

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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NUREG/BR-0058, Revision 5



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

**Final Report** 

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## 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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# **ABBREVIATIONS AND ACRONYMS**

	advanced beiling water reactor
ABWR	advanced boiling-water reactor
ADAMS	Agencywide Documents Access and Management System
ALARA	as low as reasonably achievable
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 the costs and benefits of proposed regulatory actions to protect public health and safety, promote the common defense and security, and protect the environment. These evaluations help the staff provide adequate justification for the proposed action and document a clear explanation of why the proposed action was recommended. This guidance contains the framework for (1) identifying the problem and associated objectives, (2) identifying alternatives for meeting the objectives, (3) analyzing the consequences of alternatives, (4) selecting a preferred alternative, and (5) documenting the analysis in an organized and understandable format. The resulting analysis is referred to as a cost-benefit analysis.

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

Although the NRC is not required to conduct cost-benefit analyses, it voluntarily began performing them in 1976. In preparing cost-benefit analyses, the NRC ensures that decisions imposing burdens on 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 burdens are justified and will achieve intended regulatory objectives. The NRC conducts a type of cost-benefit analysis as part of the regulatory review of cost-justified substantial safety enhancements, as well as regulatory and environmental analyses.

The cost-benefit analyses prepared by the NRC before 1983 were termed value-impact analyses and followed the value-impact guidelines in SECY-77-388A, "Value-Impact Guidelines," dated December 19, 1977. In February 1981, President Ronald Reagan issued Executive Order (EO) 12291, "Federal Regulation," that directed executive agencies to prepare 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-based philosophy for the NRC staff to use in its regulatory analysis process for proposed actions that may affect commercial nuclear power reactors. The Commission's 1986 safety goal policy provides a "safety first" test that gives added strength to the regulatory decisionmaking process for new requirements that are considered and justified as safety enhancements applicable to more than one nuclear power reactor.

Specifically, application of this philosophy minimizes the number of occasions that resources are spent on conducting extensive regulatory analyses that later determine that a proposed action is not justified because the incremental safety benefits would not substantially improve the existing level of plant safety. By defining a clear level of incremental safety for nuclear power plants, the safety goal evaluation, as part of the regulatory analysis, provides the staff with direction in deciding whether any further regulatory changes (i.e., backfits) are warranted. Thus, the safety goal evaluation can truncate the need for further analysis or consideration of proposed regulatory actions. Therefore, the regulatory analysis process for safety enhancement issues should address the safety goal analysis, discussed in Section 2.2 of this document, as early as possible.

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

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).<sup>1</sup>
- procedural changes designed to enhance the effectiveness of the NRC's cost-benefit analysis

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

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

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

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

Additionally, in 2011, the accident at the Fukushima Dai-ichi nuclear power plant in Japan initiated discussion about how the NRC's regulatory framework considers offsite property damage and the associated economic consequences that would result from a significant radiological release from an NRC-licensed facility. In response to this discussion, on August 14, 2012, the NRC staff submitted SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," for Commission consideration. The purpose of SECY-12-0110 was to give the Commission information and options to address the extent, if any, to which the NRC's regulatory framework should be modified when addressing the economic consequences of a significant radioactive release to the environment. In developing SECY-12-0110, the staff examined areas of the regulatory framework, including the guidance and tools that consider economic consequences, and identified potential changes to the framework.

<sup>&</sup>lt;sup>1</sup> 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.

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

## 1.1 Purpose

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

The guidance has several goals:

- Help the analyst understand how current NRC policy impacts are captured in a regulatory decisionmaking document.
- Incorporate changes in policy and advances in methodology that have occurred since the issuance of the 2004 NRC regulatory analysis guidelines. The NRC and other agencies have conducted considerable research on various aspects of regulatory decisionmaking. Also, staff experience has resulted in significant modifications to the regulatory decisionmaking documents. These advances have been incorporated into this guidance.
- Provide one cost-benefit guidance document—NUREG/BR-0058, Revision 5—for cost-benefit analyses that may contribute to regulatory, environmental, or backfit analyses.

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

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

## 1.2 Scope of Regulatory Decisionmaking Documents

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

#### 1.2.1 Regulatory Analysis

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

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

#### 1.2.2 Backfit Analysis and Issue Finality

When the NRC proposes a change in requirements for a facility protected by regulation from certain changes applicable to its licensed activities, this is referred to as a backfit. The NRC's policy is to have an effective program that will ensure that proposed backfitting actions to be imposed on nuclear power reactor licensees, new power reactor licensees,<sup>2</sup> and selected nuclear materials licensees are appropriately justified on the basis of the backfitting provisions of applicable NRC regulations and the Commission's backfitting policy and guidance.

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

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

<sup>&</sup>lt;sup>2</sup> 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.

item should appear. The analyst must be sure to address the 10 CFR 50.109 requirements in the backfit analysis.

Certain regulatory actions are subject to the requirements of 10 CFR 50.109 and to the review of the Committee to Review Generic Requirements (CRGR), and the analyses and information requirements within the CRGR CharterThe NRC intends that, for these actions, the analysis performed in accordance with this guidance will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter (NRC, 2011a) without a need to prepare separate submissions. As part of the regulatory analysis, the "substantial increase in overall protection" test required under the backfit rule is assessed using the safety goal screening criteria. However, a backfit analysis does not rely solely on the safety goal screening criteria to support a staff determination of a "substantial increase in overall protection."

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

CFR Citation <sup>a</sup> (Title 10)	Information Item To Be Included in a Backfit Analysis	Section of the Regulatory Analysis Where Item Should Normally Be Discussed
50.109(a)(3)	Basis and a determination that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for the affected facilities are justified in view of this increased protection	Basis—Presentation of Results Determination—Decision Rationale
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)	Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility	Implementation

Table 1-1 Checklist for Specific Backfit Analysis Requirements

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

#### 1.2.3 National Environmental Policy Act Review

NEPA requires Federal agencies to prepare a "detailed statement for major Federal actions significantly affecting the quality of the human environment" (42 U.S.C. 4332). The essential purpose of NEPA is to ensure that environmental factors are given due consideration in

decisionmaking by Federal agencies. NRC regulations for implementing NEPA are in 10 CFR Part 51. The NRC must assess the environmental impact of each proposed and final rulemaking action and include a statement about the environmental impact in the supplementary information section of the preamble to each rulemaking. The procedural requirements for considering the environmental impact of a rulemaking action are described in NUREG/BR-0053, Revision 6, "United States Nuclear Regulatory Commission Regulations Handbook," issued September 2005 (NRC Regulations Handbook).

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

#### 1.2.4 Details of Cost-Benefit Guidance

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

## 1.3 <u>Regulatory Relaxations</u>

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

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

- The public health and safety and the common defense and security would be adequately protected if the proposed relaxations were implemented.
- The cost savings would be sufficient to justify 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.
- An evaluation of whether proposed actions provide a substantial increase in overall protection of public health and safety or the common defense and security is performed 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, orders, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, NUREG publications, and standard technical specifications that establish, modify, or withdraw staff positions or guidance for applicants or licensees.

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

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

Generic actions (i.e., actions that affect all, several, or a class of licensees) that may not need a regulatory analysis include notices, policy statements, and generic communications that only transmit information and do not present new or revised staff positions, impose requirements, or recommend action. Generic information requests issued under 10 CFR 50.54(f) require a specific justification statement and are reviewed by the CRGR when directed to one or more classes of nuclear power reactors; however, these requests do not require the type of regulatory analysis discussed in this guidance because they do not impose requirements. New requirements affecting certified nuclear power plant designs will be justified 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.<sup>3</sup>

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:

<sup>&</sup>lt;sup>3</sup> In litigation, an adverse ruling may require a specific outcome with only one possible method for compliance. In such a case, cost would not be a factor because there is only a single means to achieve the specific outcome imposed by the adverse ruling, so a regulatory analysis would not be necessary. In contrast, if there are multiple ways of achieving a specific outcome imposed by an adverse ruling, a regulatory analysis would be performed to determine the costs and benefits of each alternative.

- (1) Public health and safety and the common defense and security would be adequately protected if the proposed relaxation in requirements or positions were implemented.
- (2) The cost savings would be sufficient to justify the action.

Proposed regulatory actions that would relax or reduce current requirements should give the licensee the option of whether to take advantage of the relaxation and should not be mandatory. For these voluntary relaxations of requirements, the backfit rule and the safety goal evaluation process and screening criteria are not applicable. However, for all proposed relaxations (including those affecting nuclear power plants), the staff should prepare supporting documentation that gives the basis for concluding that the two conditions listed above will be satisfied. Further, it is appropriate in justifying a proposed relaxation to cite the results or insights from risk analyses that support relaxation, as well as the NRC's original bases for having established the existing requirement.

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

## 2.1 Level of Detail

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

- (1) the complexity and policy significance of the particular problem being addressed
- (2) the magnitude and likelihood of costs and benefits
- (3) the relative amount by which projected benefits exceed costs
- (4) the immediacy of the need for a regulatory action and time constraints imposed by legislation or court decisions
- (5) any supplemental direction provided by the Commission, the EDO, or an NRC Office Director

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

For the type of information supplied and the level of detail provided, the emphasis should be on simplicity, flexibility, and common sense. The level of treatment given to a particular issue in a regulatory analysis should reflect how crucial that issue is to the bottom-line recommendation of the regulatory analysis. In all cases, regulatory analyses should be sufficiently clear and give sufficient detail to enable the NRC decisionmakers and other interested parties to easily recognize the following:

- the problem within the context of the existing regulatory framework
- the proposed regulatory action

- the conclusions reached and their associated bases
- the specific data and analytical methods used and the logic followed that led to the conclusion that the proposed new or revised requirement was appropriate and justified
- the sources and magnitude of uncertainties that might affect the conclusions and the proposed new or revised requirement
- the sensitivity of the conclusions to changes in underlying assumptions and considerations

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

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

It should be recognized that many benefits of improved regulation are not quantifiable. For example, increased confidence in the margin of safety may be a qualitative benefit of a proposed regulatory requirement. As noted in Appendix A, "Qualitative Factors Assessment Tools," qualitative factors can be significant elements of a regulatory analysis and should be appropriately considered by the analyst and decisionmaker.

## 2.2 Safety Goal Analysis

Assessing the risk of potential changes to public safety has always been a fundamental part of regulatory decisionmaking. As PRA technology has advanced since the mid-1970s, the staff has applied insights and results from risk assessment in conducting its regulatory activities. The NRC's policy statement on safety goals for the operations of nuclear power plants (NRC, 1986)

reflects an example of this change. It defines both qualitative goals and quantitative objectives that can be used to guide regulatory decisionmaking.

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

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

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

#### 2.2.1 When a Safety Goal Evaluation Is Needed

The safety goal evaluation, as discussed in this section, is required for regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). A safety goal evaluation is not needed for new requirements within the exceptions at 10 CFR 50.109(a)(4)(i)–(iii). If the proposed safety goal screening criteria are satisfied, the NRC considers, for purposes of only the regulatory analysis, that the substantial additional protection standard is met for the proposed new requirement.

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

#### 2.2.2 Safety Goal Analysis Determination

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

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

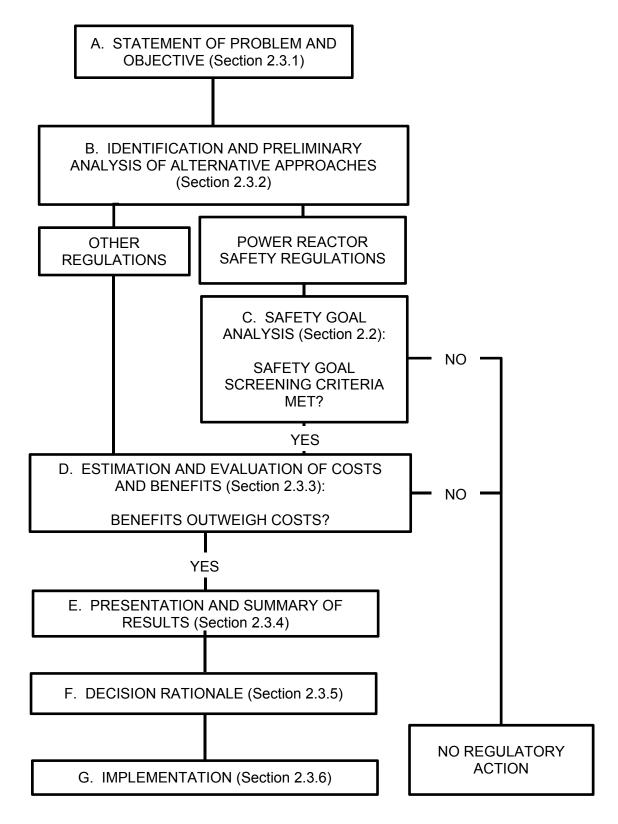
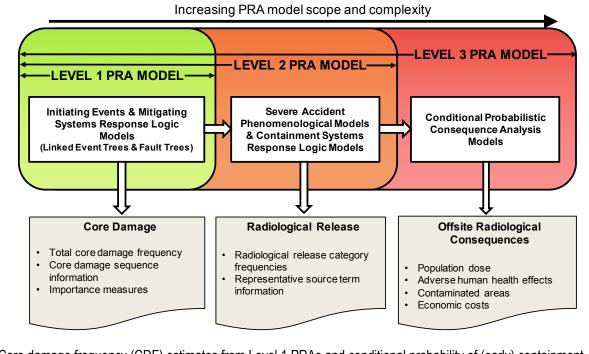


Figure 2-1 Elements of a Regulatory Analysis

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

- (1) a statement of the problem and NRC objectives for the proposed regulatory action
- (2) <u>identification and preliminary analysis of alternative approaches</u> to address the problem, including the no action alternative
- (3) <u>estimation and evaluation of costs and benefits</u> for selected alternatives, including consideration of the uncertainties affecting the estimates
- (4) <u>presentation and summary of results</u>, including the conclusion of the evaluation of costs and benefits and, when appropriate, the safety goal evaluation
- (5) the <u>decision rationale</u> for selecting the proposed regulatory action
- (6) a tentative <u>implementation</u> schedule and implementation instrument for the proposed regulatory action

A regulatory analysis should address each of these elements and should also include an executive summary, list of acronyms, and references.

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

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

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

#### 2.3.1 Statement of the Problem and Objective

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

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

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

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

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

#### Background of the Problem

The background discussion should include the following, as applicable:

- a brief history of the problem and the outcome of past efforts (if any) to resolve it
- any statutes or court decisions<sup>4</sup> that directly or indirectly addresses the problem (e.g., the Firearms Guidelines in 74 FR 46800, revised in 79 FR 36100)
- whether existing requirements have created or contributed to the problem and whether these requirements can be modified to achieve the regulatory objective more effectively
- the extent to which the immediate problem is part of a larger problem

<sup>&</sup>lt;sup>4</sup> Litigation records could come from court cases, such as decisions by an Atomic Safety and Licensing Board, or Commission decisions in cases under litigation.

- the relationship of the problem to other ongoing studies or actions (e.g., the NRC's generic safety issues [NRC, 2011b])
- the objectives of the proposed new or revised requirement and the relationship of the objectives to the NRC's legislative mandates and authority, safety goals for the operation of nuclear power plants, and policy and planning guidance (e.g., the NRC's Strategic Plan) (NRC, 2014a)
- the relationship of the problem to formal positions adopted by national and international standards organizations
- the identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness
- any constraints or other cumulative impacts that pertain to the problem
- the draft papers in development or other underlying staff documents supporting the requirements or staff positions

#### 2.3.2 Identification and Preliminary Analysis of Alternative Approaches

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

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

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

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

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

The analyst should estimate the significance of the problem using the rough estimates as well as guidance provided by the Commission, the EDO, or the appropriate NRC Office Director. The level of detail to be provided in the regulatory analysis document and the amount of effort to be made 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 implementation means should be considered when appropriate (e.g., submission of proposed legislation to Congress).

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

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

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

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

#### 2.3.3 Estimation and Evaluation of Costs and Benefits

The analyst should make every effort to use quantitative attributes relevant to the cost-benefit analysis. The quantification should employ 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 strive to use other quantifiable benefits. However, despite the analyst's best efforts at quantification, there may be some attributes that cannot be readily quantified. These attributes are termed "qualitative" and are handled separately from the quantitative attributes (see Appendix A).

Estimates are made for those attributes that lend themselves to quantification using standard techniques. Obtaining the appropriate data may be more complicated for a major effort. For cases in which a proposed action would result in significantly different attribute measures for different categories of licensees, separate estimates and evaluations should be made for each distinct category (e.g., older plants and newer plants) (see Appendix B, "Cost Estimating and Best Practices").

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

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

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

#### 2.3.4 Presentation and Summary of Results

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

- presentation of the estimated net monetized benefit (i.e., the algebraic sum of the attributes) using the discount rate procedures
- estimates of costs and benefits for each attribute for 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 the rigor of the results. All regulatory analyses should discuss the sources and magnitudes of uncertainties in attribute 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.

Net Monetary Savings (or Costs) Net Present Value	Comments
Alternative 1: No Action	In this section of the table, the analyst should discuss qualitative costs and benefits and special considerations for each alternative.
	<u>Qualitative Benefits</u> Subject of Qualitative Benefit 1: Discussion of qualitative benefit
	Subject of Qualitative Benefit n: Discussion of qualitative benefit
	<u>Qualitative Costs</u> 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	<u>Qualitative Benefits:</u> Subject of Qualitative Benefit 1: Discussion of qualitative benefit Subject of Qualitative Benefit n: Discussion of qualitative benefit
NRC: \$x.xx million using a 7-percent discount rate \$x.xx million using a 3-percent discount rate	<u>Qualitative Costs</u> Subject of Qualitative Cost 1: Discussion of qualitative cost
<b>Total:</b> \$x.xx million using a 7-percent discount rate \$x.xx million using a 3-percent discount rate	Subject of Qualitative Cost n: Discussion of qualitative cost <u>Special Considerations</u>

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

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

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

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

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

#### 2.3.5 Decision Rationale

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

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

The OMB maintains that the regulatory analysis should select the regulatory alternative that achieves the greatest present value in terms of the discounted monetized value of expected net benefits (i.e., benefits minus costs) (OMB, 1992). The OMB also notes that the ratio has characteristics that make its results potentially misleading:

Benefit-cost ratios, if used at all, must be used with care to avoid a common pitfall. It is a mistake to choose among mutually exclusive alternatives by

selecting the alternative with the highest ratio of benefits to costs. An alternative with a lower benefit-cost ratio than another may have the higher net benefits (OMB, 1993).

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

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

#### 2.3.6 Implementation

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

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

# 2.4 Safety Goal Evaluation for Operation of Nuclear Power Plants

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

When performing a safety goal evaluation, the analyst should be aware of any previous or ongoing safety improvements that have the potential to affect the status quo risks associated with the issues being addressed. Because there is not a formal process for accounting for the

potential dependencies between issues, the analyst should resort to a "best effort" approach, such as public outreach, to identify and account for preexisting or concurrent impacts. The analyst should identify any previous or ongoing safety improvements that may affect the issue being evaluated. For example, an analyst addressing proposed improvements to diesel generator performance at power reactors should be aware of any diesel generator improvements or alternate power supplied by other means (e.g., FLEX mitigating strategies) already addressed in station blackout considerations. To the extent possible, the analyst should modify the PRA model of the representative plant to reflect the upgraded status quo from these other safety improvements. The analyst can then evaluate the difference between this new status quo and the proposed improvements being considered.

#### 2.4.1 Implementation Guidance

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

- Safety goal screening criteria are to be applied only to safety enhancements and evaluated for the affected class of nuclear power plants. Safety goals are to be used as a reference point in ascertaining the need for safety enhancements. However, the safety goals are not requirements, and, with the Commission's approval, safety enhancements may be implemented without strict adherence to the Commission's safety goal policy statement.
- Safety goal evaluations are to be performed in conjunction with the substantial additional protection standard in the backfit rule and applied to 10 CFR 50.109 analyses associated with substantial safety enhancements, wherein the estimated costs of the implementation are justified in view of the estimated safety improvement.
- Evaluations of proposed regulatory initiatives for consistency with safety goals should identify and integrate related issues under study. The integration of related issues is essential to the efficient application of staff and industry resources. The overall objective is to avoid a piecemeal evaluation of issues.

The NRC's philosophy for safety goal evaluations involves the concept of defense in depth and a balance between prevention and mitigation (NRC, 1986). This traditional defense-in-depth approach and the accident mitigation philosophy require the reliable performance of containment systems. The safety goal evaluation focuses on accident prevention, that is, on issues intended to reduce core damage frequency (CDF). However, to achieve a measure of balance between prevention and mitigation, the safety goal screening criteria established for these evaluations include a mechanism to use when relatively poor containment performance results in the need for greater consideration of issues and associated accident sequences.

# 2.4.1.1 Prevention of Core Damage Accidents—Comparison with Subsidiary Goal for Mean Core Damage Frequency of 1x10<sup>-4</sup> per Reactor Year

For proposed regulatory actions to prevent or reduce the likelihood of sequences that can lead to core damage events, the change in the estimated CDF per reactor year needs to be evaluated and addressed in the regulatory analysis. CDF is defined as "the sum of the accident sequence frequencies of those accident sequences whose end state is core damage," where core damage is defined as "sufficient damage that could lead to a release of radioactive material from the core that could affect public health" (NRC, 2013c). The objective is to ensure that emphasis is placed on preventing core damage accidents.

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

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

The NRC has certified under 10 CFR Part 52 five reactor designs (see Appendices A through E of 10 CFR Part 52) for which a description of the design-specific PRA and its results have been reviewed by the staff. The bottom portion of Table 2-2 shows the key risk-related CDF and large release frequency (LRF) values for the three certified designs where an associated combined license (COL) to build and operate has also been issued by the NRC. In part because of the unique process under 10 CFR Part 52 where PRA insights have been used to

make risk-reducing changes during the design process, the related internal events CDFs for the 10 CFR Part 52 certified reactor designs as shown in Table 2-2 are less than those of the current operating reactors because of the removal of certain dominate accident sequences.

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.

Reactor Type	Containment Type	Internal Events CDFª (Average) per Reactor Year		Internal Events LERF <sup>bc</sup> (Average) per Reactor Year	
		(Range)		(Range)	
PWR <sup>d</sup>	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 <sup>e</sup>	2.9E-06		1.1E-07	
		NA	NA	NA	NA
New Reacto	r Designs	r		r	
New Reactor		At-Power Internal Events CDF per Reactor Year		At-Power Internal Events LRF <sup>f</sup> pe Reactor Year	
ABWR (GEH) <sup>g</sup>		1.6E-07		<1.0E-8	
AP1000 <sup>h</sup>		2.4E-07		2.0E-08	
ESBWR <sup>i</sup>		1.7E-08		1.4E-09	

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

Note: This table will be updated in the future.

<sup>a.</sup> Source: CDF data from NUREG-1437 supplements.

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).

<sup>c.</sup> Pressurized-water reactor (PWR).

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

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

<sup>f.</sup> 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.

<sup>9</sup> 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.

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

<sup>1</sup> 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 exactly 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  $1 \times 10^{-4}$  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 justify proceeding with further analyses. This safety goal screening criterion was selected to give some assurance that the PRA and data limitations and uncertainties, as well as the variability among plants, will not eliminate issues warranting regulatory attention. This does not mean that, in all cases, a proposed safety enhancement of at least  $1x10^{-5}$  will subsequently prove to be justified for implementation after more detailed assessments are performed in accordance with Section 2.5 of this guidance. In this regard, the effect of uncertainties should be considered and discussed.

Figure 2-3 gives guidance for further staff action after the significance has been determined as measured by the estimated reduction in CDF of the proposed new requirement for the affected class of plants.

	Estim	ated Reduction ir CDF	Staff Action		
	>1x	10 <sup>-4</sup> /reactor year	Proceed with the regulatory analysis on a high-priority basis.		
	1x10	) <sup>-4</sup> –1x10 <sup>-5</sup> /reactor year	The decision whether to proceed with the regulatory analysis is to be made by the responsible Division Director.		
	<1x	10 <sup>-5</sup> /reactor year	Terminate further analysis unless the Office Director decides otherwise, based on strong engineering or qualitative justification.		
		1x10 <sup>-3</sup>			
Change in Core Damage Frequency (ΔCDF)/Reactor Year	uency r Year	1x10 <sup>-4</sup>	Proceed to Cost-Benefit Portion of Regulatory Analysis (1x10 <sup>-6</sup> to 1x10 <sup>-4</sup> )	Proceed to Cost-Benefit Portion of Regulatory Analysis* (Priority) (.1x10 <sup>-5</sup> )	
	าage Frequ )F)/Reacto	1x10 <sup>-5</sup>	Management Decision Whether To Proceed with Cost-Benefit Portion of Regulatory Analysis (1x10 <sup>-7</sup> to 1x10 <sup>-5</sup> )	Proceed to Cost-Benefit Portion of Regulatory Analysis (1x10 <sup>-6</sup> to 1x10 <sup>-4</sup> )	
ō	Dan (∆С⊡	1x10 <sup>-6</sup>	No Action Taken** (1x10 <sup>-6</sup> )	Management Decision Whether To Proceed with Cost-Benefit Portion of Regulatory Analysis (1x10 <sup>-7</sup> to 1x10 <sup>-5</sup> )	
			-	10 <sup>-1</sup> 10-1 If Containment Failure or Bypass***	
		L.	Sumated Contractorian robability C	a containmont i anaro or Bypass	

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

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

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

#### Figure 2-3 Safety Goal Screening Criteria

The evaluation of CDF reduction provides a calibration on the significance of the proposed regulatory action. If the initiative results in a small change in CDF (less than 1x10<sup>-5</sup>/ reactor-year), the regulatory analysis should, in general, proceed only if an alternative justification for the proposed new requirement can be formulated. A class of accident 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<sup>-5</sup>/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 Office Director review.

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

The safety goal screening criteria are in terms of a mean for the class of plants. However, the range within the class of risk reduction is also important. Consequently, when performing safety goal evaluations, if specific plants are identified as "outliers," the situation should be noted for specific regulatory followup (e.g., for evaluations regarding potential facility-specific backfits).

# 2.4.1.2 Additional Consideration of Containment Performance

The previous section focuses on accident prevention, that is, on issues intended to reduce CDF. To achieve a measure of balance between prevention and mitigation, the safety goal screening criteria established for safety goal evaluations include a mechanism for use when relatively poor containment performance results in the need for greater consideration of safety issues and associated accident sequences. The measure of containment performance to be used in safety goal evaluations is the conditional probability of containment failure or bypass (CPCFB).

CPCFB in this context is the conditional probability of early containment failure or bypass, given core damage. In NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," issued December 1990, early containment failure is defined as "those containment failures occurring before or within a few minutes of reactor vessel breach for PWRs and those failures occurring before or within 2 hours of vessel breach for BWRs. Containment bypass failures (e.g., interfacing-system loss-of-coolant accidents) are categorized separately from early failures" (NRC, 1990). This definition recognizes the effects of early failure and uses that as a baseline from which to assess containment performance (e.g., CPCFB changes). It is important to note that the Fukushima-related orders associated with mitigation strategies and severe accident containments venting for BWR Mark I and II containments may have an impact on CPCFB and should be considered accordingly. In applying these screening criteria, the CPCFB definition may be extended, if appropriate, to up to 4 hours after vessel breach, to permit initiation of accident management and emergency preparedness actions.

The safety goal screening criteria shown in Figure 2-3 are subdivided to require greater staff emphasis on the higher valued (i.e., greater than 0.1) CPCFBs. A CPCFB value of 0.1 is consistent with Commission guidance on containment performance for evolutionary designs. In effect, the use of the CPCFB reduces the priority of, or eliminates the additional study of issues associated with, a CPCFB of less than 0.1.

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

- those involving core damage and release into an intact containment with early containment failure occurring
- those involving core damage and for which the containment system is breached as a result of accident phenomena either before or early in the core damage or melt progression
- those involving preexisting conditions that cause loss of containment integrity before core damage (e.g., large openings)
- those for which containment is bypassed entirely and that have a high probability of causing core damage to occur (e.g., 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 ( $\Delta$ CDF of zero), such as release mitigating initiatives, cannot be addressed with the safety goal screening criteria. As a result, mitigating initiatives should be assessed on a case-by-case basis with regard to the safety goals. The treatment of proposed release mitigating initiatives in this manner should have little overall impact from a practical perspective on the usefulness of the safety goal screening criteria.

# 2.4.1.3 Summary of Safety Goal Screening Criteria Guidance

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

#### 2.4.1.4 Regulatory Analysis

If the safety goal evaluation of the proposed regulatory action results in a favorable determination (i.e., any decision except no action), the analyst may presume the substantial additional protection standard of 10 CFR 50.109(a)(3) is achievable. The initiative should then be assessed in accordance with Section 2.2 of this guidance (see Figure 2-1). If the net-value calculation required by Section 2.2 is not positive, further activities and analyses should be terminated unless there is a qualitative justification 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 in the vicinity of 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, 1995b) 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 (NRC, 1986). New reactor designs submitted for standard certification must comply with the PRA requirements in 10 CFR Part 52.

#### 2.5 <u>Relationship to Other Procedural Requirements</u>

This section discusses the relationship of regulatory analyses to other statutory requirements applicable to the NRC. The documentation required by the Regulatory Flexibility Act (5 U.S.C. 601) 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. NRC Management Directive (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 justifying the reasons for the information request, except when the information is needed to verify licensee compliance with the current licensing basis for the facility. The written statement is to establish that the burden imposed on the licensee is justified in view of the potential safety significance of the issue. All justification statements must be approved by the EDO or his or her designee before issuance of the information request.

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

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

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

#### 2.5.3 Regulatory Flexibility Act

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis, to be made available for public comment, if a proposed rule will have a significant economic impact on a substantial number of small entities. The analysis is to describe the impact of the proposed rule on small entities (5 U.S.C. 603). The NRC uses the following size standards to qualify a licensee as a small entity, codified at 10 CFR 2.810, "NRC Size Standards":

- a small business that is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$7.0 million or less over its last 3 completed fiscal years
- a manufacturing concern with an average number of 500 or fewer employees, based on employment during each pay period for the preceding 12 calendar months
- 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" (42 U.S.C. 4332). 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, 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. The EIS or EA may be referenced at other points in the regulatory analysis to avoid duplication.<sup>5</sup>

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.

<sup>&</sup>lt;sup>5</sup> 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.

#### 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 particular 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 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.

# **3 BACKFITTING AND ISSUE FINALITY**

# 3.1 General

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

Backfitting is defined in 10 CFR 50.109 as the modification of or addition to SSCs or the design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in Commission rules or the imposition of a regulatory staff position that is either new or different from a previously applicable staff position *and* effective after specific dates described in the backfit rule. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 are slightly different.<sup>6</sup>

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

# 3.2 Relationship of Regulatory Analysis to Backfitting

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

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

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

<sup>&</sup>lt;sup>6</sup> The relevant regulations are 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"; 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste"; and 10 CFR Part 76, "Certification of Gaseous Diffusion Plants."

- the potential for change in the risk to the public from the accidental offsite release of radioactive material
- the potential effect of radiological exposure on facility employees
- the installation and continuing costs associated with the backfitting action, including the cost of facility downtime or the cost of construction delay (i.e., resource burden on licensees)
- the potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements
- the estimated resource burden on the NRC associated with the proposed backfitting action and the availability of such resources
- the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfitting action
- a statement of whether the proposed backfitting action is interim or final and, if interim, the justification 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 will not be considered in cases of ensuring, defining, or redefining adequate protection unless there are two or more ways to achieve a level of protection which is adequate. Should it be necessary or appropriate for the Commission to prescribe a specific action to comply with requirements or to achieve adequate protection, then cost may be a factor in selecting the action, provided that the objective of adequate protection is met.

Averted onsite costs can arise 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). They are, however, considered as a negative cost; that is, an offset against other licensee costs. Averted offsite costs can result from an estimated decrease in accident frequency or severity.

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

For generic backfittings, the CRGR Charter provides guidance on what cost and benefit information is needed in the backfit analyses 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 <u>General</u>

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 (42 U.S.C. 4332). 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 (42 U.S.C. 4332).

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 section 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.

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 <u>Comparison of Cost-Benefit Requirements in NEPA Reviews for NRC</u> <u>Licensing Actions</u>

The need for a cost-benefit 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.

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, 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.

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."

#### 4.3 Specific Costs and Benefits Requirements for New Reactors

For ESPs under 10 CFR Part 52, the draft EIS need 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 cannot be quantified, those considerations or factors should be discussed in qualitative terms. The environmental standard review plan (ESRP), NUREG-1555, provides guidance to the staff on the identification and tabulation of costs and benefits resulting from construction and operation of new nuclear power plants).

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

# 4.4 Costs and Benefits Guidance for Reactors and Material Licensing Actions<sup>7</sup>

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

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

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

<sup>&</sup>lt;sup>7</sup> This section does not apply to ERs prepared at the license renewal stage under 10 CFR 51.53(c), unless costs and benefits are either essential for a determination about the inclusion of an alternative in the range of alternatives considered or relevant to mitigation.

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

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

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

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

# 4.5 Environmental Justice

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

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

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

- 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 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 can be justified to further reduce the risks of severe accidents.

#### 4.6.1.1 Severe Accident Mitigation Alternatives

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

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

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

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

#### 4.6.1.2 Severe Accident Mitigation Design Alternatives

In 10 CFR 52.79(a)(38), the NRC requires that applicants for COLs 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 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," 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 completely 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 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 completely eliminate all severe accident risk from the events that are evaluated. This assumption is conservative, because it maximizes the benefit of each 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 improvements in the reliability of core and containment heat removal systems that are significant and practicable. The set of potential design improvements considered for the proposed DC includes 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 <u>statement of the problem</u> and NRC objectives for the proposed regulatory action
- (2) <u>identification and preliminary analysis of alternative approaches</u> to address the problem
- (3) <u>estimation and evaluation of costs and benefits</u> for selected alternatives, including consideration of the uncertainties affecting the estimates
- (4) <u>presentation and summary of results</u>, including the conclusion of the evaluation of costs and benefits and, when appropriate, the safety goal evaluation
- (5) the <u>decision rationale</u> for selecting the proposed regulatory action
- (6) a tentative <u>implementation</u> 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. Nonreactor facilities tend to be much simpler in system configuration than power reactors, and the potential consequences to the public from accidents compared to power reactors is much smaller. This simplifies the scope of the accident analysis and the accident frequency and population dose data; however, there are fewer data available than for power reactors. Data for nonreactor facilities may be used to quantify the incremental changes resulting from the proposed regulatory action for these attributes.

#### 5.2 Identification of Attributes

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

#### 5.2.1 Public Health (Accident)

This attribute measures expected changes in radiation exposures to the public resulting from changes in accident frequencies or accident consequences associated with the proposed

action. Expected changes in radiation exposure from a nuclear power reactor accident should be measured over a 50-mile distance from the licensed facility. Because of the nature of nuclear fabrication facilities, a 50-mile radius is not automatically required.

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

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

# 5.2.2 Public Health (Routine)

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

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

# 5.2.3 Occupational Health (Accident)

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

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

# 5.2.4 Occupational Health (Routine)

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

Because this attribute represents an actual estimate of health effects, accident probabilities are not relevant. As is true of other types of exposures, a net decrease in worker exposures is

taken as positive; a net increase in worker exposures is taken as negative. This exposure is also subject to the dollar-per-person-rem conversion factor (see NUREG-1530).

# 5.2.5 Offsite Property

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

# 5.2.6 Onsite Property

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

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

# 5.2.7 Industry Implementation

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

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

# 5.2.8 Industry Operation

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

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

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

### 5.2.9 NRC Implementation

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

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

# 5.2.10 NRC Operation

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

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

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

#### 5.2.11 Other Government Entities

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

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

#### 5.2.12 General Public

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

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

#### 5.2.13 Improvements in Knowledge

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

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

#### 5.2.14 Regulatory Efficiency

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

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

#### 5.2.15 Safeguards and Security Considerations

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

In applying this attribute, the analyst should determine whether the existing level of safeguards and security is adequate and what effect the proposed action has on achieving an adequate level of safeguards and security. If the effect of the proposed action on safeguards and security is quantifiable, then this effect should be included among the quantitative attributes. Otherwise, the contribution of the action should be evaluated in a qualitative way and treated under this attribute.

# 5.2.16 Environmental Considerations

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

# 5.2.17 Other Considerations

The staff considers the set of attributes described above to be comprehensive for most cost-benefit analyses. Any particular analysis may also identify unique attributes (e.g., 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 analysis.

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 obviate the need for new regulations. Substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues that will not compromise plant safety, and this substitution does not represent a reduction in the NRC's commitment to safety and sound regulation. The NRC and the industry are jointly responsible for the long-term success of using industry initiatives as substitutes for NRC

regulatory action. Licensees need to effectively manage and implement their commitments associated with these industry initiatives, and the NRC should provide a credible and predictable regulatory response if licensees fail to satisfy these commitments.

Industry initiatives can generally be put into one of the following three categories:

- (1) those put in place in lieu of or to complement a regulatory action to ensure that existing requirements are met
- (2) those used in lieu of or to complement a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justified by the increased protection
- (3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern

Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives.

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

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

Under this best estimate base case, the staff should evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. Clearly, the more an industry initiative satisfies criteria that assure the long-term effectiveness of these voluntary approaches, the more credit the analyst should give to the industry initiative. In performing this evaluation, the analyst should rely on relevant features and characteristics of the industry initiative. Relevant characteristics include the following:

- Costs associated with the industry initiative. If the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal, it is more likely the industry initiative will continue in the future.
- The extent to which written commitments exist. If written commitments exist, it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative.
- The degree to which the industry initiative is noncontroversial and standard industry practice. Factors to consider include whether the industry initiative is consistent with provisions of industry codes and standards, the level of participation among relevant licensees, how long the program has been operating or its effectiveness, and whether the initiative is likely to continue without the rule change.
- The scope and schedule for industry initiatives that are still pending. For industry initiatives that are still works in progress, the more well-defined the scope and the sconer the initiative is expected to be in place, the more likely it will be available in the future.
- Whether the industry has formally adopted the initiative as mandatory through the NEI's Nuclear Strategic Issues Advisory Committee.

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

# 5.3.2 Attributes Valuation

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

When choosing the appropriate time horizon for estimating costs and benefits, the analyst should consider how long the regulation being analyzed is likely to have resulting effects. The time horizon begins when the regulatory action is implemented and ends when those effects are expected to cease. Ideally, the analyst should use the expected remaining operating license term across affected entities and add an appropriate decommissioning period, if applicable.

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

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

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

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

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

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

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-quarantee 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:

- Estimate the reduction in accident frequency per facility. (1)
- Estimate the reduction in public health (accident) risk per facility. (2)
- (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<sub>PHA</sub> = monetary value of public health (accident) risk avoided per facility-year before discounting (dollars/facility-year) = avoided public dose per facility-year (person-rem/facility-year) D<sub>PA</sub> R

- = monetary equivalent of unit dose (dollars/person-rem)
- (4) Discount to present value per facility (dollars).
- Total over all affected facilities (dollars). (5)

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

where

= discounted monetary value of public health (accident) risk avoided for VPHA all affected facilities (dollars)

W<sub>PHA</sub> = 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:

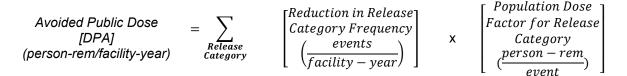
$$W_{PHA} = \sum_{i} N_i W_{PHA_i}$$

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:



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:

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

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

or

 $\begin{array}{l} \textit{Avoided Public Dose} = [\textit{Accident Frequency x Population Dose Factor}]_{\textit{Status Quo}} \\ - [\textit{Accident Frequency x Population Dose Factor}]_{\textit{After}}_{\textit{Action}} \end{array}$ 

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

# 5.3.2.1.2 Monetary Valuation of Accident-Related Health Effects

# Mortality Effects

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

# Morbidity Effects

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

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

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<sub>PHA</sub> = 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<sub>i</sub> = years before facility begins operating
- Z<sub>PHA</sub> = monetary value of public health (accident) risk avoided per facility-year before discounting (dollars/facility-year)

If a facility is already operating, t<sub>i</sub> 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<sub>PRI</sub>) and operation (D<sub>PRO</sub>).
- (2) Convert each reduction in public health (routine) risk per facility from person-rem to dollars via monetary evaluation of health effects.

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

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 <sub>PRI</sub>	=	per-facility reduction in routine public dose required to implement the
		proposed action (person-rem/facility)
D <sub>RPO</sub>	=	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):

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

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)
Ν	=	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:

$$V_{PHR} = \sum_{i} N_i \left( H_{PRI} + H_{PRO} \right)$$

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. Aaberg (1996) provides estimates of population and individual dose commitments for reported radionuclide releases from commercial power reactors operated during 1991. Conatser et al. (2013) have 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<sub>IO</sub> = monetary value of occupational health (accident) risk avoided per facility-year resulting from "immediate" doses, before discounting (dollars/facility-year)
- Z<sub>LTO</sub> = monetary value of occupational health (accident) risk avoided per facility-year resulting from long-term doses, before discounting (dollars/facility-year)
- Y<sub>IO</sub> = avoided occupational "immediate" dose per facility-year (person-rem/facility-year)
- Y<sub>LTO</sub> = 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<sub>OHA</sub> = discounted monetary value of occupational health (accident) risk avoided for all affected facilities
- W<sub>IO</sub> = monetary value of occupational health (accident) risk avoided per facility resulting from "immediate" doses, after discounting (dollars/facility)
- W<sub>LTO</sub> = 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:

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

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  $(D_{0R0})$ .
- (2) Convert each reduction in occupational health (routine) risk per facility from person-rem to dollars through monetary evaluation of health effects as follows:

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

where

- G<sub>ORI</sub> = monetary value of per-facility reduction in routine occupational dose to implement the proposed action before discounting (dollars/facility)
- G<sub>ORO</sub> = monetary value of annual per-facility reduction in routine occupational dose to operate after implementing the proposed action before discounting (dollars/facility-year)
- D<sub>ORI</sub> = per-facility reduction in routine occupational dose to implement the proposed action (person-rem/facility)
- D<sub>ORO</sub> = 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):

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

where

$V_{\text{OHR}}$	=	discounted monetary value of reduction in occupational health (routine) risk for all affected facilities (dollars)
H <sub>ORI</sub>	=	
		(dollars/facility)
H <sub>ORO</sub>	=	operate following implementation of the proposed action after
N	=	discounting (dollars/facility) number of affected facilities

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

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

$$V_{OHR} = \sum_{i} N_i \left( H_{ORI_i} + H_{ORO_i} \right)$$

where

i = facility (or group of facilities) index

# 5.3.2.3.1 Estimation of Change in Routine Exposure

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

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

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

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. Beal et al. (1987) provided generic estimates of dose rates for work on specific PWR and BWR systems and components. Sciacca (1992) used these estimates in NUREG/CR-4627, "Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses," issued February 1992, 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.

Sciacca (1992) 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<sub>ORI</sub> = 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<sub>1</sub> = 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

Doro	=	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)
Wo	=	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. The majority of 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 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 <a href="https://www.bls.gov">https://www.bls.gov</a>).

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:

$$V_{FP} = N \Delta F D$$

where

$V_{FP}$	=	monetary value of avoided offsite property damage (dollars)
Ν	=	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<sub>f</sub> = years remaining until the end of the facility life
- t<sub>i</sub> = 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 (e.g., when the timeframe is sufficiently short to mitigate the need for discounting), r effectively becomes zero in the preceding equations. In the limit as r approaches zero,  $C = t_r = t_i$  (or  $C = t_f$  when  $t_i = 0$ ). This new value for C should be used to evaluate D in the undiscounted case.

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

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

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

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

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

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

 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:

$$V_{OP} = N \Delta F U$$

where

$V_{OP}$	=	monetary value of avoided onsite property damage (dollars)	
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- N = number of affected facilities
- $\Delta F$  = 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. In particular, 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 take into account some aspects of decommissioning and nuclear waste management that will make the total cost higher. In particular, 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, Burke et al. (1984) 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 as a consequence 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. The TMI-1 unit is currently in operation, and

the NRC extended the license until April 2034. 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 <sub>RP</sub>	Replacement Power	\$1.0x10 <sup>10</sup> x F
UCD	Cleanup an Decontamination	\$1.3x10 <sup>10</sup> x F
U	Total	\$2.3x10 <sup>10</sup> x 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  $1 \times 10^{-6}$  per reactor-year and that the number of reactor units affected (N) is 100. The total averted onsite damage costs would be as follows:

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

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 (e.g., architect engineering firms). The analyst should define the incremental costs of the action at a finer level of detail. The analyst should refer to the code of accounts in the Energy Economic Data Base (United Engineers and Constructors, Inc., 1986) or Schulte et al. (1978) to prepare a detailed account of implementation costs.

# 5.3.2.6.1 Short-Term Replacement Power

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

# 5.3.2.6.2 Premature Facility Closing

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)<sup>t</sup>]:

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); Clark and Chockie (1979); Eisenhauer et al. (1982); NUS Corporation (1969); Phung (1978); Roberts et al. (1980); Stevenson (1981); 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

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

Three steps are necessary for estimating NRC implementation costs:

- (1) Determine what steps the NRC should take to put the proposed action into effect.
- (2) Determine the requirements for the staff, outside contractors, materials, and equipment.
- (3) Estimate the costs of the required resources, discount if appropriate, and then sum.

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

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

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

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

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

#### 5.3.2.9 NRC Operation

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

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

- (1) Determine the activities that the NRC should perform after the proposed action is implemented.
- (2) Estimate staff labor, contractor support, and any special equipment and material required.
- (3) Estimate the costs of the required resources, discount (usually over the remaining lifetimes of the affected facilities) to yield present value, and then sum.

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

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

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

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

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

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 a number of government branches and offices. In developing estimates for the implementation costs, the analyst is encouraged to contact all of 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 postimplementation 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 still has the burden of justifying the effort and indicating its effect. If necessary, this justification would be expressed qualitatively under this attribute. An effort should be made to identify the types of costs and benefits that are likely to be accrued and who will incur them.

Consider the following statement:

This assessment effort has a reasonable prospect of reducing our uncertainty regarding the likelihood of containment failure resulting from hydrogen burning.

Such an accident may be a significant source of risk. The knowledge from the proposed assessments would enable us to assess more accurately the overall accident risk posed by nuclear reactors, and this, in turn, should benefit the public through better policy decisions.

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

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

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

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

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

#### 5.3.2.13 Regulatory Efficiency

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

If necessary, this justification 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.<sup>8</sup>

# 5.3.2.16 Other Considerations

Other considerations may be associated with a particular 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 (<u>https://www.bls.gov/bls/blswage.htm</u>). 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 25<sup>th</sup> percentile, the mean, and the 75<sup>th</sup> 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.

<sup>&</sup>lt;sup>8</sup> 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."

# 5.5 <u>Economic Discounting and Calculation of Present Value</u>

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 by the use of the following annuity formula (but only if they are the same amount for each time period):

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

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<sup>-rt</sup>, 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, Strip (1982) 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<sub>i</sub> = time of onset of accident risk
- t<sub>f</sub> = time of end of accident risk

For public (accident) risk, the product  $C_of$  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 \$1.0x10<sup>4</sup> per facility-year ( $C_of = $1.0x10^4$ ). 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:

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

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 ( $\Delta f$ ). As an example, let the frequency reduction ( $\Delta f$ ) be  $1.0 \times 10^{-5}$  per facility-year and the cost (C<sub>0</sub>) 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<sub>i</sub> = 5) and will remain in place for 20 years (t<sub>f</sub> = 5 + 20 = 25). The present value of the avoided offsite property damage becomes:

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

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 accomplishes the three objectives that the NRC staff sought to accomplish through this update. Specifically, the revision 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, "GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs," issued 2009, 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.

# 7 REFERENCES

5 U.S.C. 601 et seq., Regulatory Flexibility Act of 1980, as amended. Available at <a href="http://www.nmfs.noaa.gov/sfa/laws\_policies/economic\_social/">http://www.nmfs.noaa.gov/sfa/laws\_policies/economic\_social/</a> rfa revised through 2010 jobs act.pdf.

5 U.S.C. 603, Initial Regulatory Flexibility Analysis (public access to budget data), 1974. Accessed at <u>https://www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-2010-2010-20-</u>

42 U.S.C. 2011 et seq., Atomic Energy Act of 1954, as amended. Available at <u>https://www.nrc.gov/docs/ML1327/ML13274A489.pdf#page=23</u>.

42 U.S.C. 4332 et seq., National Environmental Policy Act of 1969, as amended. Available at <u>https://energy.gov/nepa/downloads/national-environmental-policy-act-1969</u>.

44 U.S.C. 3501 et seq., Paperwork Reduction Act of 1995, as amended. Available at <u>http://www.reginfo.gov/public/reginfo/pra.pdf.</u>

Aaberg, R.L and D.A. Baker, "Dose Commitments Due to Radioactive Releases from Nuclear Power Plant Sites in 1992," NUREG/CR-2850, Vol. 14, 1996. Available at <a href="http://www.iaea.org/inis/collection/NCLCollectionStore/">http://www.iaea.org/inis/collection/NCLCollectionStore/</a> Public/27/059/27059899.pdf.

Amagai, M., et al., "Factors Related to the Mental Health and Suicidal Thoughts of Adults Living in Shelters for a Protracted Period Following a Large-Scale Disaster," *Academic Journal of Interdisciplinary Studies* 3(3):11–16, 2014.

Beal, S., et al., "Data Base of System-Average Dose Rates at Nuclear Power Plants," NUREG/CR-5035, 1987.

Bromet, E.J., and L. Litcher-Kelly, "Psychological Response of Mothers of Young Children to the Three Mile Island and Chernobyl Nuclear Plant Accidents One Decade Later," in *Toxic Turmoil: Psychological and Societal Consequences of Ecological Disasters*, J. Havenaar, J. Cwikel, and E. Bromet (Eds.), 2002, pp. 69–84.

Budwani, R., "Power Plant Capital Cost Analysis," *Power Engineering* 84(5):62–70, 1969.

Burke, R., et al., "Economic Risks of Nuclear Power Reactor Accidents," NUREG/CR-3673, May, 1984. ADAMS Accession No. ML103050360.

Carlson, W., et al., "Analysis of Coal Option. Vol. II of Comparative Study of Coal and Nuclear Generating Options for the Pacific National Northwest," WPPSS FTS-058-II, 1977.

Clark, L., and Chockie, A., "Fuel Cycle Cost Projections," NUREG/CR-1041, December 1979.

*Code of Federal Regulations* (CFR), Title 5, *Administration Personnel*, Part 1320, "Controlling Paperwork Burdens on the Public." Available at <u>https://www.ecfr.gov/cgi-bin/text-idx?SID=23d5b9c7b6231c35912d3ae0703ec2b4&mc=true&node=pt5.3.1320&rgn=div5</u>.

Conatser, R., et al., "Radioactive Effluents from Nuclear Power Plants: Annual Report 2009," NUREG/CR-2907, Final Report, Vol. 15, August 2013. ADAMS Accession No. ML13218A300.

CFR, Title 10, *Energy*, Part 20, "Standards for Protection against Radiation." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part020/</u>.

CFR, Title 10, *Energy*, Part 50, "Domestic Licensing of Production and Utilization Facilities." Available at <u>http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/.</u>

CFR, Title 10, *Energy*, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part051/</u>.

CFR, Title 10, *Energy*, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part052/</u>.

CFR, Title 10, *Energy*, Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part054/</u>.

CFR, Title 10, *Energy*, Part 70, "Domestic Licensing of Special Nuclear Material." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/.</u>

CFR, Title 10, *Energy*, Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part072/.</u>

CFR, Title 10, *Energy*, Part 76, "Certification of Gaseous Diffusion Plants." Available at <u>https://www.nrc.gov/reading-rm/doc-collections/cfr/part076/</u>.

CFR, Title 40, *Protection of Environment*, Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations." Available at <u>https://www.ecfr.gov/cgi-bin/text-idx?SID=23d5b9c7b6231c35912d3ae0703ec2b4&mc=true&node=pt40.27.190&rgn=div5</u>.

Danzer, A.M., and N. Danzer, "The Long-Run Consequences of Chernobyl: Evidence on Subjective Well-Being, Mental Health and Welfare," University of Munich Discussion Paper No. 2014-25, June 10, 2014. Available at <u>http://epub.ub.uni-muenchen.de/20969</u>.

Eisenhauer, J., et al., "Electric Energy Supply Systems Comparison and Choices Volume I: Technology Description Report," PNL-3277, 1982.

Electric Power Research Institute (EPRI), "Technical Assessment Guide," EPRI-P-4463-SR, Palo Alto, CA, 1986.

Energy Information Administration (EIA), U.S., "Capital Cost Estimates for Utility Scale Electricity Generating Plants," November 2016. Accessed at: <u>https://www.eia.gov/analysis/studies/powerplants/capitalcost/pdf/capcost\_assumption.pdf</u>.

Hasegawa, A., et al., "Health Effects of Radiation and Other Health Problems in the Aftermath of Nuclear Accidents, with an Emphasis on Fukushima," *The Lancet* 386(9992):479–488, August 2015.

International Atomic Energy Agency (IAEA), "Environmental Consequences of the Chernobyl Accident and Their Remediation: Twenty Years of Experience," Report of the Chernobyl Forum Expert Group 'Environment,' IAEA Publication 1239, Vienna, Austria, April 2006. Available at <a href="http://www-pub.iaea.org/mtcd/publications/pdf/pub1239">http://www-pub.iaea.org/mtcd/publications/pdf/pub1239</a> web.pdf.

Institute of Medicine, "Valuing Health for Regulatory Cost-Effectiveness Analysis," Washington, DC, 2006.

Kaplan, S., and Garrick, B. J., "On the Quantitative Definition of Risk," *Risk Analysis* 1(1):11–27, March 1981.

Karz, A., J. Reichstein, R. Yanagisawa, and C. L. Katz, "Ongoing Mental Health Concerns in Post-3/11 Japan," *Annals of Global Health* 80(2):108–114, March-April 2014.

Kemeny, J.G., et al., "Report of the President's Commission on the Accident at the Three Mile Island, The Need for Change: The Legacy of TMI," October 1979. Available at <u>http://www.threemileisland.org/downloads/188.pdf</u>.

LaGuardia, T., et al., "Guidelines for Producing Commercial Nuclear Power Plant Decommissioning Cost Estimates," AIF/NESP-036, 1986.

Masunaga, T., et al., "Mental Health Status among Younger Generation around Chernobyl," *Archives of Medical Science* 9(6):1114–1116, November 2011.

Michigan v. EPA, 135 S. Ct. 2699 (2015).

National Research Council Committee, "Estimating Mortality Risk Reduction Benefits from Decreasing Tropospheric Ozone Exposure," National Academies Press, Washington, DC, 2008.

National Safety Council, "Injury Facts: The Source for Safety Data," National Safety Council, Statistics Division, University of Michigan, Ann Arbor, MI. Available at <a href="http://www.nsc.org/learn/safety-knowledge/Pages/injury-facts.aspx">http://www.nsc.org/learn/safety-knowledge/Pages/injury-facts.aspx</a>.

Nuclear Energy Institute (NEI), "Severe Accident Mitigation Alternatives (SAMA) Analysis: Guidance Document," NEI 05-01, Revision A, Washington, DC, November 2005. ADAMS Accession No. ML060530203. Available at https://www.nrc.gov/docs/ML0605/ML060530203.pdf.

NUS Corporation, "Guide for Economic Evaluation of Nuclear Reactor Plant Designs," NUS-531, Gaithersburg, MD, 1969.

Office of the President, "Executive Order 12291: Federal Regulation," *Federal Register*, February 17, 1981 (46 FR 13193). Available at <u>http://www.archives.gov/federal-register/codification/executive-order/12291.html.</u>

Office of the President, "Executive Order 12866: Regulatory Planning and Review," *Federal* Register, September 30, 1993 (58 FR 51735; October 4, 1993). Available at <u>http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf.</u>

Office of the President, "Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations," *Federal Register*, February 11, 1994 (59 FR 7629; February 16, 1994). Available at <a href="http://www.archives.gov/federal-register/executive-orders/pdf/12898.pdf">http://www.archives.gov/federal-register/executive-orders/pdf/12898.pdf</a>.

Office of the President, "Executive Order 13563: Improving Regulation and Regulatory Review," *Federal Register*, January 18, 2011 (76 FR 3821; January 21, 2011). Available at <u>https://www.federalregister.gov/d/2011-1385</u>.

Office of the President, "Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs," *Federal Register*, January 30, 2017 (82 FR 9339; February 3, 2017). Available at <u>https://www.federalregister.gov/d/2017-02451</u>.

Office of the President, "Executive Order 13783: Promoting Energy Independence and Economic Growth," *Federal Register*, March 28, 2017 (82 FR 16093; March 31, 2017). Available at <u>https://www.federalregister.gov/d/2017-06576</u>.

Phung, D., "Method for Estimating Escalation and Interest during Construction (EDC and IDC)," ORAU/IEA-78-7(M), Institute for Energy Analysis, Oak Ridge, TN, 1978.

Regulatory Working Group, "Economic Analysis of Federal Regulations under Executive Order 12866," January 11, 1996. Available at <u>https://www.whitehouse.gov/omb/inforeg\_riaguide/</u>.

Robert Snow Means Company, Inc., "Building Construction Cost Data 1996," 54<sup>th</sup> annual edition, Kingston, MA, December 1995.

Roberts, J.O., et al., "Treatment of Inflation in the Development of Discount Rates and Levelized Costs in NEPA Analyses for the Electric Utility Industry," NUREG-0607, 1980.

Schulte, S., et al., "Fusion Reactor Design Studies—Standard Accounts for Cost Estimates," PNL-2648, Pacific Northwest Laboratory, Richland, WA, 1978.

Sciacca, F., "Generic Cost Estimates: Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses," NUREG/CR-4627, Revision 2, February 1992. ADAMS Accession No. ML13137A259.

Spensley, J.W., Esq., "National Environmental Policy Act," *Environmental Law Handbook*, 14<sup>th</sup> Edition, T.F.P. Sullivan (Ed.), 1997.

Stevenson, J., "Evaluation of the Cost Effects on Nuclear Power Plant Construction Resulting from the Increase in Seismic Design Level," NUREG/CR-1508, 1981.

Strip, D., "Estimates of the Financial Risks of Nuclear Power Reactor Accidents," NUREG/CR-2723, September 1982. ADAMS Accession No. ML103050361.

Tichler, J., et al., "Radioactive Materials Released from Nuclear Power Plants: Annual Report 1993," Volume 14, NUREG/CR-2907, December 1995.

United Engineers and Constructors, Inc., "Energy Economic Data Base (EEDB)—Phase VIII, Complete CONCISE Printouts for Model 148 Pressurized Water Reactor (Median Experience Basis) and Model 205 BWR (ME) Mark II, 1195 MWe Boiling Water Reactor," Philadelphia, PA, 1986.

United Engineers and Constructors, Inc., "Phase IX Update (1987) Report for the Energy Economic Data Base (EEDB) Program EEDB-1X," DOE/NE-0091, Philadelphia, PA, 1988a.

United Engineers and Constructors, Inc., "Technical Reference Book for the Energy Economic Data Base Program EEDB Phase IX (1987)," DOE/NE-002, Philadelphia, PA, 1988b.

U.S. Bureau of Labor Statistics, "Injuries, Illnesses, and Fatalities." Available at <u>http://www.bls.gov/iif/</u>.

U.S. Department of Energy (DOE), "Cost Guide, Volume 2: Standard Procedures for Determining Revenue Requirements (Product Cost)," Volume 2, DOE/MA-0063, 1982.

U.S. Environmental Protection Agency (EPA), "User's Guide for the COMPLY Code," EPA/520/1-89-003, 1989. Available at <u>https://www.epa.gov/sites/production/files/2015-05/documents/520-1-89-003.pdf</u>.

EPA, "Guidelines for Preparing Economic Analyses," December 17, 2010. Available at <u>https://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0568-50.pdf</u>/\$file/EE-0568-50.pdf.

U.S. Government Accountability Office (GAO), "GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs," GAO-09-3SP, March 2009. Available at <u>http://www.gao.gov/assets/80/77175.pdf.</u>

GAO, "Nuclear Regulatory Commission—NRC Needs To Improve Its Cost Estimates by Incorporating More Best Practices," Report to Congressional Requesters, GAO-15-98, December 12, 2014. Available at <u>http://www.gao.gov/assets/670/667501.pdf.</u>

U.S. Nuclear Regulatory Commission (NRC), "Value-Impact Guidelines," SECY-77-388A, December 19, 1977. ADAMS Accession No. ML12234B122 (nonpublic).

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, January 1983a. ADAMS Accession No. ML15027A412.

NRC, "A Handbook for Value-Impact Assessment," NUREG/CR-3568, December 1983b. ADAMS Accession No. ML062830096.

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 1, NUREG/BR-0058, May 1984. ADAMS Accession No. ML15027A413.

NRC, "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, Republication," *Federal Register*, August 21, 1986 (51 FR 30028). Available at <a href="http://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf">http://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf</a>.

NRC, "Backfitting Guidelines," NUREG-1409, July 1990a. Available at <u>https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/</u>.

NRC, "SECY-89-102—Implementation of the Safety Goals," SRM-SECY-89-102, June 15, 1990b. ADAMS Accession No. ML003707881.

NRC, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," NUREG-1150, December 1990c. ADAMS Accession No. ML040140729.

NRC, "Requirements Concerning the Accessible Air Gap for Generally Licensed Devices," *Federal Register,* November 27, 1992 (57 FR 56287).

NRC, "Backfit Considerations," SECY-93-086, June 30, 1993a. ADAMS Accession No. ML003760758 (nonpublic).

NRC, "Self-Guarantee as an Additional Financial Assurance Mechanism," *Federal Register*, December 29, 1993b (58 FR 68726).

NRC, "Final Safety Evaluation Report Related to the Certification of the Advanced Boiling Water Reactor Design," Main Report, NUREG-1503, July 1994. ADAMS Accession No. ML080670592 (package).

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Final Report, Revision 2, NUREG/BR-0058, November 1995a. ADAMS Accession No. ML111180434.

NRC, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, Final Policy Statement," *Federal Register*, August 16, 1995b (60 FR 42622). Available at <a href="http://www.gpo.gov/fdsys/pkg/FR-1995-08-16/pdf/95-20237.pdf">http://www.gpo.gov/fdsys/pkg/FR-1995-08-16/pdf/95-20237.pdf</a>.

NRC, "Regulatory Analysis Technical Evaluation Handbook," Final Report, NUREG/BR0184, January 1997a. ADAMS Accession No. ML050190193.

NRC, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," NUREG-1560, December 1997b (nonpublic).

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 3, NUREG/BR-0058, Final Report, Revision 3, July 2000a. ADAMS Accession No. ML023290519.

NRC, "NMSS Decommissioning Standard Review Plan," NUREG-1727, September 2000b. ADAMS Accession No. ML003761169.

NRC, "NRC Information Quality Guidelines," *Federal Register*, October 1, 2002a (67 FR 61695). Available at <u>http://www.nrc.gov/public-involve/info-quality/fr67p61695.html.</u>

NRC, "Perspectives Gained from the Individual Plant Examination of External Events (IPEEE) Program," NUREG-1742, Final Report, Volumes 1 and 2, April 2002b. Available at <a href="https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1742/">https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1742/</a>.

NRC, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," NUREG-1748, Final Report, August 2003. ADAMS Accession No. ML032450279.

NRC, "U.S. NRC Strategic Plan: Fiscal Years 2014-2018," NUREG-1614, Vol. 6, 2014a. ADAMS Accession No. ML14246A439.

NRC, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Revision 4, September 2004b. ADAMS Accession No. ML042820192.

NRC, "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design," Initial Report, NUREG-1793, September 2004c. Available at <u>https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1793/initial/index.html</u>.

NRC, "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions," *Federal Register*, August 24, 2004d (69 FR 52040).

NRC, "United States Nuclear Regulatory Commission Regulations Handbook," NUREG/BR-0053, Revision 6, September 2005. ADAMS Accession No. ML052720461.

NRC, "Environmental Standard Review Plan: Standard Review Plans for Environmental Reviews for Nuclear Power Plants," NUREG-1555, initial issuance in October 1999 and selected sections revised in July 2007. Available at <u>http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1555/.</u>

NRC, "Charter: Committee to Review Generic Requirements," Revision 8, March 2011a. Available at <u>https://www.nrc.gov/about-nrc/regulatory/crgr/charter.html</u>.

NRC, "A Prioritization of Generic Safety Issues," NUREG-0933, Main Report with Supplements 1-34, 2011b. Available at <u>https://www.nrc.gov/sr0933/.</u>

NRC, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," SECY-12-0110, August 14, 2012. ADAMS Accession No. ML12173A478 (package).

NRC, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," Revision 1, Final Report, NUREG-1437, June 2013a. ADAMS Accession No. ML13107A023 (package).

NRC, "Staff Requirements—SECY-12-0110—Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," SRM-SECY-12-0110, March 20, 2013b. ADAMS Accession No. ML13079A055.

NRC, "Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking," NUREG-2122, November 2013c. ADAMS Accession No. ML13311A353.

NRC, "History of the Use and Consideration of the Large Release Frequency Metric by the U.S. Nuclear Regulatory Commission," SECY-13-0029, March 22, 2013d. ADAMS Accession No. ML13022A207.

NRC, "Management of Facility-Specific Backfitting and Information Collection," Management Directive 8.4, October 9, 2013e. ADAMS Accession No. ML12059A460.

NRC, "Procedural Guidance for Preparing Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues," Revision 3, Office of Nuclear Reactor Regulation LIC-203, July 1, 2013. ADAMS Accession No. ML12234A708.

NRC, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal," Revision 1, Final Report, NUREG-1555, June 2013. ADAMS Accession No. ML13106A246.

NRC, "Memorandum and Order in the Matter of U.S Department of Energy (High Level Waste Repository)," CLI-13-08, November 2013. ADAMS Accession No. ML13322A744.

NRC, "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design," NUREG-1966, April 2014. ADAMS Accession No. ML14100A304 (package).

NRC, "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy," Draft Report for Comment, Revision 1, NUREG-1530, August 2015. ADAMS Accession No. ML15237A211.

NRC, "NRC Information Collections Program," Management Directive 3.54, March 29, 2016. ADAMS Accession No. ML15239A370.

U.S. Office of Management and Budget (OMB), "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs," Circular No. A-94 Revised, October 29, 1992. Available at <u>https://www.whitehouse.gov/omb/circulars\_a094/.</u>

OMB, "Regulatory Impact Analysis Guidance," Appendix V, in "Regulatory Program of the United States Government: April 1, 1992–March 31, 1993," Document No. S/N 041-001-00388-6.

OMB, "Regulatory Analysis," Circular No. A-4, September 17, 2003. Available at <u>https://www.whitehouse.gov/omb/circulars\_a004\_a-4/.</u>

Van Houtven, G., et al., "Valuing Avoided Morbidity Using Meta-Regression Analysis: What Can Health Status Measures and QALYs Tell Us about WTP?," *Health Economics* Vol. 15-8, March 17, 2006.

Wright, M., *Discounted Cash Flow*, 2<sup>nd</sup> Edition, McGraw-Hill Education, New York, NY, 1973.