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Regulatory Analysis Technical Evaluation Handbook

Final Report

Office of Nuclear Regulatory Research

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Abstract

The purpose of this Handbook is to provide guidance to the regulatory analyst to promote preparation of quality regulatory analysis documents and to implement the policies of the *Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission* (NUREG/BR–0058 Rev. 2). This Handbook expands upon policy concepts included in the NRC Guidelines and translates the six steps in preparing regulatory analyses into implementable methodologies for the analyst. It provides standardized methods of preparation and presentation of regulatory analyses, with the inclusion of input that will satisfy all backfit requirements and requirements of NRC's Committee to Review Generic Requirements. Information on the objectives of the safety goal evaluation processs and potential data sources for preparing a safety goal evaluation is also included. Consistent application of the methods provided here will result in more directly comparable analyses, thus aiding decision–makers in evaluating and comparing various regulatory actions.

The handbook is being issued in loose–leaf format to facilitate revisions. NRC intends to periodically revise the handbook as new and improved guidance, data, and methods become available.

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Foreword

This document is a Handbook to be used by the NRC and its contractors in the preparation of regulatory analyses to aid NRC decision-makers in deciding whether a proposed new regulatory requirement should be imposed. In addition, it is anticipated that the Handbook will be useful to the Agreement States in their assessment of new regulatory requirements. The Handbook is an updated and revised version of an earlier document, *A Handbook for Value-Impact Assessment* (NUREG/CR-3568), issued by the NRC in 1983.

The 1983 document is being updated in this Handbook to accomplish the following objectives:

- To reflect the content of NRC's Regulatory Analysis Guidelines, NUREG/BR-0058 Rev. 2, issued in November 1995.
- To expand the scope of the Handbook to include the entire regulatory analysis process and to address facilities other than power reactors.
- To reflect NRC experience and improvements in data and methodology since the 1983 Handbook was issued.
- To reflect the guidance in the 1996 document, *Economic Analysis of Federal Regulations Under Executive Order 12866*. This document was prepared by a Federal interagency regulatory working group convened by the Office of Management and Budget.

NRC obtained review comments on the draft Handbook from the following organizations: Westinghouse Savannah River Co., Brookhaven National Laboratory, Argonne National Laboratory, and Science and Engineering Associates, Inc. The comments of these organizations are reflected in the Handbook. The draft version of the Handbook has also been used by NRC staff members since 1993 and staff comments have been incorporated. A draft version of the Handbook was made available to the public in September 1993 (58 FR 47160), but comments were not specifically requested.

The Handbook is being issued in loose-leaf format to facilitate future revisions. NRC intends to periodically revise the Handbook as new and improved guidance, data, and methods become available. Comments on the Handbook from users and the public are welcome at any time. Comments should be submitted to: Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publication Services, Mail Stop T-6 D59, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001.

Thomas O. Martin, Chief
Regulation Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

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Abbreviations and Acronyms

AC	alternating current
AE	architect engineer
AEC	U.S. Atomic Energy Commission
AEOD	NRC Office for Analysis and Evaluation of Operational Data
ANL	Argonne National Laboratory
ATWS	anticipated transient without scram
B&W	Babcock & Wilcox
BEIR	biological effects of ionizing radiation
BLS	Bureau of Labor Statistics
BLSV	bulk liquids and scintillation vials
BNL	Brookhaven National Laboratory
BWR	Boiling Water Reactor
CAP	Clean Air Act Assessment Package
CDF	core damage frequency
CE	Combustion Engineering
CFR	Code of Federal Regulations
CPCFB	conditional probability of containment failure or bypass
CRAC	calculation of reactor accident consequences
CRDM	control rod drive mechanism
CRGR	Committee to Review Generic Requirements
cSv	centisievert
CVCS	chemical and volume control system
DRW	dry radioactive waste
DE	dose equivalent
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
EA	environmental assessment
ECCS	emergency core cooling system
EDE	effective dose equivalent
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
FR	Federal Register
FSAR	final safety analysis report
FY	fiscal year
GDP	gross domestic product
GE	General Electric
GEIS	generic environmental impact statement
Guidelines	Regulatory Analysis Guidelines of the U.S. NRC
GWe	gigawatt electric
HAF	high aqueous feed
HAW	high activity waste

HEP	human error probability
HEPA	high efficiency particulate air
HESAP	human error sensitivity assessment of a PWR
HFPP	human factors program plan
HLW	high level waste
HPCS	high pressure core spray
HVAC	heating, ventilation, air conditioning
ICRP	International Commission on Radiological Protection
IDCOR	Industry Degraded Core Rulemaking
IEEE	Institute of Electrical and Electronic Engineers
IPE	individual plant examination
IPEEE	individual plant examination of external events
IREP	Interim Reliability Evaluation Program
IRRAS	Integrated Reliability and Risk Analysis System
LAW	low activity waste
LCF	latent cancer fatality
LCS	leakage control system
LER	licensee event report
LHE	latent health effect
LOCA	loss of coolant accident
LPCS	low pressure core spray
LQR	licensed quantity released
LWR	light water reactor
MACCS	MELCOR Accident Consequence Code System
MOV	motor operated valve
MOX	mixed oxide fuel
MRS	monitored retrievable storage
MT	metric tons
MTHM	metric tons of hazardous materials
MTU	metric tons of uranium
MWe	megawatt electric
NCRP	National Council on Radiation Protection and Measurements
NEPA	National Environmental Policy Act
NHLW	Non-HLW
NMED	Nuclear Material Event Database
NMSS	Office of Nuclear Material Safety and Safeguards
NPP	nuclear power plant
NPRDS	Nuclear Plant Reliability Data System
NRC	U.S. Nuclear Regulatory Commission
NRER	non-reactor event report
NRR	Office of Nuclear Reactor Regulation
OMB	Office of Management and Budget
PASNY	Power Authority of the State of New York
PNNL	Pacific Northwest National Laboratory
PRA	probabilistic risk assessment/analysis
PSE	Projekt Sicherkeitsstudien Entsorgung
PV	present value
PWR	pressurized water reactor
RCIC	reactor core isolation cooling

RECAP	Replacement Energy Cost Analysis Package
REIRS	Radiation Exposure Information and Reporting System
RES	Office of Nuclear Regulatory Research
RHR	residual heat removal
RMIEP	Risk Methods Integration and Evaluation Program
ROR	Reduction-Oxidation Reactor
RSS	reactor safety study
RSSMAP	RSS Methodology Applications Program
RWG	Regulatory Working Group
RWCU	Reactor Water Cleanup
SARA	system analysis and risk assessment
SBO	station blackout
SF	spent fuel
SGBD	steam generator blowdown
SGTR	steam generator tube rupture
SGTS	standby gas treatment system
SECY	Staff Papers Before the Commission
SLCS	standby liquid control system
SRM	Staff Requirements Memorandum
SRP	Standard Review Plan
SST	siting source term
Staff	NRC staff members
TAP	TMI Action Plan
TASC	The Analytic Sciences Corporation
TB	Turbine Building
THERP	technique for human error rate prediction
TMI	Three Mile Island
TRU	transuranic
URL	uniform resource locator
USI	unresolved safety issue
W	Westinghouse

1 Introduction

The past two decades have seen an increasing recognition that governmental actions need to account for their societal and economic impacts. As early as 1969, the National Environmental Policy Act required an assessment of environmental impacts of major federal actions including descriptions of alternatives and any unavoidable environmental insults. In December 1977, the U.S. Nuclear Regulatory Commission (NRC) established value-impact analysis guidelines (SECY-77-388A) to aid its decision-making. Executive Order 12291 was issued in February 1981 (46 FR 13193) requiring that executive agencies prepare regulatory impact analyses for all major rules and directing that regulatory actions be based on adequate information regarding the need for and consequences of proposed actions. Although the order was not binding on the NRC, the Commission decided to meet its spirit to enhance the effectiveness of NRC regulatory actions. Accordingly, in January 1983, the NRC issued *Regulatory Analysis Guidelines* (NUREG/BR-0058) for performing regulatory analyses for a broad range of NRC regulatory actions (NRC 1983c). These guidelines established a framework for 1) analyzing the need for and consequences of alternative regulatory actions, 2) selecting a proposed alternative, and 3) documenting the analysis in an organized and understandable format. In December 1983, the NRC issued *A Handbook for Value-Impact Assessment* (NUREG/CR-3568 [Heaberlin et al. 1983]) (hereafter called the "1983 Handbook"). Its basic purpose was to set out systematic procedures for performing value-impact assessments. Revision 1 to NUREG/BR-0058 (NRC 1984b) was issued in May 1984 to include appropriate references to the 1983 Handbook.

In 1995, NRC's guidance on preparing regulatory analyses was updated in Revision 2 to NUREG/BR-0058 (NRC 1995a), hereafter referred to as the "NRC Guidelines" or simply the "Guidelines." Revision 2 was issued to reflect the NRC's experience implementing Revision 1 of the Guidelines; changes in NRC regulations since 1984, especially the backfit rule (10 CFR 50.109) and the Commission's 1986 Policy Statement on Safety Goals for the Operation of Nuclear Power Plants (NRC 1986); advances and refinements in regulatory analysis techniques; regulatory guidance in Executive Order 12866 (58 FR 51735; October 4, 1993); and procedural changes designed to enhance the NRC's regulatory effectiveness.

This revision to NUREG/CR-3568 (hereafter called the "Handbook") has been prepared to accomplish several objectives. First, the expanded guidance included in Revision 2 of the NRC Guidelines has been incorporated. Second, the scope of the Handbook has been increased to include the entire regulatory analysis process (not only value-impact analyses) and to address not only power reactor, but also non-reactor applications.[1] Third, NRC experience and improvements in data and methodology since the 1983 Handbook have been incorporated. Fourth, an attempt has been made to make the Handbook more "user friendly." Fifth, the Handbook incorporates guidance included in the document *Economic Analysis of Federal Regulations Under Executive Order 12866* (Regulatory Working Group 1996). This document, which superseded the Office of Management and Budget's (OMB's) "Regulatory Impact Analysis Guidance" (reference 6 in the NRC Guidelines), was prepared by a federal interagency regulatory working group.

This Handbook has been designed to assist the analyst in preparing effective regulatory analyses and to provide for consistency among them. The guidance provided is consistent with NRC policy and, if followed, will result in an acceptable document. It must be recognized, however, that all conceivable possibilities cannot be anticipated. Therefore, the Handbook guidance is intended to allow flexibility in interpretation for special circumstances. It must also be recognized that regulatory analysis methods continue to evolve, along with the applicable data. The NRC and other federal agencies (e.g., OMB, the U.S. Environmental Protection Agency [EPA], and the U.S. Department of Transportation [DOT]) continue to undertake research and development to improve the regulatory decision-making process.

1.1 Purpose

The purpose of this Handbook is to provide guidance to the regulatory analyst to promote preparation of high-quality regulatory decision-making documents and to implement the policies of the NRC Guidelines. In fulfilling this purpose, there are several objectives of the Handbook.

First, the Handbook expands upon policy concepts included in the NRC Guidelines. The steps in preparing regulatory analyses are translated into implementable methodologies for the analyst. An attempt is made to provide the rationale behind current NRC policy to assist the analyst in understanding what the decision-maker will likely need in the regulatory analysis. Second, the Handbook has been expanded to address the entire regulatory analysis process, i.e., all six steps (see Handbook Section 1.2.2) identified in the NRC Guidelines. The 1983 Handbook only addressed value-impact analysis, just one element of a regulatory analysis. Also, unlike the 1983 Handbook, this Handbook addresses not only power reactor but also non-reactor applications.

Third, the Handbook has been updated to incorporate changes in policy and advances in methodology that have occurred since the 1983 Handbook was issued. Considerable research has been conducted by the NRC and other agencies on various aspects of regulatory decision-making. Also, NRC staff experience has resulted in significant modifications to the regulatory analysis process. Advances resulting from the above have been appropriately incorporated in this Handbook.

Fourth, the Handbook has consolidated relevant information regarding regulatory analyses. As mentioned above, many activities have improved the ability to make better decisions. The resulting information has been used in the preparation of this Handbook. Where the information is not presented explicitly, references lead the analyst to the appropriate documents.

Fifth, the Handbook provides standardized methods of preparation and presentation of regulatory analyses, including backfit and Committee to Review Generic Requirements (CRGR) regulatory analyses. Consistent application of the methods provided here will result in more directly comparable analyses, thus aiding decision-makers in evaluating and comparing various regulatory actions.

The Handbook cites numerous references throughout, often extracting information from them directly. Where practical, the bases for extracted information have been summarized from the references. However, this does not imply that the analyst should use the information exclusively without consulting the references themselves. Where supplied data seem to contradict the analyst's "common sense," examination of the references may be crucial.

1.2 Regulatory Analysis Overview

The following sections provide an overview of a regulatory analysis. Section 1.2.1 discusses key terms and concepts in a regulatory analysis. Section 1.2.2 discusses the appropriate steps.

1.2.1 Key Terms and Concepts

Backfitting. Backfitting is defined at 10 CFR 50.109(a)(1) as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; 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... ." Backfitting requirements apply only to production and utilization facilities as those terms are defined at 10 CFR 50.2.

Backfit Regulatory Analysis. A backfit regulatory analysis is a regulatory analysis prepared for a generic backfit. A backfit regulatory analysis is prepared to meet the requirements of 10 CFR 50.109(c) and the NRC Guidelines.[2]

CRGR Regulatory Analysis. A Committee to Review Generic Requirements (CRGR) regulatory analysis is a regulatory analysis that satisfies the requirements of the CRGR Charter and the NRC Guidelines. CRGR regulatory analyses are prepared for proposed actions within the CRGR scope as set out in Chapter III of the CRGR Charter. In general, the scope covers new or amended generic requirements and staff positions to be imposed on one or more classes of power reactors.

Generic Backfit. A generic backfit is a backfit applicable to multiple facilities.

Plant-Specific Backfit. A plant-specific backfit is a backfit applicable to a single facility. Backfits of this type are subject to the requirements of NRC Management Directive 8.4 (NRC Manual Chapter 0514).

Regulatory Analysis. A regulatory analysis is a structured evaluation of all relevant factors associated with the making of a regulatory decision. As used by the NRC, a regulatory analysis consists of the six steps described in Handbook Section 1.2.2 and NRC Guidelines Chapter 4.

Safety Goal Evaluation. An evaluation prepared to determine whether a proposed generic safety enhancement backfit for nuclear power plants meets the safety goal screening criteria in the Commission's safety goal policy statement (see Appendix D).

Value-Impact (Benefit-Cost) Analysis. A value-impact analysis is a balancing of the benefits (values) and costs (impacts) associated with a proposed action or decision. Values and impacts should be evaluated in monetary terms when feasible, resorting to qualitative terms where conversion to monetary equivalents cannot be done. A value-impact analysis is a substantial part of a regulatory analysis.

1.2.2 Steps in a Regulatory Analysis

Chapter 4 of the NRC Guidelines provides for six steps in a complete regulatory analysis, corresponding with the six elements to be included in a regulatory analysis. The first step is identifying the problem and establishing the analysis objective. The nature of the problem and its history, boundaries, and interfaces must be clearly established. The objective is the conceptual improvement sought by the proposed regulatory action. It is typically a qualitative statement establishing a basis for judging the results of the subsequent analysis elements.

The second step is identifying alternative approaches to the problem and doing a preliminary analysis of these approaches. Development of a reasonably broad and comprehensive set of alternatives is required to ensure identification of all significant approaches. The initial set of alternatives is reduced by eliminating ones based on obvious feasibility, value, and impact considerations. Alternatives that cannot be clearly eliminated will be subjected to the next step (value-impact analysis).

The third step is estimating and evaluating values and impacts. Step 3 also includes preparation of a safety goal evaluation if the alternatives involve a proposed generic safety enhancement backfit to nuclear power reactors which is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). Safety goal evaluations are discussed in Chapter 3. There are many factors that complicate this step (e.g., imperfect knowledge, many possible evaluation methods, and

values and impacts that are difficult to quantify). Despite the difficulties, a best effort must be made to characterize the factors pertinent to a decision. Even if values and impacts cannot be sufficiently characterized, use of consistent methods, data, and presentation can form an adequate basis on which to prioritize alternative regulatory actions. Much of this Handbook addresses this step.

The fourth step is presenting results. A tabular presentation is typically optimal, with the results displayed to facilitate comparison of the evaluated alternatives. Values and impacts not quantified in monetary terms also need to be presented. The goal is to clearly convey the complex value-impact results to the decision-maker. It is also important to reveal the uncertainties associated with the results so that the decision-maker can assess the confidence associated with them. In this Handbook, steps three and four are together referred to as value-impact analysis.

The fifth step is preparing the decision rationale for selecting the proposed action. In this step the analyst recommends and justifies an action based on the previous analyses. Any decision criteria used in the selection are identified.

The sixth and final step is developing a schedule for the activities that will be required to implement the proposed actions. Implementation activities could include such things as needed analyses, approvals, procurement, installation and testing, procedure development, training, and reporting. The schedule should be realistic and can include alternative schedules if appropriate.

1.3 Handbook Overview

Chapter 1 provides introductory and conceptual information regarding the performance of a regulatory analysis and some historical perspective. The relationship of this Handbook with the NRC Guidelines and other NRC policy is established.

Chapter 2 explains the scope of regulatory analyses and the appropriate level of detail to be used.

Chapter 3 discusses the safety goal evaluation required by Chapter 3 of the NRC Guidelines for generic safety enhancement backfits to nuclear power reactors when the proposed backfit is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3).

Chapter 4 presents the methodology to be used in performance of a regulatory analysis.

Chapter 5 presents detailed guidance on the performance of the value-impact analysis portion of a regulatory analysis for both power reactor and non-reactor facilities.

Chapter 6 lists all Handbook references.

Appendix A discusses topics of particular importance in regulatory analyses that are not covered specifically in other areas of the Handbook, especially human factors issues.

Appendix B contains supplementary information for the value-impact portion of a regulatory analysis.

Appendix C presents supplemental information on regulatory analyses for non-reactor facilities.

Appendix D reproduces the Safety Goals for the Operations of Nuclear Power Plants Policy Statement and the Backfit Rule.

Appendix E is an index to the Handbook.

1.4 Endnotes for Chapter 1

1. The variety of non-reactor facility types and the relatively non-integrated sets of available information add difficulty to the preparation of regulatory analyses for non-reactor facilities. Appendix C represents an attempt to coordinate available information to provide guidance for conducting a non-reactor regulatory analysis, especially the value-impact analysis segment. The nature of regulatory analyses for non-reactor facilities will continue to evolve as more analyses are performed and more information becomes available.

2. As discussed in Section 2.2 of the Handbook, some backfit regulatory analyses fall within the scope of the CRGR Charter, and therefore, are subject to the requirements for CRGR regulatory analyses as well. Commission approval of Revision 6 to the CRGR Charter was announced in SECY-96-032 issued in March 1996.

2 Scope of a Regulatory Analysis

Most NRC regulatory actions require some form of analysis and supporting documentation, the exact nature of which is determined by the type of action. This chapter discusses the scope of the particular type of analysis termed a "regulatory analysis," defined in Section 1.2.1.

2.1 When a Regulatory Analysis is Required

Section 2.2 of the NRC Guidelines states that, in general, all mechanisms proposed to be used by the NRC to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by NRC licensees, include an accompanying regulatory analysis. Specific criteria for determining whether a regulatory analysis will need to be performed are also presented in Section 2.2 of the NRC Guidelines.

Section 2.1 of the NRC Guidelines makes it clear that a regulatory analysis is an integral part of NRC decision-making. It is necessary, therefore, that the regulatory process begin as soon as it becomes apparent that some type of regulatory action by the NRC to address an identified problem may be needed.

Many regulatory analyses will fall into the classifications of backfit regulatory analyses and/or CRGR regulatory analyses. Table 2.1 summarizes important characteristics of these two classifications of regulatory analyses. Additional information is provided in Sections 2.2 and 2.3 of this Handbook.

An additional consideration impacts regulatory analyses involving generic safety enhancement backfits to nuclear power plants that are subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). As discussed in Chapter 3 of the Guidelines, a safety goal evaluation is needed for these regulatory analyses. The result of this evaluation determines the extent to which further development of the regulatory analysis is appropriate.

2.2 When a Backfit Regulatory Analysis is Required

The term "backfitting" is defined at 10 CFR 50.109(a)(1). Backfitting only applies to facilities licensed under 10 CFR Part 50. Such facilities are called production facilities or utilization facilities (these terms are defined at 10 CFR 50.2). A nuclear power plant is a utilization facility. For a detailed discussion of concepts related to backfitting, the reader is referred to the *Backfitting Guidelines*, NUREG-1409 (NRC 1990a). The guidance provided in this Handbook applies to generic backfits (defined in Section 1.2.1) and, in certain instances, plant-specific backfits as well (also defined in Section 1.2.1). NRC Management Directive 8.4 should be consulted for requirements related to plant-specific backfits.

Ordinarily, any proposed action fitting the definition of a backfit will require the preparation of a backfit regulatory analysis. The only instances where a backfit regulatory analysis will not be required for a proposed backfit are the three exceptions identified at 10 CFR 50.109(a)(4). These exceptions are determinations by the Commission or NRC staff, as appropriate, that:

- a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

- regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

Table 2.1 Applications of backfit and CRGR regulatory analyses

Characteristic	Backfit Regulatory Analyses	CRGR Regulatory Analyses
Facilities	Production and utilization facilities (e.g., nuclear power plants).	Nuclear power plants; Materials licensees (to the extent directed by the Executive Director of Operations [EDO] or the Director of the Office of Nuclear Material Safety and Safeguards [NMSS]).
Type of Action	New or amended rule or staff position covering modification of or additions to systems, structures, components, or design of a facility or the procedures or organization required to design, construct, or operate a facility [with the three exceptions described at 10 CFR 50.109(a)(4)].	New or amended generic requirements and staff positions to be imposed on one or more classes of power reactors or materials licensees, including reductions in existing requirements.
Type of Backfit Covered	Backfits where there are substantial increases in the overall protection of the public health and safety or the common defense and security and the implementation costs are justified in view of the increased protection.	All backfits meeting other CRGR criteria, including backfits considered necessary to ensure adequate protection to public health and safety.

- the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

When one of these exceptions is relied upon for not performing a backfit regulatory analysis, a written evaluation meeting the requirements of 10 CFR 50.109(a)(6) and Section IV.B(ix) of the CRGR Charter (for proposed actions within the scope of the CRGR) must be prepared. Also, costs are not to be considered in justifying the proposed action.

A backfit regulatory analysis is similar to, and should generally follow the requirements for, a regulatory analysis.[1] There are certain requirements specific to a backfit regulatory analysis that are identified at 10 CFR 50.109(a)(3) and 10 CFR 50.109(c). These requirements are identified in Table 2.2 and at appropriate parts of the Handbook. Table 2.2 also cites where in the CFR the requirement is located and indicates where in the regulatory analysis the discussion of each

Table 2.2 Checklist for specific backfit regulatory analysis requirements

CFR Citation (Title 10)	Information Item to be Included in a Backfit Regulatory 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 the 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 cost 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.	Burden - 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

Table 2.2 (Continued)

CFR Citation (Title 10)	Information Item to be Included in a Backfit Regulatory Analysis	Section of the Regulatory Analysis Where Item Should Normally be Discussed
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(c)	Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility.	Implementation

item should normally appear. The analyst must be sure to integrate the 10 CFR 50.109 requirements into the backfit regulatory analysis. Section 2.3 of the Guidelines requires that the findings required by 10 CFR 50.109 are to be highlighted in a backfit regulatory analysis. The recommended method of highlighting backfit rule findings is a vertical line in the left margin adjacent to the text to be highlighted.

If the proposed backfit falls within the scope of the CRGR (as set out in Section III of the CRGR Charter), the information requirements identified in Section IV.B of the Charter and Section 2.3 of this Handbook should be incorporated into the backfit regulatory analysis. (Inclusion of these items will, in effect, render the backfit regulatory analysis a CRGR regulatory analysis). A proposed backfit 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 the EDO or the Director of NMSS) will ordinarily require CRGR review.

2.3 When a CRGR Regulatory Analysis is Required

The CRGR has the responsibility to review and recommend to the EDO approval or disapproval of requirements or NRC staff positions to be imposed on one or more classes of power reactors and, in some cases, on nuclear materials licensees. The review applies to requirements or positions which reduce existing requirements or positions and proposals which increase or change requirements. The CRGR's purpose, membership, scope, operating procedures, and reporting requirements are set out in the CRGR Charter. The most recent version of the Charter is Revision 6, issued in 1996 (NRC 1996c).

Section IV.B of the Charter lists the information that is required to be submitted to the CRGR for review of proposed actions within its scope. One item (identified in Section IV.B(v) of the Charter) is a regulatory analysis conforming to the direction in the NRC Guidelines and this Handbook.[2] There are other requirements included in Section IV.B as shown in Table 2.3. Table 2.3 includes the citation to the portion of the CRGR Charter where the requirement is found and also indicates where in the regulatory analysis the discussion of each item should normally appear. The analyst should generally ensure that each item in Table 2.3 is included in a regulatory analysis prepared for CRGR review. The items included in Table 2.3 are identified and discussed at appropriate parts of this Handbook. Section 2.3 of the Guidelines

Table 2.3 Checklist for specific CRGR regulatory analysis requirements

CRGR Charter Citation	Information Item to be Included in a Regulatory Analysis Prepared for CRGR Review	Section of the Regulatory Analysis Where Item Should Normally be Discussed
IV.B(i)	The proposed generic requirement or staff position as it is proposed to be sent out to licensees.	Implementation
	When the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirement should specify the objective or result to be attained rather than prescribing how the objective or result is to be attained.	Identification of Alternatives
IV.B(iii)	The sponsoring office's position on whether the proposed action would increase requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.	Presentation of Results
IV.B(iv)	The proposed method of implementation.[3]	Implementation
IV.B(vi)	Identification of the category of power reactors or nuclear materials facilities/activities to which the generic requirement or staff position will apply.	Identification of Alternatives
IV.B(vii) IV.B(viii)	If the proposed action involves a power reactor backfit and the exceptions at 10 CFR 50.109(a)(4) are not applicable, the items identified at 10 CFR 50.109(c) and the required rationale at 10 CFR 50.109(a)(3) are to be included (these items are included in Table 2.2)[4]	See Table 2.2

Table 2.3 (Continued)

CRGR Charter Citation	Information Item to be Included in a Regulatory Analysis Prepared for CRGR Review	Section of the Regulatory Analysis Where Item Should Normally be Discussed
IV.B(x)	For proposed relaxations or decreases in current requirements or staff positions, a rationale is to be included for the determination that (a) the public health and safety and the common defense and security would be adequately protected if the proposed reduction in requirements or positions were implemented, and (b) the cost savings attributed to the action would be substantial enough to justify taking the action.[5]	Decision Rationale
IV.B(xii)	Preparation of an assessment of how the proposed action relates to the Commission's Safety Goal Policy Statement (see NRC Guidelines Chapter 3 and Handbook Chapter 3).	Estimation and Evaluation of Values and Impacts

requires that the findings required by the CRGR Charter are to be highlighted in a CRGR regulatory analysis. The recommended method of highlighting CRGR Charter findings is a vertical line in the right margin adjacent to the text to be highlighted.

2.4 Level of Detail

An overview of NRC policy regarding the level of detail to be provided in regulatory analyses is provided in Chapter 4 of the NRC Guidelines. The emphasis in implementation of the NRC Guidelines should be on simplicity, flexibility, and commonsense, both in terms of the type of information supplied and in the level of detail provided. The level of treatment given to a particular issue in a regulatory analysis should reflect how crucial that issue is to the bottom line recommendation of the regulatory analysis. In all cases, regulatory analyses are to be sufficiently clear and detailed for use by NRC decision-makers and other interested parties.

With respect to the appropriate level of detail, the analyst must first determine the level of effort to be expended in analyzing the problem. A greater expenditure of effort will result in a greater expenditure of NRC resources, and vice versa.

The expenditure of resources to analyze a regulatory action is to be correlated with the safety and cost impacts of the action. Chapter 4 of the Guidelines lists factors that should be considered to determine the appropriate level of detail.

This Handbook presents direct guidance for performing what is termed a "standard" analysis. This is expected to encompass one to two person-months, a level of effort believed sufficient for many regulatory analyses. The Guidelines and this

Handbook, including references suggested by this Handbook, should be sufficient for performing the analysis. Where larger levels of effort may be involved, this Handbook suggests additional methods and references which can be used. These could entail major efforts, possibly on the order of a person-year.

A decision tree has been developed to assist the analyst in determining the appropriate level of effort to be applied in a particular case (see Figure 2.1). If the NRC action will result in a regulatory burden on licensees, a regulatory analysis will typically be required. The level of effort will depend on the complexity of the issue. A complex issue would clearly justify a major effort based on the significant impacts of the regulatory decision. If NRC management specifically direct that a major effort be undertaken, the decision is clear. If the issue is not complex, the standard analysis should suffice. The level of detail to be included in the regulatory analysis document can generally be expected to follow the level of effort expended in performing the analysis. The Guidelines establish the minimum requirements. In determining the appropriate level of detail, the best guidance is that the analyst view the presentation objectively from the point of view of the decision-maker.

In cases where there is uncertainty as to the correct level of detail, it is probably better to err on the side of providing too much information. A decision-maker can always filter out unnecessary information, but may have considerable difficulty filling in the blanks. Tables and figures should be used to the maximum extent possible to convey information, particularly where the amount of information is substantial or where comparisons are involved.

2.5 Units

Regulatory analyses should be prepared consistently with NRC's final metrication policy statement (61 FR 31170; June 19, 1996). Regulatory analyses affecting more than one licensee should be prepared in dual (i.e., metric and English) units. Metric units should be shown first with the value in English units shown in parenthesis. Regulatory analyses affecting a single licensee should use the system of units employed by the licensee.

2.6 Regulatory Relaxations

NRC's position on regulatory analysis requirements for relaxation of regulatory requirements is in Section 2.2 of the Guidelines. Preparation of a regulatory analysis for a proposed relaxation is generally required. However, the backfit rule requirements in 10 CFR 50.109 and the safety goal evaluation process set out in Chapter 3 of the Guidelines are not applicable to proposed relaxations.

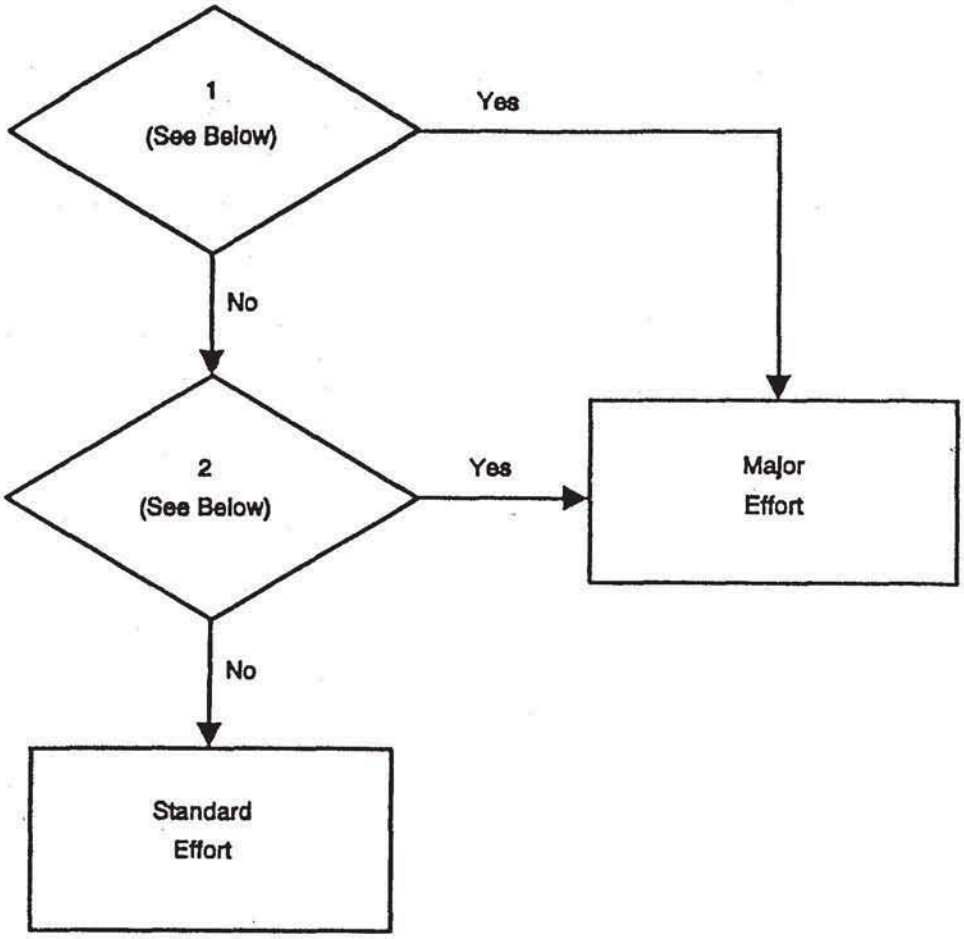
For all regulatory analyses of proposed relaxations, information should be presented in the decision rationale section (see Section 4.4) indicating whether:

1. The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented.

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

3. The proposed relaxation is optional or mandatory for affected licensees.

Inclusion of the three preceding items will satisfy the requirements in Section IV.B(x) of the CRGR Charter.



1. Has the Commission, EDO, or Office Director requested a major effort?

2. Are any of the following likely to occur:

- an annual effect on the economy of $100 million or more
- a major increase in costs or prices for consumers; individual industries; federal, state, or local government agencies or geographic regions
- significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets
- roughly comparable values and impacts
- potential for considerable controversy, complexity, or policy significance?

Figure 2.1 Decision tree to determine level of effort

2.7 Endnotes for Chapter 2

1. NRC's Final Policy Statement on the use of probabilistic risk assessment (PRA) 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 (see Section 5.6).

2. Section IV.B(iv) of the CRGR Charter states that a regulatory analysis is not required for backfits within the scope of 10 CFR 50.109(a)(4).

3. Section IV.B(iv) of the CRGR Charter also requires the concurrence of the NRC Office of the General Counsel (and any comments) and the concurrence of affected program offices or an explanation of their non-concurrence in the proposed method of implementation. These concurrences and related information can be included in the transmittal memorandum to the CRGR and need not be included in the CRGR regulatory analysis.

4. Section IV.B(viii) of the CRGR Charter also requires, in the case of power reactor backfits, a determination by the proposing office director that there is a substantial increase in the overall protection of the 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 that facility are justified in view of this increased protection. A statement of this determination may be included in the transmittal memorandum to the CRGR rather than in the CRGR regulatory analysis. Guidance on application of the "substantial increase" standard is in Attachment 3 to the CRGR Charter.

5. Section IV.B(x) of the CRGR Charter requires the proposing office director to determine that conditions (a) and (b) are met for the proposed action. A statement of this determination may be included in the transmittal memorandum to the CRGR rather than in the CRGR regulatory analysis.

3 Safety Goal Evaluation for Operation of Nuclear Power Plants

The Commission has directed that NRC's regulatory actions affecting nuclear power plants be evaluated for conformity with NRC's Policy Statement on Safety Goals for the Operations of Nuclear Power Plants (NRC 1990b). The Safety Goal Policy Statement is reproduced in Appendix D. The Policy Statement sets out two qualitative safety goals and two quantitative objectives. Both the goals and objectives apply only to the risks to the public from the accidental or routine release of radioactive materials from nuclear power plants.

The qualitative safety goals in the Policy Statement are

- 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

- 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% 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% of the sum of cancer fatality risks resulting from all other causes.

Chapter 3 of the NRC Guidelines contains specific information implementing the quantitative objectives which the analyst should carefully follow.

Section 3.1 of the Guidelines states that a safety goal evaluation is needed for a proposed generic safety enhancement backfit to nuclear power plants which is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). Thus, proposals for a plant-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. Section 3.1 of the Guidelines also states that a safety goal evaluation is not needed for a proposed relaxation of a requirement affecting nuclear power plants.

Section 3.2 of the Guidelines states that a probabilistic risk assessment (PRA) should normally be used in performing a safety goal evaluation to quantify the risk reduction and corresponding values of a proposed new requirement.[1] NRC's Final Policy Statement on the use of PRA methods in nuclear regulatory activities (NRC 1995b) contains the following statement:

> 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.

Table 5.2 in this Handbook contains a list of PRAs and their characteristics which can potentially be used in performing safety goal evaluations. Additional sources of PRAs are Individual Plant Examination (IPE) and Individual Plant Examination of External Events (IPEEE) reports submitted to the NRC by nuclear power plant licensees (see Section 5.6.1).[2]

Section 3.3.1 of the Guidelines provides an illustration of when an IPE report can be used in a safety goal evaluation. The example is that if a proposed backfit will only affect older boiling water reactors (BWRs), one or more IPEs conducted for older BWRs should be utilized in the evaluation. IPE and IPEEE reports are available through the NRC public document room (telephone: 202-634-3273 or 800-397-4209). A draft NUREG report was issued in late 1996 covering 1) insights gained from staff review of IPE reports, and 2) NRC's overall conclusions and observations including comparisons of IPE results with the Commission's safety goals (NRC 1996b). This report also contains a discussion of acceptable attributes of a quality PRA.

If conducted, a safety goal evaluation should be included in Section 3 of the regulatory analysis document which covers "estimation and evaluation of values and impacts." The results of the safety goal evaluation should be included in Section 4 of the regulatory analysis document which covers "presentation of results."

It is planned that additional supplementary material will be added to Chapter 3 of this Handbook in the future after more safety goal evaluation experience is gained.

As this version of the Handbook was being completed, a number of NRC staff activities were underway which relate to PRA use in safety goal evaluations and other NRC regulatory activities. These include

- completion of the staff's review of licensee-submitted IPEs
- evaluation of these IPEs for potential use in other regulatory activities, documented in a draft report to be published as NUREG-1560 (NRC 1996b)
- development of guidance on the use of PRA in plant-specific requests for license changes, including regulatory guides for use by licensees in preparing applications for changes and standard review plans for use by the NRC staff in reviewing proposed changes.

These activities should result in a more consistent and technically justified application of PRA in NRC's regulatory process. This work, along with staff work planned for fiscal year (FY) 1997 to initiate improvements to the economic models now used in NRC's offsite consequence analyses (e.g., in NRC's MELCOR Accident Consequence Code System [MACCS] code), should have a significant impact on the PRA-related portions of this Handbook. Consequently, the discussion in this Handbook on the use of PRA and offsite consequence estimates should be viewed as interim guidance that may be relied upon until the Handbook is updated to accommodate the NRC's new position on these regulatory issues. The staff expect to initiate this update as the preceding PRA guidance nears completion.

3.1 Endnotes for Chapter 3

1. SECY-95-079 contains a status update of NRC's PRA implementation plan. SECY-95-280 contains a framework for applying PRA in reactor regulation.

2. SECY-96-051 (NRC 1996a) contains the following statement:

   Licensees were not requested to calculate offsite health effects in Generic Letter 88-20 and, therefore, most of the IPE results cannot be used directly to compare with the quantitative health objectives of the Commission's Safety Goals (i.e., early and latent cancer fatalities). However, all licensees did estimate two related risk measures: containment failure frequencies and radionuclide release frequencies. These results can be examined in light of other studies of similar scope where explicit comparisons of plant risks with safety goals were performed, specifically

NUREG-1150. In this (indirect) way, insights can be provided on the IPE results and the current level of risk of U.S. plants, and comparisons made with the Commission's Safety Goals.

4 Regulatory Analysis Methods and Supporting Information

A regulatory analysis consists of six elements:

1. Statement of the problem and objective.
2. Identification and preliminary analysis of alternative approaches.
3. Estimation and evaluation of values and impacts (incorporating a safety goal evaluation in appropriate cases).
4. Presentation of results.
5. Decision rationale.
6. Implementation.

Each of these elements is very briefly summarized in Section 1.2.2 of this Handbook, and addressed in detail in the six major sections (4.1 through 4.6) in this chapter. The conceptual requirements associated with the regulatory analysis elements are also described. The safety goal evaluation process is discussed in Chapter 3.

To promote consistency, standard format and content guidance for regulatory analysis documents have been developed as shown in Figure 4.1. The six major sections of the regulatory analysis document are mandatory, as well as the basic information indicated for each. Subsections under each section may be included at the discretion of the analyst. Additional information not indicated in Figure 4.1 may be included as appropriate. The guidance provided is intended to allow the analyst the maximum amount of flexibility within the constraint of ensuring reasonable consistency among regulatory analysis documents.

4.1 Statement of the Problem and Objective

This element allows the analyst to carefully establish the character of the problem, its background, boundaries, significance, and what is hoped to be achieved (the objective).

The character of the problem consists of several factors. A concise description of the problem or concern needs to be developed. Included in the description is 1) the basis for the decision that a problem exists (e.g., a series of equipment failures during operation or a major incident that reveals an inherent design weakness), and 2) the fundamental nature of the problem (e.g., inadequate design, inadequate inspection or maintenance, operator failure, failure to incorporate adequate human factors). Care should be taken to neither define the problem too broadly (making it difficult to target a regulatory action) nor too narrowly (risking non-solution of the problem when the regulatory action is implemented). A background discussion of the problem should be provided, including relevant items from Section 4.1 of the Guidelines.

If appropriate, a statement of why 1) market forces cannot alleviate the problem [see Section I.A of RWG (1996) for a discussion of the role market forces play in regulatory decision-making], and 2) the NRC, as opposed to other organizations (e.g., licensees, vendors, owners groups or state agencies), is considering action should be included. The scope of the problem should be discussed in terms of the classes of licensees or facilities being affected, including their numbers, sizes, etc. Any distinction between NRC and Agreement State[1] licensees should be made. The implications of taking no action (i.e., maintaining the status quo) should be identified.

Table of Contents

Executive Summary

1 Statement of the Problem and Objective	Describe the nature of the problem, any relevant history, the boundaries of the problem, interfaces with other NRC activities, and a clear statement of the objective of the proposed action (see Section 4.1).
2 Identification and Preliminary Analysis of Alternative Approaches to the Problem	Identify alternative approaches considered and those approaches eliminated due to obvious reasons, provide the basis for eliminating alternatives, clearly explain alternatives to be considered, and determine the level of effort to be applied (see Section 4.2).
3 Estimation and Evaluation of Values and Impacts	If appropriate, evaluate compliance with the Safety Goals guidance (see Chapter 3 of the Guidelines and Handbook). Summarize methods used and results for all alternatives evaluated in the value-impact analysis (see Section 4.3).
4 Presentation of Results	Present results for alternatives evaluated, including discussion of supplemental considerations, uncertainties in estimates, and results of sensitivity analyses (see Section 4.4). Present results of safety goal evaluation if conducted.
5 Decision Rationale	Present the preferred alternative and the basis for selection, discuss any decision criteria used, identify and discuss the regulatory instrument to be used, and explain the statutory basis for the action (see Section 4.5).
6 Implementation	Present implementation milestones and associated schedule; discuss the relationships of the proposed action to other ongoing or proposed activities (see Section 4.6).

References

Appendixes (as needed)

Figure 4.1 Standard format and content of regulatory analyses

Establishment of problem boundaries entails the making of decisions as to how far the regulatory analysis will go in solving the problem. Systems, equipment, and operational activities at licensed facilities are highly interrelated, and there are typically numerous ways of viewing any particular problem. For example, consider the failure of a particular type of valve that serves two different safety-related coolant injection systems and concurrently serves as a containment isolation valve. The problem resulting from failure of the valve can be viewed as a system problem for either of the injection systems or a problem related to isolation valves or systems, or it could be viewed as part of a larger problem, such as inadequate maintenance or an inadequate quality assurance program.

Establishment of the appropriate boundaries can be a complicated matter. It is incumbent upon the regulatory analyst to identify other NRC programs (both ongoing and proposed) that could overlap or otherwise interface with the problem under consideration. The analyst should confer with those responsible for identified programs to determine appropriate boundaries. Interfacing programs should also be identified in the regulatory analysis document to facilitate communication between related programs.

A statement of what is hoped to be achieved is also referred to as the objective. This is a concise statement of the conceptual improvement sought by the proposed action. The objective should also be as specific as possible (assuring the public health and safety and minimizing occupational radiation exposures are two examples of objectives that are unacceptably broad). Precluding a fire from disabling redundant safety systems or reducing the probability of component failure to some particular value would be acceptably specific. Some elaboration may be required to show the reader how the objective would resolve the problem. The relationship of the objective to NRC's legislative mandates, safety goals[2] (NRC 1986), and most recent prioritization of generic safety issues (NUREG-0933 [NRC 1983b]) should be identified in appropriate cases.

4.2 Identification and Preliminary Analysis of Alternative Approaches

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

Developing a set of alternative approaches needs to be done early in the analysis process to help maintain objectivity and prevent premature drawing of conclusions.

The initial set of alternatives should be broad and comprehensive, but should also be sufficiently different to provide meaningful comparison and to represent the spectrum of reasonable possibilities. Alternatives that are minor variations of each other should be avoided. Table 4.1 contains a list of potential alternatives that may be used to begin identification of alternatives; however, the analyst should recognize that this generic list cannot envision every possibility associated with specific issues. 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.

Table 4.1 List of potential alternative actions

• Taking no action (i.e., maintaining the status quo eliminate for all entries).
• Installation of new equipment (various possibilities).
• Replacement of equipment (various possibilities).
• Modification of design.
• Modification of equipment.
• Removal of equipment.
• Change in inventory amount.
• Development of new procedures.
• Use of alternative processes.
• Modification of existing procedures.
• Deletion of existing procedures.
• Development of research programs to better understand the problem.
• Facility staffing changes.
• Technical specification changes.
• Imposition of license conditions.
• Augmented or decreased NRC inspection.
• Varying requirements across licensee groups.

Chapter II of the Regulatory Working Group's report *Economic Analysis of Federal Regulations Under Executive Order 12866* (RWG 1996) can be used in the identification and preliminary assessment of alternatives and to assist in determining which alternatives need to be subjected to a comprehensive value-impact analysis. The following six considerations adapted from the RWG report reflect principles included in Sections 4.2 and 4.6 of the NRC Guidelines:

1. Performance-oriented standards are generally preferred to engineering or design standards because performance standards generally allow licensees to achieve the regulatory objective in a more cost-effective manner. (Section IV.B(i) of the CRGR Charter supports performance-oriented standards.)

2. Different requirements for different segments or classes of licensees should be avoided unless it can be shown that there are perceptible differences in the impacts of compliance or in the values to be expected from compliance.

3. Alternative levels of stringency should be considered to better understand the relationship between stringency and values and impacts.

4. Alternative effective dates of regulatory compliance should be considered, with preference given to dates which favor cost-effective implementation of the regulatory action.

5. Alternative methods of ensuring compliance should be considered, with emphasis on those methods which are most cost effective.

6. The use of economic incentives (e.g., fees, subsidies, penalties, marketable permits or offsets, changes in liabilities or property rights, and required bonds, insurance, or warranties) instead of traditionally used command and control requirements should be considered in appropriate cases.

Once a broad and comprehensive list of alternatives has been developed, a preliminary analysis of the feasibility, values, and impacts of each alternative is performed. Some alternatives usually can be eliminated based on clearly exorbitant impacts in relation to values, technological infeasibility, severe enforcement or implementation problems, or other fairly obvious considerations. Reduction of the list of alternatives at this point in the analysis will reduce the resources needed to perform detailed evaluation of values and impacts. The regulatory analysis document should list all alternatives identified and considered, and provide a brief explanation of the reasons 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 values and impacts should be made using very simple analyses (in many cases, judgement may suffice). If several alternative actions are considered, comparison can be based on the "expected-value" of each.

Using the rough estimates, and guidance provided by the Commission, the EDO, or the appropriate NRC office director, the significance of the problem should be estimated. This determination will usually result in a conclusion that a major or standard effort will be expended to resolve the problem (see Figure 2.1). These two classifications are used to establish the level of detail to be provided in the regulatory analysis document and the amount of effort to be expended in performing the value-impact analysis. The significance of the problem will also help determine the priority assigned to its resolution.

Alternative regulatory documents which could be used to address regulatory concerns should also be identified at this time.[3] The most common forms of documents include regulations, policy statements, orders, generic letters, 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 value-impact analysis if preliminary assessment indicates significant differences in the values or impacts among such alternatives. Otherwise, the means of implementing the proposed action should be discussed in the section of the regulatory analysis document covering implementation (see Section 4.6).

For alternatives that survive 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 regulatory analysis process. Preparation of this information will satisfy the requirements at 10 CFR 50.109(c)(2) and Section IV.B(vii)(b) of the CRGR Charter.

The alternative approaches that remain after the preliminary analysis is completed will be subjected to a detailed value-impact evaluation according to the guidance presented in Section 4.3 below. Alternative instruments will be subjected to detailed value-impact analysis only if the preliminary analysis indicates that significant differences among these alternatives exist.

4.3 Estimation and Evaluation of Values and Impacts

This section provides general guidance on performance of a value-impact analysis. The value-impact portion of a regulatory analysis encompasses steps three and four in the six-step regulatory analysis process discussed in Section 1.2.2. Detailed guidance on the value-impact analysis process is presented in Chapter 5 of this Handbook.

The following definitions of values and impacts (benefits and costs) are taken from NRC Guidelines Section 4.3 and used in this Handbook:

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

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

The algebraic signs of values and impacts that can be quantified are provided in the description of attributes (see Section 5.5).

The process of selecting alternatives and performing a value-impact analysis is shown pictorially in Figure 4.2. Figure 4.2 shows each of the steps to be performed and the relationships among steps. The figure also indicates the section of this Handbook where each step is described in detail. The following discussion briefly explains each step.

For alternatives involving generic safety enhancement backfits to multiple operating nuclear power plants, the analyst begins with safety goal evaluation (i.e., whether core damage frequency (CDF) thresholds are satisfied or exceeded). Based on the guidance provided in Chapter 3 of the Guidelines, the analyst determines whether or not to proceed with the

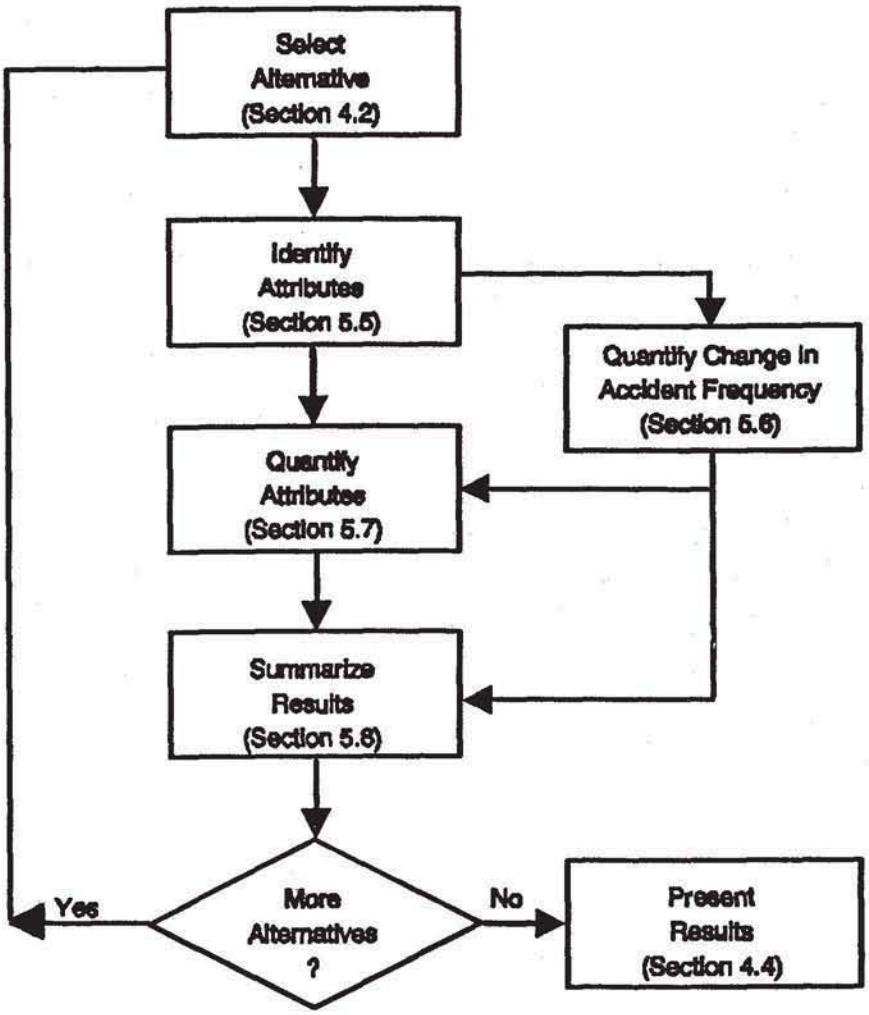


Figure 4.2 Steps in a value-impact analysis

value-impact analysis. If the safety goal evaluation of the proposed regulatory action results in a favorable determination, the analyst may presume that the substantial additional protection standard of 10 CFR 50.109(a)(3) is achievable (see Section 3.3.4 of the Guidelines).

Next, the analyst proceeds with the value-impact analysis by selecting one of the alternatives to be evaluated (see Section 4.2). For this alternative, those attributes that would be affected by implementation of the proposed action are identified. Attributes are standardized categories of values and impacts (e.g., public health [accident] or industry implementation cost).

The analyst should make every effort to use quantitative attributes relevant to the value-impact analysis. The quantification should employ monetary terms whenever possible. Dollar values should be established in real or constant dollar values (i.e., dollars of constant purchasing power). If monetary terms are inappropriate, the analyst should strive to use other quantifiable values. However, despite the analyst's best efforts at quantification, there may be some attributes which cannot be readily quantified. These attributes are termed "qualitative" and handled separately from the quantitative ones.

If appropriate, an estimate is made of the change in accident frequency which would result if the alternative were implemented. Parameters affected by the proposed action are identified, estimates are made for these affected parameters before and after implementation of the action, and the change in accident frequency is estimated by calculating the change in each affected accident sequence and summing them.[4]

Estimates are made for those attributes which lend themselves to quantification using standard techniques. Obtaining the appropriate data may be more complicated when a major effort is being undertaken. In cases where 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 vs. newer plants). In backfit regulatory analyses, it is also required that the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit be evaluated [10 CFR 50.109(c)(8)].

Section 4.3 of the Guidelines identifies the need to consider attributes in terms of the different groups that may be affected by a proposed action. This Handbook accommodates this need by the way that the suggested attributes are defined (e.g., impacts on the industry, the NRC, and other governmental units). If appropriate, qualitative considerations may 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.

Section 4.3 of the Guidelines requires the use of best estimates. Often these are evaluated in terms of "expected value," the product of the probability of some event occurring and the consequences which would occur assuming the event actually happens. Sometimes, measures other than the expected value may be appropriate, such as the mean, median, or some other point estimate. However, the expected value is generally preferred.

Section 4.3.2 of the Guidelines states that transfer payments such as insurance payments and taxes should not be included as impacts. Transfer payments are payments that reflect a redistribution of wealth rather than a social cost. Additional information on identifying transfer payments is in Section III.C.2 of the RWG report (RWG 1996).

Depending upon the level of effort, either sensitivity or uncertainty analyses should be performed while quantifying the attributes to estimate the effect upon 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. A number of techniques are available, each with differences in 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. The differences between sensitivity and uncertainty analyses and their respective roles in regulatory analysis are discussed in Section 5.4.

At this point, the above steps are repeated if there is another alternative to be evaluated. If not, results for all evaluated alternatives are put into a form for presentation in the regulatory analysis document. Guidance for performing each of the above steps is provided in detail in Chapter 5.

4.4 Presentation of Results

The following items must be included in the presentation of results section of the regulatory analysis document for each alternative:

- results of the evaluation for compliance with the Safety Goal guidance, if appropriate (see Section 4.4 of the Guidelines)
- presentation of the net value (i.e., the algebraic sum of the attributes) using the discount rate procedures stated in Section 4.3.3 of the Guidelines and discussed in Sections 5.7 and B.2 of this Handbook
- estimates for each attribute for each alternative (the analyst can choose to present the estimates in tabular or graphical form if such presentation would aid the reader)
- presentation of any attributes quantified in non-monetary terms in a manner to facilitate comparisons among alternatives
- the distribution of values and impacts on various groups if significant differences exist between recipients of values and those who incur impacts (see Section 4.4 of the Guidelines)
- discussion of key assumptions and results of sensitivity analyses or uncertainty analyses
- impacts on other NRC programs and federal, state, or local government agencies.

Key assumptions are to be specifically stated so that readers of the regulatory analysis have a clear understanding of the analysis and the decision-maker will be able to assess the confidence to place in the results. Sources and magnitudes of uncertainties in attribute estimates and the methods used to quantify sensitivity or uncertainty estimates should be discussed in all regulatory analyses.

For alternatives projected to result in significantly different attribute measures 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 effects of the proposed action on other NRC programs need to be assessed. These could include eliminating or creating a need for other programs; use of limited NRC resources resulting in postponement or rescheduling of other programs; modifying accident probabilities resulting in changes to 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.

In cases where uncertainties are substantial or where important values cannot be quantified, alternatives that yield equivalent values may be evaluated based on their cost-effectiveness. This methodology should also be used when the levels of values are specified by statute.

Proposed actions subject to the backfit rule should be evaluated against the following two criteria from 10 CFR 50.109(a)(3):

- Is there a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit?

- Are the direct and indirect costs of implementation justified in view of this increased protection?

Guidance on application of the "substantial increase" standard is in Attachment 3 to the CRGR Charter. Each alternative that meets both of the preceding criteria should be so indicated, and a discussion of why the criteria are met should be developed. Backfitting will be required by the NRC only if both criteria are met.

For CRGR regulatory analyses, the following information (from Table 2.3) should be included in the presentation of results:

- The sponsoring office's position on whether the proposed action would increase requirements or staff positions, implement existing requirements or staff positions, or relax or reduce existing requirements or staff positions.

4.5 Decision Rationale

This element of the regulatory analysis provides the basis for selection of the recommended alternative over the other alternatives considered. In selecting the preferred alternative, decision criteria are used and reported in the regulatory analysis document. Section 4.5 of the Guidelines gives the minimum set of decision criteria to be used, as well as other considerations.

The net-value calculation is a compilation of all of the attributes that can be quantified in monetary terms. Certain attributes are generally quantified in other than monetary terms (e.g., public health [accident], which is measured in person rems of exposure) and converted to monetary terms with an established conversion factor (see Section 5.7.1.2). These attributes are included in the net-value calculation. To aid the decision maker, the net value is to be computed for each alternative.

In considering the net value, care must be taken in interpreting the significance of the estimate. An algebraically positive estimate would indicate that the action has an overall beneficial effect; a negative estimate would indicate the reverse. However, if the net value is only weakly positive or negative, it would be inappropriate to lean strongly either way since minor errors or uncertainties could easily change the sign of the net value.

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

Non-quantifiable attributes can only be factored into the decision in a judgmental way; the experience of the decision-maker will strongly influence the weight that they are given. These attributes may be significant factors in regulatory decisions and should be considered, if appropriate.

In addition to being the "best" alternative based on monetary and non-monetary considerations, the selected alternative must be within the NRC's statutory authority and, when applicable, consistent with NRC's safety goals and policy. A showing of acceptable impact 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.

Recommended actions in backfit regulatory analyses must meet the two additional criteria from 10 CFR 50.109(a)(3), namely that 1) there is substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit, and 2) the direct and indirect costs of implementation are justified in view of this increased protection. The recommended action must be shown to meet these criteria, and, therefore, must be selected from those alternatives shown to meet the criteria.

Each proposed alternative should be reviewed to determine whether it is an interim or final action. In cases where the action is interim, it is necessary to develop an adequate justification for imposing the proposed backfit on an interim basis. If such justification cannot be satisfactorily developed, the alternative should be dropped from further consideration.

For CRGR regulatory analyses, the following information (from Table 2.3) should be included in the decision rationale:

- For proposed relaxations or decreases in current requirements or staff positions, a rationale for the determination that 1) the public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented; and 2) the cost savings attributed to the action would be substantial enough to justify taking the action, and clearly outweigh any reduction in benefits.

Recommended actions in CRGR regulatory analyses involving proposed relaxations or decreases in current requirements or staff positions must meet the following two additional criteria found in Section IV.B(x) of the CRGR Charter: 1) the public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented, and 2) the cost savings attributed to the action would be substantial enough to justify taking the action, and clearly outweigh any reduction in benefits. Also, the analysis must indicate whether the proposed relaxation or decrease in current requirements or staff positions is optional or mandatory.

4.6 Implementation

An implementation schedule for the proposed action must be prepared. The schedule must 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 must 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 must be specifically identified. Availability and lead time required for acquisition and installation of new equipment and replacement parts must be addressed. For NRC planning purposes, short- and long-term actions are to be identified in such a way as to clearly differentiate the two.

For backfit regulatory analyses, the implementation schedule should account for other ongoing regulatory activities at the facility. The backfit regulatory analysis document should describe how this is accomplished in the recommended schedule. For CRGR regulatory analyses, the proposed method of implementation and the proposed generic requirement or staff position as it is proposed to be sent out to licensees should be included in the implementation section (see Table 2.3).

The implementation section of the regulatory analysis document should also identify the proposed NRC instrument (e.g., rule, regulatory guide, policy statement) for implementing the proposed action and the reasons for selecting the proposed instrument. 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 effects of implementation of the proposed action on the priorities of other actions and requirements and the potential need to revisit other regulatory analyses.

4.7 Endnotes for Chapter 4

1. Agreement States are states which have entered into an agreement with the NRC under Section 274b of the Atomic Energy Act to assume regulatory authority over byproduct materials, source materials, and small quantities of special nuclear materials insufficient to form a critical mass.

2. The Commission has directed NRC staff to ensure that future regulatory actions involving generic safety enhancements to nuclear power plants are evaluated for conformity with the NRC Safety Goals (NRC 1990b).

3. NUREG/BR-0070 (NRC 1984a) discusses various types of formal NRC documents. Attachment 2 to the CRGR Charter identifies mechanisms that can and cannot be used to establish, interpret, or communicate generic requirements or staff positions to licensees.

4. Although most actions are expected to affect risk through a change in accident frequency, some may change consequences instead. Evaluating the change in risk for these latter actions is discussed in Section 5.7.1.1.

5 Value-Impact Analysis

The discussions presented in this chapter generally apply to both power reactor and non-reactor facilities. To simplify the presentation, the term "facility" has been selected to serve as the generic indicator for both types. Where the discussion is specific to power reactor versus non-reactor facilities, this will be indicated. Material supplemental to that presented in this chapter for power reactor and non-reactor value-impact analyses is included in Appendixes B and C, respectively.

5.1 Background

Value-impact analysis is one form of formal decision analysis, not necessarily binding. Formal decision methods can

- help the analyst and decision-maker clearly define and think through the problem
- segment complex problems into conceptually manageable portions
- provide a logical structure for the combination of issues contributing to a decision
- clearly display beneficial and detrimental aspects of a decision
- provide a record of the decision rationale, helping to provide documentation, defensibility, and reproducibility
- focus debate on the specific issues of contention, thereby assisting resolution
- provide a framework for the sensitivity testing of data and assumptions.

However, limitations must be noted. Formal decision methods cannot

- completely remove subjectivity
- guarantee that all factors affecting an issue are considered
- produce unambiguous results in the face of closely valued alternatives and/or large uncertainties
- be used without critical appraisal of results; to use a decision analysis method as a black box decision-maker is both wrong and dangerous.

5.2 Methods

The value-impact portion of a regulatory analysis encompasses the third and fourth steps of the complete six-step regulatory analysis process discussed in Section 1.2.2. Value-impact analysis identifies and estimates the relevant values and impacts likely to result from a proposed NRC action. The methodology outlined in this chapter guides the systematic definition and evaluation of values and impacts. It also provides guidance on the reporting of results.

Values and impacts are classified as "attributes." Attributes are the principal components of value-impact assessment that are used to characterize the consequences of a proposed action. Any given NRC action can affect a large number of factors within the public and private sectors. The attributes represent the factors that are most frequently affected by a proposed NRC action. The attributes affected by any given proposed action will vary, however, and the analyst will have to determine the appropriateness of each attribute. Attributes, whether values or impacts, 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 consequences are positive; adverse consequences are negative. Each attribute measures the change from the existing condition due to the proposed action. Attributes are discussed in detail in Sections 5.5 and 5.7.

Section 4.4 of the Guidelines requires that the value-impact of an alternative be quantified as the "net value" (or "net benefit"). To the extent possible, all attributes, whether values or impacts, are quantified in monetary terms and added together (with the appropriate algebraic signs) to obtain the net value in dollars. The net value calculation is generally favored over other measures, such as a value-impact ratio or internal rate of return (RWG 1996, Section III.A.2).[1]

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 values and impacts are added together and the total is intended to reflect the aggregate effect of the proposed action on the national economy. The net-value measure does not, and is not intended to, provide any information about the distribution of values and impacts within the national economy. The values and impacts to all affected parties are simply added together.

Section 4.4 of the Guidelines states that if significant differences exist between recipients of values and those who incur impacts, the distribution of values and impacts on various groups should be presented and discussed. Section III.A.8 of the 1996 RWG report supports this position.

To calculate a net value, all attributes must be expressed in common units, typically dollars. Person-rems of averted exposure, a measure of safety value, is converted to dollars via a dollar/person-rem equivalence factor (see Section 5.7.1.2). Net value is an absolute measure. It indicates the magnitude of the proposed action's contribution toward the specified goals. When faced with a choice between two mutually exclusive actions, the "optimal" decision is to select the action with the larger net value.

5.3 Standard Analysis

Section 2.4 introduced the concept of a standard regulatory analysis, generally expected to encompass approximately one to two person-months of effort using specific guidance provided in this Handbook. The standard analysis should be adequate for most regulatory analyses, requiring guidance only from the NRC Guidelines, Handbook, and appropriate references.

Sections 5.4-5.8 and Appendixes A, B, and C provide information for the level of detail deemed sufficient for a standard regulatory analysis. For those issues which require major levels of effort, this Handbook suggests additional methods and references which should prove useful. In general, the numerical values provided by this Handbook represent "generic" values which, in practice, apply better to multiple licensees than to individual licensees. For regulatory actions involving individual licensees, plant-specific values are recommended. However, as these are often unavailable, the analyst may be limited in some cases to applying generic values to plant-specific cases.

5.4 Treatment of Uncertainty

Chapter 4 of the NRC Guidelines requires that uncertainties be addressed in regulatory analyses, both for exposure and cost measures. In addition, NRC's Final Policy Statement on the use of probabilistic risk assessment (PRA) in nuclear regulatory activities (NRC 1995b) states that sensitivity studies, uncertainty analysis, and importance measures should be used in regulatory matters, where practical within the bounds of the state-of-the-art. Uncertainties in exposure measures, especially those related to facility accidents, have traditionally been difficult to estimate. With respect to power reactor facilities, much has been written about uncertainty analysis in risk assessments. The more rigorous assessments typically provide an uncertainty analysis, usually performed via stochastic simulation on a computer. Briefly, the analyst determines probability distributions for as many of his input parameters as deemed necessary and practical. A computer code then samples values from each distribution randomly and propagates these values through the risk equation to yield one result. When repeated a large number of times (at least several hundred), a probability distribution for the result is generated, from which the analyst can extract meaningful statistical values (e.g., mean, standard deviation, median, and upper and lower bounds for given confidence levels).

Risk assessments for non-reactor facilities often identify best estimates only. Some have provided uncertainty ranges (see Appendix C), but their development has generally been less rigorous than that for reactor facilities. On the positive side, accident scenarios for non-reactor facilities are much less complex than for power reactors, facilitating uncertainty estimation, at least from a calculational perspective.

This Handbook is not intended to provide basic information on probability and statistics, and therefore does not attempt to describe the details of uncertainty analysis techniques. The analyst needing information on these topics is referred to text-books on probability and statistics, as well as the following references: Seiler (1987), Iman and Helton (1988), Morgan and Henrion (1990), and DOE (1996). Instead, this Handbook presents a general discussion of the types of uncertainty that will be encountered in a regulatory analysis, primarily the value-impact portion, and outlines some of the more recent approaches to deal with them.

5.4.1 Types of Uncertainty

Vesely and Rasmuson (1984) identified seven categories of uncertainties in PRA, the majority of which, if treated at all, have only recently begun to receive attention. The seven categories are uncertainties in data, analyst assumptions, modeling, scenario completeness, accident frequencies, accident consequences, and interpretation. These seven categories, going from first to last, represent a progression from uncertainties in the PRA input to higher-level uncertainties with the PRA results. Vesely and Rasmuson considered these categories to be generally applicable to any modeling exercise, not just a PRA. Thus, they would also apply to the cost analysis portion of the regulatory analysis.

The first category, data uncertainty, is the most familiar and most often treated. It can be divided into four groups: population variation, imprecision in values, vagueness in values, and indefiniteness in applicability. Population variation refers to parameter changes from scenario to scenario, usually due to physical causes. The variations occur among the random variables which, when treated as constants, give a false impression of the stability of the results. Parameter imprecision and vagueness refer to separate concepts. Imprecision occurs when only limited measurements are available from which to estimate parameter values. Vagueness occurs when definitive values or intervals cannot be assigned to parameters. Indefinite applicability deals with the extrapolation of parameter values to situations different from those for which they were derived (e.g., extrapolating component failure data for normal environments to accident conditions).

The second category, analyst uncertainty, refers to variations in modeling and quantification which arise when different analysts perform different portions of the analysis. Often included with data uncertainty, analyst uncertainty provides its own separate contribution. Modeling uncertainty, the third category, arises from the indefiniteness in how comprehensive

and how well characterized are the numerous models in the analysis. Do the models account for all significant variables? How well do the models represent the phenomena? Is the dependence between two phenomena accurately modeled? Similar to modeling uncertainty is completeness uncertainty, the fourth category. It differs only in that it occurs at the initial, identification stage in the analysis. When the analytic "boundaries" are drawn at the start of the analysis, how can one be sure that all "important" items have been included (e.g., the Three-Mile Island core-damage scenario was not specifically identified in PRAs until it had occurred)? Even if the important items have been included, are their interrelationships adequately defined (if even known)?

The last three uncertainty categories—those for accident frequencies and consequences, and interpretation—deal with the analytic output and results. Accident frequency uncertainties arise from two sources: variations between accidents of the same type and limited knowledge of the data, models, and completeness. Accident consequence uncertainties parallel those in accident frequency, except that they involve consequence modeling rather than frequency estimation. Interpretation uncertainty arises from the combination of all previous uncertainties plus the difficulty in conveying the information to the decision-maker. Even the most precise uncertainty analysis can be wasted if the meaning cannot be transferred to the decision-maker. Often, this results from difficulty in the way the results are presented. Ernst (1984) provides insight on reducing the uncertainty in interpretation of results.

5.4.2 Uncertainty Versus Sensitivity Analysis

As defined by Vesely and Rasmuson, uncertainty and sensitivity analyses are similar in that both strive to evaluate the variation in results arising from the variations in the assumptions, models, and data. However, they differ in approach, scope, and the information they provide.

Uncertainty analysis attempts to describe the likelihood for different size variations and tends to be more formalized than sensitivity analysis. An uncertainty analysis explicitly quantifies the uncertainties and their relative magnitudes, but requires probability distributions for each of the random variables. The assignment of these distributions often involves as much uncertainty as that to be quantified.

Sensitivity analysis is generally more straightforward than uncertainty analysis, requiring only the separate (simpler) or simultaneous (more complex) changing of one or more of the inputs. Expert judgment is involved to the extent that the analyst decides which inputs to change, and how much to change them. This process can be streamlined if the analyst knows which variables have the greatest effect upon the results. Variation of inputs one at a time is preferred, unless multiple parameters are affected when one is changed. In this latter case, simultaneous variation is required. Hamby (1993) provides a detailed description of the most common techniques employed in sensitivity analysis.

Vesely and Rasmuson identify which of the seven types of uncertainties encountered in PRAs are best handled by uncertainty versus sensitivity analysis. They are as follows:

1. Data Uncertainty: Use uncertainty analysis for population variation and value imprecision, sensitivity analysis for value vagueness and indefiniteness in applicability.

2. Analyst Uncertainty: Use sensitivity analysis.

3. Modeling Uncertainty: Use sensitivity analysis.

4. Completeness Uncertainty: Use sensitivity analysis.

5. Frequency Uncertainty: Use uncertainty analysis for variation from one accident to another, sensitivity analysis for the limited knowledge of the data, models, and completeness.

6. Consequence Uncertainty: Use uncertainty analysis for variation from one accident to another, sensitivity analysis for the limited knowledge of the data, models, and completeness.

7. Interpretation Uncertainty: Use sensitivity analysis.

5.4.3 Uncertainty/Sensitivity Analyses

Three major NRC studies involving detailed uncertainty/sensitivity analyses were NUREG-1150, *Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants* (NRC 1991); NUREG/CR-5381, *Economic Risk of Contamination Cleanup Costs Resulting from Large Non-Reactor Nuclear Material Licensee Operations* (Philbin et al. 1990); and NUREG/CR-4832, *Analysis of the LaSalle Unit 2 Nuclear Power Plant: Risk Methods Integration and Evaluation Program (RMIEP)* (Payne 1992). The first and third studies address reactor facilities, the second non-reactor facilities. The approach used in each study is summarized below.

5.4.3.1 NUREG-1150

"An important characteristic of the PRAs conducted in support of this report [NUREG-1150] is that they have explicitly included an estimation of the uncertainties in the calculations of core damage frequency and risk that exist because of incomplete understanding of reactor systems and severe accident phenomena." With this introduction, NUREG-1150 identified four steps in the performance of its uncertainty/sensitivity analysis:

1. Define the Scope. The total number of parameters that could be varied to produce uncertainty estimates was quite large and limited by computer capacity. Thus, only the most important sources were included, these sources being identified from previous PRAs, discussion with phenomenologists, and limited sensitivity analyses. For those parameters important to risk and having large uncertainties and limited, if any, data, subjective probability distributions were generated by expert panels.

2. Define Specific Uncertainties. Each section of the risk assessment was conducted at a slightly different level of detail, none of which to the degree involved in a mechanistic analysis. This resulted in the uncertain input parameters being "high level" or summary parameters, for which their relationships with their fundamental physical counterpart parameters were not always clear. This resulted in Vesely and Rasmuson's "modeling uncertainties." In addition, "data uncertainties" arose from limited knowledge of some important physical or chemical parameters. NUREG-1150 included both types of uncertainty, with no consistent effort to distinguish between them.

3. Define Probability Distributions. Probability distributions were developed by several methods, paramount among these being "expert elicitation" (discussed below). "Standard" distributions employed in previous risk assessments were used when the experts' estimation was not needed.

4. Combination of Uncertainties. The Latin hypercube method, a specialized form of stochastic simulation, was employed to sample from the various probability distributions. The sampled values were propagated through the constituent analyses to produce probability distributions for core damage frequency and risk. Results were presented graphically as histograms and complementary cumulative distribution functions showing the mean, median, and two-sided 90% confidence intervals.

A major innovation of the NUREG-1150 project was the development of a formal method for elicitation of expert judgment. Nine steps were involved:

1. Selection of Issues. The initial list of issues was identified from the important uncertain parameters specified by each plant analyst.

2. Selection of Experts. Seven expert panels were assembled to address issues in accident frequency (two panels), accident progression and containment loading (three panels), containment structural response (one panel), and source terms (one panel). Selection was based on recognized expertise in the nuclear industry, the NRC and its contractors, and academia. Each panel contained 3-10 experts.

3. Elicitation Training. Decision analysis specialists trained both the experts and analysis team members in elicitation methods, including the psychological aspects of probability estimation. The experts perfected their estimation techniques by conjuring probabilities for items for which "true" values were known.

4. Presentation and Review of Issues. The analysis staff formally presented the relevant issues to each panel over the course of several days. Interactive discussions ensued.

5. Preparation of Expert Analyses. Over a periods ranging from one to four months, each panel deliberated on its issues. However, each panel member arrived at his/her own quantitative results.

6. Expert Review and Discussion. At a final meeting, each expert presented his/her analysis which, in some cases, resulted in members modifying their preliminary results subsequent to the meeting.

7. Elicitation of Experts. Two analysis staff members, one trained in elicitation techniques, the other familiar with the technical subject, interviewed each expert privately. The expert's final quantitative results were documented.

8. Aggregation of Judgments. From each expert's results, the analysis staff composed probability distributions which were then aggregated to produce a single composite for each issue. Each expert was equally weighted in the composite.

9. Review by Experts. Each expert's probability distribution, as developed by the analysis staff from the expert's interview, was reviewed privately with that expert to correct any misconceptions that may have arisen. The probability distribution was then finalized, as was the composite.

5.4.3.2 NUREG/CR-5381

In NUREG/CR-5381, Philbin et al. took advantage of some of the convenient combinatorial properties of the lognormal distribution to facilitate a straightforward uncertainty analysis. NUREG/CR-5381 assessed the economic risk of cleanup costs resulting from non-reactor NRC licensee contamination incidents (see Section C.4). The calculational procedure involved three steps: estimating the frequency and cleanup cost of each accident scenario, taking their product to yield the "cleanup risk" (probabilistically-weighted cleanup cost) per scenario, and summing the scenario risks to yield the total facility risk. The uncertainty analysis paralleled these three steps.

For both the accident frequency and cleanup cost, probability distributions were selected from the available data, if possible, or by expert judgment. When using historical data to obtain frequency estimates, the assumption was made that the number of incidents for a specified scenario followed the Poisson distribution. This was deemed reasonable in light of the small number of incidents over a relatively large number of operating years and the absence of any obvious trends. The

Poisson point estimate incident rate was taken to be the historical rate, with two-sided 80% confidence bounds derived from the properties of the Poisson distribution.

When a calculational model was used to estimate the frequency, the uncertainty was based on expert judgment. Unless deemed inappropriate, the frequency distribution was taken to be lognormal with an error factor of 10. If previous analyses provided only a frequency range, the distribution was again assumed to be lognormal, with the upper and lower bounds taken as the endpoints of this range. Thus, the point estimate (median, in this case) became their geometric mean. For the cleanup costs, the point estimates were derived from historical data of calculational models. These costs were assumed to be lognormally distributed with error factors of 1.25.

Philbin et al. defended their choice of the lognormal as a "generically" representative probability distribution for several reasons. The lognormal has a minimum value of zero, a realistic limit on the minimum frequency and cost, and is skewed in a way which yields relatively wider error bounds on the upper than lower side. Thus, it produces an uncertainty band which is conservative. Also, the lognormal has two convenient combinatorial properties. The product of two lognormally distributed variables is lognormally distributed, while the sum can be approximated by another lognormal provided one variable dominates the other.

The economic risk per accident scenario was estimated by propagating the frequency and cost uncertainties through their product. When both frequency and cost were lognormally distributed, this product was also lognormal. When the frequency distribution was Poisson, it was approximated by a lognormal to simplify the calculation. Each scenario thus resulted in an economic risk which was lognormally distributed. These were summed to yield the total economic risk per facility. The individual variances were summed and the resultant total economic risk was assumed to be approximately lognormal, a reasonable assumption if it was dominated by one scenario risk. Referring to Tables C.4-C.8 in Section C.4, one can see that this assumption was generally valid for three of the five facilities (i.e., one scenario risk contributed over 50% to the total facility risk). The final results were reported as two-sided 80% confidence bounds.

5.4.3.3 NUREG/CR-4832

In NUREG/CR-4832, Payne generally followed an uncertainty/sensitivity calculational procedure similar to that employed in NUREG-1150. The major contribution was the development of a new computer code, TEMAC (Iman and Shortencarier 1986) to perform the final quantification of the accident sequence uncertainties via the Latin hypercube sampling method. The TEMAC code also calculated various risk importance measures (Vesely et al. 1983) and ranked the basic events by their contribution to mean core damage frequency.

Three importance measures were estimated in NUREG/CR-4832. The first, risk reduction importance, calculates the decrease in the total core damage frequency which could result if a single basic event's probability were set to zero (i.e., the component could not fail or the event could not occur). The second, risk increase importance, calculates the increase in the core damage frequency which could result if a single basic event's probability were set to one (i.e., the component would always fail or the event would always occur). The third, uncertainty importance, estimates the extent to which the uncertainty in the total core damage frequency depends upon the underlying uncertainty in a common contributor to a set of related basic events (e.g., a failure to actuate in all motor-operated valves). These importance measures represent a combination of sensitivity with uncertainty analyses which feature some of the better aspects of each.

5.4.4 Suggested Approach

The value-impact portion of a regulatory analysis will often require use of an existing risk assessment for the estimation of some of the attributes. If the risk assessment has an uncertainty/sensitivity analysis accompanying it, the analyst should

try to adapt it for use in the value-impact analysis. Unfortunately, this is often impractical for the standard analysis since the analyst does not have access to the computer code and numerous data and assumptions necessary to generate the resultant probability distributions.

When a detailed uncertainty/sensitivity analysis is not possible or practical, the following approach is suggested for the standard analysis. The standard analysis should attempt to include an uncertainty/sensitivity analysis approaching the level of that conducted by Philbin et al. in NUREG/CR-5381 (see Section 5.4.3.2). This analysis can be done with varying degrees of formality and rigor. First, a systematic attempt should be made to identify all of the pertinent factors (assumptions, data, models) that could affect the results. Since the number of such factors is usually very large, not all of them can be treated in detail. Nevertheless, it is useful to make a systematic effort at least to identify them. As a second step, the list of factors should be screened to select a subset for detailed examination. The screening process should concentrate on eliminating unimportant factors (for example, those that are known to contribute little to the overall uncertainty or those that have minimal effect on the bottom line results) and reducing the list to manageable size. Typically, the screening will be done on the basis of judgment and experience, but more formal methods and calculations may be appropriate in some circumstances (e.g., an abridged form of the "expert elicitation" procedure in NUREG-1150 [see Section 5.4.3.1]). The third step is to define a set of cases to be evaluated. The most common approach is to define a best estimate, establish a range of interest for each factor, and then systematically vary the factors, one or more at a time. The results are then expressed as a range (low value, best estimate, high value) which indicates the effect on the output of variations in the factors, and thus provides some insight concerning uncertainties and their effects.

Uncertainty/sensitivity analysis for the cost measures is generally simpler than that for exposures. Complex accident scenarios are not involved. Moreover, the analyst usually has a better "feel" for cost-related measures (e.g., labor rates, interest rates, and equipment costs) than for risk-related ones. Thus, such analyses require no more than the straightforward variation of interest rates, labor hours, contingency factors, etc. However, the analyst is cautioned that, while the calculational techniques may be simple, wide ranges can still result.

To assist the analyst in performing uncertainty/sensitivity analyses for the standard analysis, this Handbook provides high and low values for selected best estimates in the evaluation of certain attributes (see, for example, Section 5.7.3.1). Should the analyst have access to better estimates, they should be used. In the cases where the analyst has access to a computerized assessment, the uncertainty/sensitivity analysis results obtainable via computer can be incorporated into the standard analysis. However, it is felt that more formal uncertainty/sensitivity analyses will only be practical for regulatory analyses requiring major efforts.

Finally, automated uncertainty calculations using default distributions are a feature of the FORECAST computer code for regulatory effects cost analysis (Lopez and Sciacca 1996). Uniform, lognormal, and several user-specified probability distributions are options.

5.5 Identification of Attributes

For every value-impact analysis to be performed, those attributes that could be affected by the proposed action must be identified. Once identified, the attributes may be quantified using the techniques presented in Sections 5.6 and 5.7. Note that the subsections of this section and Section 5.7 are numbered so as to correspond to one another in their discussions of the attributes. This section introduces the most commonly used attributes. Most of the attributes presented may be quantified in monetary terms, either directly or through use of a radiation exposure-to-money conversion factor (see Section 5.7.1.2). The remaining attributes are not readily quantifiable and are treated in a more qualitative manner. However, the analyst should attempt quantitative estimation whenever possible, relying on qualitative descriptions when no quantification is feasible.

Table 5.1 is a checklist for identifying affected attributes. The analyst is encouraged to use this checklist when first determining the attributes that will need to be evaluated. For each attribute listed, a check should be made if it is affected. Each affected attribute can then be evaluated according to the instructions included in Sections 5.6 and 5.7.

Table 5.1 Checklist for identification of affected attributes

Attribute	Affected
Public Health (Accident)	☐
Public Health (Routine)	☐
Occupational Health (Accident)	☐
Occupational Health (Routine)	☐
Offsite Property	☐
Onsite Property	☐
Industry Implementation	☐
Industry Operation	☐
NRC Implementation	☐
NRC Operation	☐
Other Government	☐
General Public	☐
Improvements in Knowledge	☐
Regulatory Efficiency	☐
Antitrust Considerations	☐
Safeguards and Security Considerations	☐
Environmental Considerations	☐
Other Considerations (Specify)	☐

5.5.1 Public Health (Accident)

This attribute is a value which measures expected changes in radiation exposures to the public due to changes in accident frequencies or accident consequences associated with the proposed action. For nuclear power plants, expected changes in radiation exposure should be measured over a 50-mile radius from the plant site. The appropriate distance for other types of licensed facilities should be determined on a case-by-case basis. In most cases, the effect of the proposed action would be to decrease public exposure. A decrease in public exposure (given in person-rems) assumes a positive sign. Therefore, this decrease multiplied by the monetary conversion factor ($/person-rem) will give a positive monetary value.

It is possible that a proposed action could increase public exposure due to potential accidents. In this case, the increase in public exposure (person-rems) assumes a negative sign. When this increase is multiplied by the monetary conversion factor ($/person-rem), the resulting monetary term is interpreted as negative.

5.5.2 Public Health (Routine)

This attribute is a value which accounts for changes in radiation exposures to the public during normal facility operations (i.e., non-accident situations). It is expected that this attribute would not be affected as often in reactor regulatory analyses as in non-reactor ones. When used, this attribute would employ an actual estimate; accident probabilities are not involved.

Similar to the attribute for public health (accident), a decrease in public exposure would be positive. Therefore, the product of a decrease in exposure and the monetary conversion factor (assumed to be the same factor as that for public health [accident]) would be taken as positive. The product of an increase in public exposure and the monetary conversion factor would be taken as negative.

5.5.3 Occupational Health (Accident)

This attribute is a value which measures health effects, both immediate and long-term, associated with site workers as a result of changes in accident frequency or accident mitigation. A decrease in worker radiological exposures is taken as positive; an increase in worker exposures is considered negative.

As is the case for public exposure, the directly calculated effects of a particular action are given in person-rems. A monetary conversion factor must be used to convert the effect into dollars. Under current NRC policy the value to be used is $2000 per person-rem (see Section 5.7.1.2). This value is subject to future revision.

5.5.4 Occupational Health (Routine)

This attribute is a value which accounts for radiological exposures to workers during normal facility operations (i.e., non-accident 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.

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 Section 5.7.1.2).

5.5.5 Offsite Property

This attribute is a value which 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, and 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 offsite property damage is taken as positive; an increase in offsite property damage is considered negative.

5.5.6 Onsite Property

This attribute is an impact which measures the expected monetary effects on onsite property, including replacement power (specifically for power reactors), decontamination, and refurbishment costs, from the proposed action. This attribute is typically the product of the change in accident frequency and the onsite property consequences given that an accident were to occur. A reduction in expected onsite property damage is taken as positive; an increase in onsite property damage is considered negative. Particular care should be taken in estimating dollar savings associated with this attribute because 1) values for this attribute are difficult to accurately estimate, and 2) estimated values can potentially significantly outweigh other values and impacts associated with an alternative.

5.5.7 Industry Implementation

This attribute is an impact which accounts for the projected net economic effect on the affected licensees to install or 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 (see Section 5.7.7.1), as appropriate. Additional costs above the status quo are considered negative; cost savings would be considered positive.

This attribute, and the following five, reflect actual estimated costs; accident probabilities are not involved. In this regard, these attributes are measured very differently from those associated with accident-related health effects and onsite and offsite property.

5.5.8 Industry Operation

This attribute is an impact which measures the projected net economic effect due to routine and recurring activities required by the proposed action on all affected licensees. If applicable, replacement power costs (power reactors only) directly attributable to the proposed action will be included. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive.

Costs falling in this category, and those associated with NRC operational considerations, generally occur over long periods of time (the facility lifetime). These costs are particularly sensitive to the discount factor used.

5.5.9 NRC Implementation

This attribute is an impact which measures the projected net economic effect on the NRC to place the proposed action into operation. Costs already incurred, including all pre-decisional activities performed by the NRC, are viewed as "sunk" costs and are not to be included. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive.

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.

5.5.10 NRC Operation

This attribute is an impact which 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. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive. As with industry operation costs, NRC operation costs generally occur over long periods of time and are sensitive to the assumed discount factor.

Here too, the NRC may seek compensation from the licensee to provide needed services; any compensation received should not be subtracted from the cost to the NRC.

5.5.11 Other Government

This attribute is an impact which 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. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive.

This attribute will be affected less often than some attributes, but can be material in certain types of actions (e.g., changes to offsite emergency planning, provision of offsite services, and new requirements affecting Agreement States). The government entities may seek compensation from the licensee to provide the needed services; any compensation received should not be subtracted from the cost to the government units.

5.5.12 General Public

This attribute is an impact which 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 due to dust and construction-related pollutants, property value losses due to the action, or inconveniences (e.g., testing of evacuation sirens). Increases in costs from the status quo are taken to be negative; decreases in costs from the status quo are taken as positive.

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

5.5.13 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.

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