of Mechanical Engineers
BPV	boiler and pressure vessel
CC	concrete containment
CFR	*Code of Federal Regulations*
FR	*Federal Register*
ISI	inservice inspection
IST	inservice testing
MC	metal containment
NRC	U.S. Nuclear Regulatory Commission
OM	operation and maintenance

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 and does not constitute a backfit or a forward fit.

- 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.

- In a typical incorporation of the ASME Code and associated Code Cases, the NRC incorporation by reference can involve hundreds, if not thousands, of individual provisions. Evaluating the benefit *vis-à-vis* the cost of each individual provision in a regulatory analysis would be prohibitive, and the value gained by performing such an exercise would be limited.

However, where the NRC : ~~(i)~~ imposes conditions or exceptions on the use of an ASME Code provision already incorporated by the NRC~~;(ii) incorporates a new provision of the ASME Code that is substantially different from existing requirements;~~ or ~~(iii)~~ requires that licensees adopt provisions of the ASME Code on an expedited schedule (i.e., sooner than the 120 month updating interval in 10 CFR 50.55a[1]), then the NRC prepares a regulatory analysis that is limited to the consideration of those provisions or circumstances for which the NRC is imposing conditions or the impact of the expedited adoption. These ~~three~~ cases represent situations where a regulatory analysis would be ~~justified~~ necessary to support ~~as a matter of~~ regulatory decisionmaking under the reasoned decisionmaking requirements of the Administrative Procedure Act ~~policy~~ and would require consideration of backfitting and forward fitting as described in NUREG-1409, "Backfitting Guidelines." ~~By contrast, the NRC need not prepare a regulatory analysis if the NRC is proposing a new condition on a new Code provision that is not present in an earlier Code Edition.~~

~~Finally~~In addition, where ~~the NRC determines that~~ one or more new ASME Code provisions are a significant departure from the overall approach embodied in the comparable provisions of the existing NRC-incorporated Code Editions[2], then the NRC will prepare a regulatory analysis for those Code provisions constituting such a significant departure, including consideration of backfitting and forward fitting as described in NUREG-1409, "Backfitting Guidelines." The NRC's rationale is that the regulatory approach embodied in 10 CFR 50.55a contemplated an evolutionary approach to ASME Code changes, with incremental changes to technical requirements within the purview of the Code. When the ASME Code Edition adopts a

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1 Examples in which the NRC required implementation of the later ASME BPV or OM Code provisions on an expedited basis are provided in the final rule (64 FR 51370; September 22, 1999) that incorporated by reference the 1989 Addenda through the 1996 Addenda of Section III and Section XI of the ASME BPV Code, and the 1995 Edition with the 1996 Addenda of the ASME OM Code and the final rule that incorporated by reference in 10 CFR 50.55a the 1986 Addenda through the 1989 Edition of Section III and Section XI of the ASME BPV Code (57 FR 34666; August 6, 1992).

2 Such cases are rare and should be considered exceptional. One example is the NRC's initial endorsement of Subsections IWE and IWL of Section XI, which imposed containment inspection requirements on operating reactors for the first time. The final rule (Volume 61 of the *Federal Register* (FR), page 41303 (61 FR 41303); August 8, 1996) incorporated by reference in 10 CFR 50.55a the 1992 Edition with the 1992 Addenda of Subsections IWL and IWE of Section XI to require that containments be routinely inspected to detect defects that could compromise a containment's structural integrity. This action expanded the scope of 10 CFR 50.55a to include components not considered by the existing regulations to be within the scope of in service inspections.

significantly new provision representing a fundamental paradigm shift in technical or regulatory terms, then a regulatory analysis is appropriate and ~~should~~ must be performed by the NRC.[3]

[3] An example of this case is presented in the portion of the final rule in which the NRC adopted requirements for dissimilar metal piping weld ultrasonic testing examination coverage that were different from those in the ASME Code (67 FR 60520; September 26, 2002).

D.2 REFERENCES

American Society of Mechanical Engineers (ASME), "Boiler and Pressure Vessel Code," New York, NY, Current Edition.

ASME, "Operation and Maintenance of Nuclear Power Plants Code," New York, NY, Current Edition.

National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, 110 Stat. 775. Available at http://energy.gov/ehss/national-technology-transfer-and-advancement-act-1995-public-law-pl-104-113.

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NRC, "Codes and Standards for Nuclear Power Plants; Subsection IWE and Subsection IWL," Final Rule, 10 CFR Part 50, *Federal Register*, Vol. 61, August 8, 1996, (61 FR 41303-41312). Available at https://www.gpo.gov/fdsys/pkg/FR-1996-08-08/pdf/96-20215.pdf.

NRC, "Industry Codes and Standards; Amended Requirements," Final Rule, 10 CFR Part 50, *Federal Register*, Vol. 64, September 22, 1999, (64 FR 51370-51400). Available at https://www.gpo.gov/fdsys/pkg/FR-1999-09-22/pdf/99-24256.pdf.

NRC, "Industry Codes and Standards; Amended Requirements," Final Rule, 10 CFR Part 50, *Federal Register*, Vol. 67, September 26, 2002, (67 FR 60520-60542). Available at https://www.gpo.gov/fdsys/pkg/FR-2002-09-26/html/02-23811.htm.

NRC, "Backfitting Guidelines," NUREG-1409. Available at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/.

KLS edits

APPENDIX E
SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

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ABBREVIATIONS AND ACRONYMS

ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
CDF	core damage frequency
CFR	*Code of Federal Regulations*
CRGR	Committee to Review Generic Requirements
EIS	environmental impact statement
MD	Management Directive
NEPA	National Environmental Policy Act
NRC	U.S. Nuclear Regulatory Commission
OMB	U.S. Office of Management and Budget
SBREFA	Small Business Regulatory Enforcement Fairness Act
U.S.C.	United States Code

SPECIAL CIRCUMSTANCES AND RELATIONSHIP TO OTHER PROCEDURAL REQUIREMENTS

E.1 INTRODUCTION

The purpose of this appendix is to provide uniform guidance to assist the analyst in preparing effective regulatory, backfit, forward fit, issue finality, and environmental review 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, backfit, forward fit, issue finality, and environmental review analyses continue to evolve, and applicable data may change over time. This appendix provides 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 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 (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," to this NUREG 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 action 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 backfitting 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 be considered in deciding whether the exceptions are justified (although costs may be considered in determining how to achieve a certain level of protection).[2]

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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 (10 CFR 50.109) and the provisions of the Committee to Review Generic Requirements (CRGR) Charter.

[2] In response to Commission direction (NRC, 2016a) ~~a December 2016 memorandum~~, the NRC Solicitor provided guidance in a December 2016 memorandum ~~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, 2016b). This is reflected in the policy in Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," that, in order to comply with the Administrative Procedure Act's reasoned decisionmaking requirement, there must be some consideration of cost except for instances when the NRC has reached a new or changed position with respect to whether regulatory action is needed to ensure adequate protection.

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 all of the individual requirements ~~is~~are needed for the regulatory action to resolve the problems and concerns and meet the stated objectives[3] that are the focus of the regulatory action. Even though inclusion of individual requirements is necessary in this case, the analyst should obtain separate cost and benefit estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements.

However, in some cases the individual requirement is not a necessary component of ~~the~~ a regulatory action and can stand on its own, and thus the NRC will have some discretion about its inclusion. In these circumstances, the NRC should consider that, if the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory action, it should be included only if its overall effect is to make the bundled regulatory requirement more cost beneficial. This would involve a quantitative or qualitative (or both) evaluation of the costs and benefits of the regulatory action, with and without the individual requirement included, and a direct comparison of those results.

In some circumstances, the analyst might consider including an individual requirement that is unrelated to the overall regulatory action. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory action more cost beneficial. Otherwise, the analysis must analyze this individual requirement separately to determine whether the effect of this change is cost-beneficial.

In general, the analyst should consider reasonableness and practicality when making a decision on the level of disaggregation. For example, more detailed disaggregation is appropriate only if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public comment stage.[4] This aligns with OMB guidance used in other regulatory agencies that:

> You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

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[3] The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule. The analyst should give caution to the mere inclusion of individual requirements in the stated objectives of a rule and consider whether they could be imposed separately.

[4] NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook," issued September 2005 (NRC Regulations Handbook), discusses the treatment of comments.

> Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis. (OMB, 2003)

A special case involves the NRC's periodic review and endorsement of consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. Appendix D, "Guidance on Regulatory Analysis Related to ASME Code Changes," to this NUREG provides guidance for addressing consensus standards.

E.2.4 Intergenerational Cost-Benefit Assessments

For certain regulatory actions, such as those involving decommissioning and waste disposal issues, the regulatory analysis may have to consider consequences that can occur over hundreds, or even thousands, of years. ~~The~~ OMB recognizes that special considerations arise when comparing benefits and costs across generations. Under these circumstances, ~~the~~ OMB continues to see value in applying discount rates of 3 and 7 percent. However, ~~ethical and~~ technical arguments can also support the use of lower discount rates. Thus, if a rule will have important intergenerational consequences, the analyst should consider supplementing the analysis with an explicit discussion of the intergenerational concerns, such as how the regulatory decision will affect future generations. Additionally, supplemental information could include a presentation of the costs and benefits at the time in which they are incurred with no present-worth conversion (e.g., no discounting). In this case, the resulting net cost should not be calculated. Also, the analyst should consider a sensitivity analysis using a lower, but positive, discount rate.

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 one or more classes of power reactors and, in some cases, selected 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 procedures and internal administrative process (NRC, 2018b) list 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]

A regulatory analysis prepared in accordance with this guidance document meets 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 proposed facility-specific or generic backfits to be imposed on NRC-licensed power reactors, new reactors, or selected nuclear materials facilities under applicable regulations, as discussed in Management Directive (MD) 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," and NUREG-1409, "Backfitting Guidelines."

The consideration of costs depends on whether the backfit meets certain exception criteria as described in NUREG-1409. The staff should prepare ~~a~~ backfitting documentation~~ed 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 backfitting documentation~~ed evaluation~~ are contained in MD 8.4 and NUREG-1409.

A regulatory analysis, in addition to any backfitting documentation, may be prepared in these instances for use as a management decisionmaking tool. In particular, if there is more than one way to achieve compliance or reach a level of adequate protection and the Commission finds it necessary or appropriate to specify the way, costs may be a factor in that decision. A regulatory analysis that explores the cost effectiveness of the various alternatives under consideration could therefore be valuable to a decisionmaker.

E.3.2 Paperwork Reduction Act

The Paperwork Reduction Act contains procedural requirements designed to minimize and control the burdens associated with collections of information by Federal agencies from

[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.

individuals, businesses, and other private entities, as well as State and local governments. The NRC provides its internal procedures for complying with the Paperwork Reduction Act and preparing justifications for OMB approval of information collections in the NRC Regulations Handbook and in Office of the Chief Information Officer guidance (NRC, 2014).

Whenever a proposed regulatory action will probably involve information collections subject to OMB approval, the NRC will prepare an OMB clearance package for the rulemaking. While the OMB clearance package need not be included as part of the rulemaking package that is submitted to the Office of the Executive Director for Operations or Commission for approval, the Office of the Chief Information Officer should approve the clearance package for its submittal to the OMB before the rule can be submitted to the Office of the *Federal Register* for publication.

Under the Paperwork Reduction Act, agencies are required to obtain OMB approval for collections of information if (1) the information collection involves 10 or more persons by means of identical questions or reporting or recordkeeping requirements, (2) the information collection is contained in a rule of general applicability, or (3) the collection is addressed to all or a substantial majority of an industry, even if that majority involves fewer than 10 persons (5 CFR 1320.3(c) and 5 CFR 1320.5, "General Requirements").

The OMB's criteria for approving information collections are contained in 5 CFR 1320.5(d)(1). To obtain OMB approval for information collections, an agency must demonstrate that the collection of information (1) is the least burdensome necessary for the proper performance of the agency's functions, (2) is not duplicative of information otherwise available to the agency, and (3) has practical utility. The agency should minimize its cost of collecting, processing, and using the information, but not by shifting disproportionate costs or burdens onto the public. Agencies should consult with interested agencies and members of the public to minimize the burden of the information collection to the public. OMB clearance packages identify any significant burdens placed on a substantial number of small businesses or entities (5 CFR 1320.9(c)).

If ~~the~~ OMB disapproves an information collection, independent regulatory agencies, such as the NRC, may override the disapproval or stay of effectiveness of approval of a collection of information by a majority vote of the Commissioners (5 CFR 1320.15, "Independent Regulatory Agency Override Authority").

E.3.3 Regulatory Flexibility Act

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis if a proposed rule will have a significant economic impact on a substantial number of small entities. The initial regulatory flexibility 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, codified at 10 CFR 2.810, "NRC Size Standards," to qualify a licensee as a small entity:

- A small business is a for-profit concern providing a service with average gross receipts of $7 million or less over its last 3 completed fiscal years, or a manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months.

- A small organization is a not-for-profit organization that is independently owned and operated and has annual gross receipts of $7 million or less.

- A small governmental jurisdiction is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000 people.

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

The NRC Regulations Handbook sets out procedural requirements for preparing regulatory flexibility analyses. The NRC public Web site provides a summary of these procedures (NRC, 2017). If a proposed rule would likely have a significant economic impact on a substantial number of small entities, the NRC must prepare an initial regulatory flexibility analysis, consistent with the NRC procedural requirements. After revisions are made to the rule package in response to public comments, the NRC must prepare a final regulatory flexibility analysis to update information and to explain what was done to minimize the adverse economic impact, as appropriate, of the rule on small entities. The agency issues a small-entity compliance guide along with the rule. The regulatory flexibility analysis may be included as an appendix to the regulatory analysis document and as an insert to the proposed rule. The regulatory flexibility analysis need not repeat information discussed in the body of the regulatory analysis; such information may be referenced. If the NRC determines that the rule would not have a significant economic impact on a substantial number of small entities, both the proposed rule and final rule will include a certification to this effect. The regulatory analysis should contain sufficient information concerning the potential impact of the proposed rule on small entities to support this certification.

E.3.4 Small Business Regulatory Enforcement Fairness Act

Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA) requires Federal agencies to publish a small-entity compliance guide for each rulemaking that requires a regulatory flexibility analysis under 5 U.S.C. 605(b). The Fair Minimum Wage Act of 2007 amended the SBREFA and requires agencies to (1) publish, distribute, and post on their public Web sites compliance guides on the same date of publication of the final rule and (2) submit an annual report (signed by the head of the agency) to the appropriate congressional committees, describing the status of the agency's compliance with the Act. The NRC Regulations Handbook 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." 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 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 is warranted in view of the potential safety significance of the issue. The cognizant NRC office director or regional administrator should approve the 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 statement is required, it should 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 for the respondents is warranted in view of the potential safety significance of the issue

MD 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 for information requests are not regulatory analyses within the scope of this document. Nevertheless, the written statement 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 statement. An information request statement 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 backfit of one or more facilities regulated under the Backfit Rule 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). MD 8.4 and NUREG-1409 provide additional guidance for preparing and processing the documented evaluation for backfitting and

issue finality. In the case of compliance exceptions under 10 CFR 50.109(a)(4)(i), some consideration of costs is required (NRC, 2016a, 2016b).

E.4 REFERENCES

5 U.S.C. 601 et seq., Regulatory Flexibility Act of 1980, as amended. Available at http://www.nmfs.noaa.gov/sfa/laws_policies/economic_social/rfa_revised_through_2010_jobs_act.pdf.

5 U.S.C. 603, Initial regulatory flexibility analysis.

42 U.S.C. 4321 et seq., National Environmental Policy Act of 1969, as amended. Available at https://www.gpo.gov/fdsys/pkg/USCODE-2014-title42/pdf/USCODE-2014-title42-chap55-sec4321.pdf.

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[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2017-0091]

Regulatory Analysis Guidelines

KLS edits

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, backfit, forward fit, issue finality, and National Environmental Policy Act (NEPA) environmental review analyses 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:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2017-0091. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual(s) listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. In addition, for the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Pamela Noto, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-6795, e-mail: Pamela.Noto@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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, 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, backfit, forward fit, issue finality, and environmental review 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 consistency of the agency's existing regulatory analysis guidance and bringing it up-to-date through revisions to cost-benefit analysis guidance documents, including aligning cost-benefit guidance across the agency in both reactor and materials program areas.[1] In the staff requirements memorandum (SRM) to SECY-12-0110, dated March 20, 2013, 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 environmental analyses. Further, the Commission directed the NRC staff to provide a regulatory gap analysis prior to developing new cost-benefit guidance.

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

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.

The NRC staff issued SECY-14-0002, which 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, the NRC staff recommended a two-phased approach to revise the content and structure of the cost-benefit guidance documents. Phase 1 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 and other senior management direction,[2] the NRC staff determined that NUREG-1409 should be kept as a standalone document and the revision to NUREG-1409 is being addressed through a separate effort. Additionally, Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," has been updated to provide ~~additional~~ guidance to the staff in the area of backfitting, forward fitting and issue finality.

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 were revised and consolidated into a single guidance document that includes updated data, methods, and references, as well as best practices from GAO audit findings and case-study

[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. ADAMS Accession No. ML17198C141.

recommendations. Subsequently, Phase 2 will identify and discuss policy issues for Commission consideration that could affect the NRC's cost-benefit guidance.

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 the consideration of qualitative ~~consideration of~~ factors within a cost-benefit analysis for regulatory and backfit analyses.[3] 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 analysts to assist them in clearly articulating how they considered qualitative factors. Appendix A, "Qualitative Factors Assessment Tools," of the revision to NUREG/BR-0058 provides this toolkit.

In 2014, the U.S. Government Accountability Office (GAO) conducted a performance audit to review the NRC's cost-estimating procedures. The 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, it consolidates cost-benefit guidance that is used across the agency. The document provides additional discussion of cost-benefit guidance for NRC's regulatory, backfit, forward fit, issue finality, and NEPA environmental review analyses.[4]

[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.
[4] NRC "Staff Requirements Memorandum – SECY-18-0042 – Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'" SRM-SECY-18-0042, July 26, 2019.

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 includes guidance intended to enhance the clarity, transparency, and consistency of analyses for the decisionmaker.

Finally, the appendices provide detailed technical material that is subject to future changes. These appendices will be issued and controlled separately to 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 cost-benefit guidance in Phase 1. The staff's presentation can be found in ADAMS under Accession No. ML15189A463, and the meeting summary can be found under Accession No. ML15217A415. The NRC staff held a second Category 3 public workshop on March 3, 2016, to discuss activities to improve 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 under Accession No. ML16084A167. The NRC staff published the draft revision, in the *Federal Register* (82 FR 18163, April 17, 2017) for a 60-day public comment period. To encourage public comment, the NRC 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. The NRC staff's presentation can be found in ADAMS under Accession No. ML17135A037, and the meeting summary can be found 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 to Review 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 stated that seven of the twelve appendices remained under development. The ACRS determined 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." The ACRS plans to review the NUREG in its entirety during Phase 2 of the update.

II. **Procedural Requirements**

This NUREG is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the U.S. Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

III. Availability of Documents

The documents identified in the following table are publicly available.

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
SRM-SECY-18-0042, "Draft Final NUREG/BR-0058, Revision 5, 'Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,'", July 26, 2019	ML19207A042
NUREG-1409, "Backfitting Guidelines"	https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1409/
MD 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests"	ML18093B087

"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
SRM-COMSECY-16-0020, "Revision of Guidance Concerning Consideration of Cost and Applicability of Compliance Exception to Backfit Rule," November 29, 2016	ML17198C141
GAO-15-98, "NRC Needs to Improve its Cost Estimates by Incorporating More Best Practices"	http://www.gao.gov/assets/670/667501.pdf
GAO-09-3SP, "GAO Cost Estimating and Assessment Guide"	http://www.gao.gov/new.items/d093sp.pdf
ACRS Regulatory Policies and Practices Subcommittee Transcripts, February 7, 2017	ML17058A357
ACRS Meeting Transcripts, March 9, 2017	ML17086A361

Dated at Rockville, Maryland, this ___th day of _____ 2019.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

SUBJECT: DRAFT FINAL NUREG/BR-0058, REVISION 5, “REGULATORY ANALYSIS GUIDELINES OF THE U.S. NUCLEAR REGULATORY COMMISSION” **DATED:**

ADAMS Accession Number: ML19261A289 *via e-mail

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