



NUREG/BR-0058, Revision 5

U.S. Nuclear Regulatory Commission Regulatory and Cost-Benefit Analysis Guidance

Draft Report for Comment

PREDECISIONAL
BEING PROVIDED TO SUPPORT THE 2/7/2017 ACRS REGULATORY
POLICIES AND PRACTICES SUBCOMMITTEE MEETING
AND NOT TO SOLICIT EXTERNAL STAKEHOLDER FEEDBACK

**AVAILABILITY OF REFERENCE MATERIALS
IN NRC PUBLICATIONS**

NRC Reference Material

As of November 1999, you may electronically access NUREG-series publications and other NRC records at NRC's Public Electronic Reading Room at <http://www.nrc.gov/reading-rm.html>. Publicly released records include, to name a few, NUREG-series publications; *Federal Register* notices; applicant, licensee, and vendor documents and correspondence; NRC correspondence and internal memoranda; bulletins and information notices; inspection and investigative reports; licensee event reports; and Commission papers and their attachments.

NRC publications in the NUREG series, NRC regulations, and Title 10, *Energy*, in the *Code of Federal Regulations* may also be purchased from one of these two sources.

1. The Superintendent of Documents
U.S. Government Printing Office
Mail Stop SSOP
Washington, DC 20402-0001
Internet: bookstore.gpo.gov
Telephone: 202-512-1800
Fax: 202-512-2250
2. The National Technical Information Service
Springfield, VA 22161-0002
www.ntis.gov
1-800-553-6847 or, locally, 703-605-6000

A single copy of each NRC draft report for comment is available free, to the extent of supply, upon written request as follows:

Address: U.S. Nuclear Regulatory Commission
Office of Administration
Publication Branch
Washington, DC 20555-0001

E-mail: DISTRIBUTION.RESOURCE@NRC.GOV
Facsimile: 301-415-2289

Some publications in the NUREG series that are posted at NRC's Web site address <http://www.nrc.gov/reading-rm/doc-collections/nuregs> are updated periodically and may differ from the last printed version. Although references to material found on a Web site bear the date the material was accessed, the material available on the date cited may subsequently be removed from the site.

Non-NRC Reference Material

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions, *Federal Register* notices, Federal and State legislation, and congressional reports. Such documents as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings may be purchased from their sponsoring organization.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at—

The NRC Technical Library
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

These standards are available in the library for reference use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from—

American National Standards Institute
11 West 42nd Street
New York, NY 10036-8002
www.ansi.org
212-642-4900

Legally binding regulatory requirements are stated only in Regulations; NRC regulations; licenses, including technical specifications; or orders, not in NUREG-series publications. The views expressed in contractor-prepared publications in this series are not necessarily those of the NRC.

The NUREG series comprises (1) technical and administrative reports and books prepared by the staff (NUREG-XXXX) or agency contractors (NUREG/CR-XXXX), (2) proceedings of conferences (NUREG/CP-XXXX), (3) reports resulting from international agreements (NUREG/IA-XXXX), (4) brochures (NUREG/BR-XXXX), and (5) compilations of legal decisions and orders of the Commission and Atomic and Safety Licensing Boards and of Directors' decisions under Section 2.206 of NRC's regulations (NUREG-0750).

DISCLAIMER: This report was prepared as an account of work sponsored by an agency of the U.S. Government. Neither the U.S. Government nor any agency thereof, nor any employee, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for any third party's use, or the results of such use, of any information, apparatus, product, or process disclosed in this publication, or represents that its use by such third party would not infringe privately owned rights.



NUREG/BR-0058 Revision 5

U.S. Nuclear Regulatory Commission Guidance on Performing Cost-Benefit Analyses

Draft Report for Comment

Manuscript Completed:
Date Published:

Prepared by

Division of Policy and Rulemaking
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

PREDECISIONAL
BEING PROVIDED TO SUPPORT THE 2/7/2017 ACRS REGULATORY
POLICIES AND PRACTICES SUBCOMMITTEE MEETING
AND NOT TO SOLICIT EXTERNAL STAKEHOLDER FEEDBACK

COMMENTS ON DRAFT REPORT

Any interested party may submit comments on this report for consideration by the NRC staff. Comments may be accompanied by additional relevant information or supporting data. Please specify the report number **NUREG/BR-0058 Revision 5** in your comments, and send them by the end of the comment period specified in the *Federal Register* notice announcing the availability of this report.

Addresses: You may submit comments by any one of the following methods. Please include Docket ID **NRC-2016-XXXX** in the subject line of your comments. Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site <http://www.regulations.gov>.

Federal Rulemaking Website: Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2016-XXXX**. Address questions about NRC dockets to Carol Gallagher at 301-415-3463 or by e-mail at Carol.Gallagher@nrc.gov.

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Division of Administrative Services, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For any questions about the material in this report, please contact: Pamela S. Noto, Project Manager, at 301-415-6795 or by e-mail at Pamela.Noto@nrc.gov.

Please be aware that any comments that you submit to the NRC will be considered public records and entered into the Agencywide Documents Access and Management System (ADAMS). Do not provide information you would not want to be publically available.

**PREDECISIONAL
BEING PROVIDED TO SUPPORT THE 2/7/2017 ACRS REGULATORY
POLICIES AND PRACTICES SUBCOMMITTEE MEETING
AND NOT TO SOLICIT EXTERNAL STAKEHOLDER FEEDBACK**

ABSTRACT

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

PREDECISIONAL

TABLE OF CONTENTS

ABSTRACT	V
ACKNOWLEDGEMENTS.....	X
LIST OF FIGURES AND TABLES.....	XI
ABBREVIATIONS AND ACRONYMS	XIII
1. INTRODUCTION.....	1
1.1 Purpose.....	3
1.2 Scope of Regulatory Decisionmaking Documents	3
1.2.1 Regulatory Analysis	4
1.2.2 Backfit Analysis and Issue Finality	4
1.2.3 National Environmental Policy Act Review	6
1.2.4 Details Regarding Cost-Benefit Guidance	7
1.3 Regulatory Relaxations.....	7
2. REGULATORY ANALYSIS	8
2.1. Level of Detail	10
2.2 Safety Goal Analysis.....	11
2.2.1 When a Safety Goal Evaluation Is Needed.....	12
2.2.2 Safety Goal Analysis Determination.....	12
2.3 Elements of a Regulatory Analysis	15
2.3.1 Statement of the Problem and Objective	16
2.3.2 Identification and Preliminary Analysis of Alternative Approaches.....	18
2.3.3 Estimation and Evaluation of Costs and Benefits	19
2.3.4 Presentation and Summary of Results.....	20
2.3.5 Decision Rationale	21
2.3.6 Implementation.....	22
2.4 Safety Goal Evaluation for Operation of Nuclear Power Plants	22
2.4.1 Implementation Guidance	22
2.4.2 New Power Reactors under 10 CFR Part 52	30
2.5 Relationship to Other Procedural Requirements.....	31
2.5.1 Paperwork Reduction Act.....	31
2.5.2 Regulatory Flexibility Act.....	32
2.5.3 National Environmental Policy Act	32
2.5.4 Information Requests under 10 CFR 50.54(f)	33
3. BACKFITTING AND ISSUE FINALITY	34
3.1 General	34
3.2 Relationship of Regulatory Analysis to Backfitting	34
4. NATIONAL ENVIRONMENTAL POLICY ACT	36
4.1 General	36
4.2 Cost-Benefit Analyses in 10 CFR Part 51	36
4.2.1 Requirements.....	36
4.2.2 Costs and Benefits for the Proposed Action and Each Alternative	37
4.3 Environmental Justice.....	38
4.4 Public and Occupational Health Impact Analyses.....	39
4.4.1 Reactors – SAMA/SAMDA Analyses	39
4.4.2 Materials.....	42
5. DETAILS OF A COST-BENEFIT ANALYSIS	43
5.1 General	43

5.1.1	Methods	43
5.1.2	Attribute Considerations for Materials Licensees	44
5.2	Identification of Attributes	45
5.2.1	Public Health (Accident)	45
5.2.2	Public Health (Routine)	45
5.2.3	Occupational Health (Accident)	45
5.2.4	Occupational Health (Routine)	46
5.2.5	Economic Consequences (Offsite Property)	46
5.2.6	Onsite Property	46
5.2.7	Industry Implementation	46
5.2.8	Industry Operation	46
5.2.9	NRC Implementation	47
5.2.10	NRC Operation	47
5.2.11	Other Government Entities	47
5.2.12	General Public	47
5.2.13	Improvements in Knowledge	48
5.2.14	Regulatory Efficiency	48
5.2.15	Safeguards and Security Considerations	48
5.2.16	Environmental Considerations	49
5.2.17	Other Considerations	49
5.3	Quantification of Attributes	49
5.3.1	Treatment of Industry Initiatives	49
5.3.2	Attributes Valuation	51
5.4	Labor Rates	86
5.5	Economic Discounting and Calculation of Present Value	86
5.6	Discount Rate	87
5.7	Discrete Discounting	87
5.8	Continuous Discounting	88
6.	CONCLUSION	91
7.	REFERENCES	92
APPENDIX A: QUALITATIVE FACTORS ASSESSMENT TOOLS		A-1
APPENDIX B: COST ESTIMATING AND BEST PRACTICES		B-1
APPENDIX C: TREATMENT OF UNCERTAINTY		C-1
APPENDIX D: GUIDANCE ON REGULATORY ANALYSES RELATED TO ASME CODE CHANGES		D-1
APPENDIX E: SPECIAL CIRCUMSTANCES		E-1
APPENDIX F: DATA SOURCES		F-1
APPENDIX G: HISTORICAL DATA		G-1
APPENDIX H: SEVERE ACCIDENT CONSEQUENCE ANALYSIS		H-1
APPENDIX I: NATIONAL ENVIRONMENTAL POLICY ACT COST-BENEFIT ANALYSIS		I-1
APPENDIX J: BACKFITTING PROCEDURES		J-1
APPENDIX K: MORBIDITY		K-1
APPENDIX L: REPLACEMENT POWER COSTS		L-1

PREDECISIONAL

ACKNOWLEDGEMENTS

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

PREDECISIONAL

PREDECISIONAL

LIST OF FIGURES AND TABLES

List of Figures

Figure 2-1 Elements of a Regulatory Analysis	15
Figure 2-2 Safety Goal Screening Criteria	27

List of Tables

Table 1-1 Checklist for Specific Backfit Regulatory Analysis Requirements	6
Table 2-1 PRA-Related Information for Use in Preliminary Screening Analyses.....	25
Table 5-1 Expected Population Doses for Power Reactor Release Categories	54
Table 5-2 Weighted Population Dose Factors for the Five NUREG-1150 Power Reactors.....	57

PREDECISIONAL

ABBREVIATIONS AND ACRONYMS

ABWR	advanced boiling water reactor
ADAMS	Agencywide Documents Access and Management System
ALARA	as low as reasonably achievable
AOC	averted offsite costs
AOE	averted occupational exposure
AOSC	averted onsite costs
APE	averted public exposure
BLS	Bureau of Labor Statistics (U.S. Department of Labor)
BWR	boiling-water reactor
CDF	core damage frequency
CFR	<i>Code of Federal Regulations</i>
COE	cost of enhancement
COI	cost-of-illness
COL	combined license
CPCFB	conditional probability of containment failure or bypass
CRGR	Committee to Review Generic Requirements
Cs	cesium
DC	design certification
D.C.	District of Columbia
DCR	design certification rule
DOE	U.S. Department of Energy
EA	environmental assessment
EDO	Executive Director for Operations
EIS	environmental impact statement
E.O.	Executive Order
EPA	U.S. Environmental Protection Agency
EPRI	Electric Power Research Institute
ER	environmental report
ESBWR	economic simplified boiling water reactor
ESP	early site permits
ESRP	environmental standard review plan
FR	<i>Federal Register</i>
FSAR	final safety analysis report
GAO	Government Accountability Office
GDP	gross domestic product
GE	General Electric
GEH	General Electric - Hitachi
GEIS	generic environmental impact statements
IAEA	International Atomic Energy Agency

ICRP	International Commission on Radiological Protection
IPE	individual plant examination
IPEEE	individual plant examination of external events
ISFSI	independent spent fuel storage installation
km	kilometer
kWh	kilowatt-hours
LERF	large early release frequency
LRF	large release frequency
LWR	light-water reactor
MACCS	MELCOR Accident Consequence Code System
MD	management directive
ML	manufacturing license
NEI	Nuclear Energy Institute
NEPA	National Environmental Policy Act
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NRC	U.S. Nuclear Regulatory Commission
NRR	Office of Nuclear Reactor Regulation
NUREG	NRC technical report designation
NUREG/BR	NUREG brochure
NUREG/CR	NUREG contractor report
OMB	Office of Management and Budget
PRA	probabilistic risk assessment
PV	present value
PWR	pressurized-water reactor
QALY	quality-adjusted life-year
RES	Office of Nuclear Regulatory Research
SAMA	severe accident mitigation alternatives
SAMDA	severe accident mitigation design alternatives
SDA	standard design approval
SDC	standard design certifications
SECY	staff papers before the Commission
SEIS	supplemental environmental impact statement
SNM	special nuclear material
SRM	staff requirements memorandum
SSC	systems, structures, and components
TMI	Three Mile Island
U.S.	United States
U.S.C.	United States Code

VSI	value of statistical illness
VSL	value of statistical life
WTP	willingness-to-pay
yr	year

PREDECISIONAL

1. INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) uses this guidance to evaluate costs and benefits of proposed regulatory actions to protect public health and safety, promote the common defense and security, and protect the environment. These evaluations aid the staff in (1) providing adequate justification for the proposed action, and (2) documenting a clear explanation of why the proposed action was recommended. This guidance contains the framework for (1) identifying the problem and associated objectives, (2) identifying alternatives for meeting the objectives, (3) analyzing the consequences of alternatives, (4) selecting a preferred alternative, and (5) documenting the analysis in an organized and understandable format. The resulting analysis is referred to as a cost-benefit analysis.

Although the NRC is not required to conduct cost-benefit analyses, it voluntarily began performing them in 1976. In preparing cost-benefit analyses, the NRC intends to ensure that decisions imposing burdens on licensees are based on adequate information regarding the costs and benefits associated with a reasonable set of alternatives and to follow a systematic and disciplined process that is open and transparent. The ultimate objective of this process is to ensure that all burdens are justified and will achieve intended regulatory objectives. The NRC conducts cost-benefit analyses as part of the regulatory review of cost-justified substantial safety enhancements (i.e., backfit analysis), as well as regulatory and environmental analyses.

The cost-benefit analyses prepared by the NRC before 1983 were termed value-impact analyses and followed the value-impact guidelines in SECY-77-388A, "Value-Impact Guidelines," dated December 19, 1977. In February 1981, President Reagan issued Executive Order (E.O.) 12291 that directed executive agencies to prepare a cost-benefit impact analysis for all major rules and stated that cost-benefit actions should be based on adequate information concerning the need and consequences of proposed actions. Moreover, E.O. 12291 directed that actions were not to be undertaken unless they resulted in a positive net value to society. As an independent agency, the NRC was not required to comply with E.O. 12291; and the Commission noted that its established cost-benefit review procedures included an evaluation of proposed and existing rules consistent with the cost-benefit impact analysis provisions of E.O. 12291. However, the Commission determined that clarifying and formalizing its existing cost-benefit procedures for the analysis of cost-benefit actions would enhance the effectiveness of such actions and further meet the spirit of E.O. 12291. The NRC issued the original version of these guidelines as NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," in January 1983.

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

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

In November 1995, the NRC issued Revision 2 to NUREG/BR-0058 to reflect: (1) the NRC's accumulated experience with implementing Revision 1 to NUREG/BR-0058, (2) changes in NRC regulations and procedures since 1984, particularly the backfit rule in 10 CFR 50.109, and the "Safety Goals for the Operations of Nuclear Power Plants, Policy Statement, Republication" published in the *Federal Register* (51 FR 30028) on August 21, 1986, (3) advances and refinements in cost-benefit analysis techniques, (4) cost-benefit guidance for Federal agencies in E.O. 12866 and in issuances of the Administrative Conference of the United States and the Office of Management and Budget (OMB),¹ and (5) procedural changes designed to enhance the NRC's cost-benefit effectiveness.

Certain regulatory actions are subject to the backfit rule in Title 10, Energy, in the *Code of Federal Regulations* (10 CFR), Part 50.109 and to the analysis and information requirements of the Committee to Review Generic Requirements (CRGR). The NRC intends that, for these actions, the analysis performed in accordance with this guidance will satisfy the documentation requirements of the backfit rule and the provisions of the CRGR Charter without a need to prepare separate submissions. As part of the regulatory analysis, the "substantial increase in overall protection" test required under the backfit rule is assessed using the safety goal screening criteria.

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

In July 2000, the NRC issued Revision 3 of NUREG/BR-0058 to address the NRC's policy concerning the treatment of industry initiatives in cost-benefit analyses.

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

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

In the Staff Requirements Memorandum (SRM) in response to SECY-12-0110, dated March 20, 2013, the Commission affirmed the agency's current approach to the issue of land contamination from reactor accidents and approved the staff's plan for enhancing the currency and consistency of the existing framework through updates to cost-benefit guidance documents.

¹ OMB's "Regulatory Impact Analysis Guidance" was based on E.O. 12291. Both E.O. 12291 and OMB's guidance were revoked by E.O. 12866.

The Commission also found that economic consequences should not be treated as equivalent in regulatory character to matters of adequate protection of public health and safety. This revision of NUREG/BR-0058 responds, in part, to this Commission direction (SRM-SECY-12-0110).

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

1.1 Purpose

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

The expanded guidance has several goals:

- Assist the analyst in understanding how current NRC policy impacts what will likely need to be captured in a regulatory decisionmaking document.
- Incorporate changes in policy and advances in methodology that have occurred since the issuance of the 2004 NRC Regulatory Analysis Guidelines. The NRC and other agencies have conducted considerable research on various aspects of regulatory decisionmaking. Also, NRC staff experience has resulted in significant modifications to the regulatory decisionmaking documents. These advances have been incorporated into this guidance.
- Consolidate relevant information regarding regulatory, environmental and backfit analyses into one cost-benefit guidance document, NUREG/BR-0058, Revision 5.

1.2 Scope of Regulatory Decisionmaking Documents

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

1.2.1 Regulatory Analysis

All mechanisms 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, should include justification that the benefits of the action would outweigh the costs.

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

Many regulatory analyses are prepared to support generic backfit analyses (i.e., a generic backfit is a backfit applicable to multiple facilities). These are referred to as backfit regulatory analyses. Regulatory analyses also assess the environmental impacts of proposed and final rulemaking actions and include a statement concerning the environmental impact in the Supplementary Information section of the preamble to each rulemaking.

1.2.2 Backfit Analysis and Issue Finality

It is the policy of the NRC to have an effective program that will ensure that proposed backfits to be imposed on nuclear power reactor licensees, new power reactor licensees,² and select nuclear materials licensees are appropriately justified on the basis of the backfitting provisions of applicable NRC regulations and the Commission's backfitting policy and guidance. Additionally, the NRC requires the staff to appropriately justify information requests to the licensees.

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

A backfit regulatory analysis is similar to, and should generally follow the requirements for, a regulatory analysis. NRC's policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities (Ref. 25) 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. 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 1-1 and at appropriate parts of the guidance. Table 1-1

² The term "new power reactor licensees" refers to holders of early site permits (ESPs), standard design approvals (SDAs), combined licenses (COLs), manufacturing licenses (MLs), and applicants for design certifications (DCs); applicants for COLs if the application references an ESP, design certification rule (DCR), or SDA; and applicants for MLs if the application references a DCR or SDA.

also cites where in the *Code of Federal Regulations* each requirement is located and indicates where in the regulatory analysis the discussion of each item should appear. The analyst must be sure to address the 10 CFR 50.109 requirements in the backfit analysis.

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 of the Charter and in this guidance should be incorporated into the backfit analysis. (Inclusion of these items will, in effect, satisfy the backfit analysis requirement of a CRGR review package.) 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 Executive Director for Operations (EDO) or the Director of the NRC Office of Nuclear Material Safety and Safeguards (NMSS)) will ordinarily require CRGR review.

Table 1-1 Checklist for Specific Backfit Regulatory Analysis Requirements

CFR Citation^a (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 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.	Estimation and Evaluation of Values and Impacts Availability - Implementation
50.109(c)(8)	Potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit.	Presentation of Results Implementation
50.109(c)(9)	Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.	Decision Rationale
50.109(e)	Consideration of how the backfit should be scheduled in light of other ongoing regulatory activities at the facility.	Implementation

^a Similar provisions detailing what information is to be contained in a backfit analysis are contained in 10 CFR 70.76, 10 CFR 72.62, 10 CFR Part 76, and, for issue finality, 10 CFR Part 52. These provisions should be considered, as appropriate, when considering backfit-related matters for independent spent fuel storage installations and the monitored retrievable storage installations, gaseous diffusion plants, and new reactors, respectively. In addition, in the context of Part 70 licensing actions, the Commission supported the requirement that "...any new backfit pass a cost-benefit test without the substantial increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost should be justified on a cost-benefit basis." (Ref. 26)

1.2.3 National Environmental Policy Act Review

NEPA requires Federal agencies to prepare a "detailed statement for major Federal actions significantly affecting the quality of the human environment" (Ref. 27). This statement is defined

by NRC regulations as an environmental impact statement (EIS) (Ref. 28). The essential purpose of NEPA is to ensure that environmental factors are given the same consideration as other factors in decisionmaking by Federal agencies. Additionally, an environmental assessment (EA) may be prepared to demonstrate that an EIS is not necessary (Ref. 29). NRC regulations for implementing NEPA are in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions."

In addition to NRC licensing reviews deemed major Federal actions, the NRC must assess the environmental impact of each proposed and final rulemaking action and include a statement concerning the environmental impact in the Supplementary Information section of the preamble to each rulemaking. The NRC Regulations Handbook describes the procedural requirements for considering the environmental impact of a rulemaking action.

1.2.4 Details Regarding Cost-Benefit Guidance

In analyses for proposed materials and reactor regulatory actions, the analyst should include a cost-benefit analysis. There are several aspects that should be accounted for, including determining the appropriate method and the consideration and identification of the various attributes. These attributes range from public health to environmental considerations. Other aspects include the quantification of the attributes, consideration of labor rates, present value, and the various discount rates. Section 5 of this guidance provides the details needed by the analyst to conduct a comprehensive cost benefit analysis.

1.3 Regulatory Relaxations

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

For all regulatory analyses of proposed relaxations, information should be presented in the Decision Rationale section (see Section 2.3.5) regarding the following findings:

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

2. REGULATORY ANALYSIS

The statutory mission of the NRC is to ensure that civilian use of nuclear materials in the United States, in operating nuclear power plants and related fuel cycle facilities or in medical, industrial, or research applications, are carried out with proper regard and provisions for protecting public health and safety, property, environmental quality, and the common defense and security. Accordingly, the principal purposes of a regulatory analysis are to ensure the following:

- The NRC's regulatory decisions made in support of its statutory responsibilities are based on adequate information concerning the need for and consequences of proposed actions.
- Alternative approaches to meet the regulatory objectives are identified and analyzed, and no preferable alternative is available to the proposed action.
- Proposed actions subject to the backfit rule (10 CFR 50.109), and not within the exceptions at 10 CFR 50.109(a)(4) and 10 CFR 76.76(a)(4), provide a substantial increase in the overall protection of public health and safety or the common defense and security and that the direct and indirect costs of implementation are justified in view of this substantial increase in protection.

The Commission has stated that "substantial" means important or significant in a large amount, extent, or degree (Ref. 31). Applying such a standard, the NRC would not ordinarily expect that safety or security enhancements would be required as backfits that result in an insignificant or small benefit to public health and safety, regardless of costs. On the other hand, the standard is not intended to be interpreted in a manner that would result in disapprovals of safety or security enhancements having costs that are justified in view of the increased protection that would be provided. This approach is flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety. The approach is also flexible enough to allow for arguments that consistency with national and international standards, or the incorporation of widespread industry practices, contributes either directly or indirectly to a substantial increase in safety. Such arguments concerning consistency with other standards, or incorporation of industry practices, would have to rest on the particulars of a given proposed rule. This approach of "substantial increase" is consistent with the Agency's policy of encouraging voluntary initiatives.

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

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

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licenses. Executive Order 12866 requires that a regulatory analysis be prepared for all significant regulatory actions. Significant regulatory actions are defined in E.O. 12866 to include actions that “are likely to result in a rule that may (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The NRC requires regulatory analyses for a broader range of regulatory actions than just “significant rulemakings” as defined in E.O. 12866. In general, each NRC office should ensure that the mechanisms used by the NRC staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees include an accompanying regulatory analysis. This requirement applies to actions initiated internally by the NRC, from a petition to the NRC, or industry initiatives. These mechanisms include rules, generic communications, cost-benefit guides, orders, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, NUREG publications, and standard technical specifications that establish, modify, or withdraw expectations or guidance for applicants or licensees.

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

For several types of regulatory actions, a detailed cost-benefit analysis could introduce additional costs that are disproportionate relative to the action being undertaken. These include the issuance of generic communications, regulatory guides, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, some NUREG publications, standard technical specifications, and other documents that provide guidance for applicants or licensees. In general regulatory analysis should be limited only in terms of depth of discussion and analysis, not in the reduction of the scope of the regulatory analysis and not in the need to justify the proposed action.

Generic actions (i.e., actions that affect all, several, or a class of licensees) that may not need a regulatory analysis include notices, policy statements, and generic communications that only transmit information and do not present new or revised staff positions, impose requirements, or recommend action. Generic information requests issued under 10 CFR 50.54(f) require a specific justification statement and are reviewed by the CRGR when directed to one or more classes of nuclear power reactors; however, these requests do not require the type of regulatory analysis discussed in this guidance. New requirements affecting certified nuclear power plant designs will be justified through a notice and comment rulemaking process, as specified in 10 CFR 52.63, “Finality of Standard Design Certifications.” Regulatory analyses are not necessary for requirements arising out of litigation.

The analytical needs of regulatory analyses involving the relaxation of requirements can be markedly different. In these cases, the regulatory analysis should provide the level of assessment that will demonstrate that the two following conditions are satisfied.

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

For proposed regulatory actions that would relax or reduce current requirements, the backfit rule and the safety goal evaluation process and screening criteria are not applicable. However, for all proposed relaxations (including those affecting nuclear power plants), supporting documentation should be prepared that contains the basis for concluding that the two conditions previously identified will be satisfied. Further, it is appropriate in justifying a proposed relaxation to cite the results or insights from risk analyses that support relaxation, as well as the NRC's original bases for having established the existing requirement.

In general, actions that would relax or reduce requirements should give licensees the option of taking advantage of the change and should not be mandatory. However, a calculation of the cost savings should be based on the assumption that all licensees will take advantage of the change.

2.1. Level of Detail

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

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

A 2-month level of effort is sufficient for many regulatory analyses. Where larger levels of effort may be involved, this guidance suggests additional methods and references that can be used. These could entail major efforts, possibly up to a year.

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

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

There may be instances when it would be beneficial for a regulatory analysis to include supplemental information (e.g., analyses and results that go beyond the guidance provided in these documents). This might be the case when, for example, the regulatory initiative is a “significant regulatory action,” (i.e., greater than \$100 million annually) as defined in E.O. 12866, or of such policy import that a major controversy is likely to ensue. In OMB Circular A-4, additional regulatory analysis guidance is provided for such initiatives. Among other things, this additional guidance includes the use of a standardized accounting statement, a cost-effectiveness analysis, incremental analyses of costs and benefits, and the calculation of internal rates of return. In addition, it calls for both a more expansive treatment of monetized health and safety benefits and the characterization of key attributes that are not readily quantified. This includes the use of shadow prices and willingness-to-pay measures to monetize attributes where no markets or imperfect markets prevail, and the use of alternative health and safety measures that consider quality-adjusted life years, equivalent lives, and nonfatal risks. In practice, NRC initiatives rarely meet the high economic and policy thresholds of OMB Circular A-4, and therefore, for most NRC regulatory analyses, this level of analysis would not be required nor justified, given the increased level of effort involved. Rather than provide more detailed guidance in this document, analysts are referred to OMB Circular A-4 when a specific regulatory action satisfies OMB’s high threshold standards.

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

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

2.2 Safety Goal Analysis

Assessing the risk of potential changes to public safety has always been a fundamental part of regulatory decisionmaking. As PRA technology has advanced since the mid-1970’s, the NRC

staff has relied on the insights and results from risk assessment in management of regulatory activities. The NRC's policy statement on safety goals for the operations of nuclear power plants (Ref. 9) reflects an example of this change, and defines both qualitative goals and quantitative objectives that can be used to guide regulatory decisionmaking.

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

Additionally, note that the Commission's safety goals reflect a mean value for a class or for all U.S. nuclear power reactors. In this regard, the Commission specified in an SRM dated June 15, 1990, that "safety goals are to be used in a more generic sense and not to make specific licensing decisions" (Ref. 32).

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

2.2.1 When a Safety Goal Evaluation Is Needed

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

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

2.2.2 Safety Goal Analysis Determination

The staff should first determine whether a regulatory action needs to consider safety goals. The discussion in Section 2.2.1 provides guidance for making this determination. If the proposed regulatory action meets the safety goal screening criteria (see Section 2.4), the regulatory analysis should include the results of the safety goal evaluation. Figure 2-1 depicts the steps performed in a regulatory analysis, including the safety goal evaluation. References to appropriate sections of the elements of a regulatory analysis are included. Depending on the

results of steps C and D in Figure 2-1, the regulatory analysis may be terminated with no regulatory action taken. In performing steps C and D, a PRA (see text box 2-1 which provides a primer on PRA) should be relied upon to quantify the risk reduction and corresponding values of the proposed new requirement.

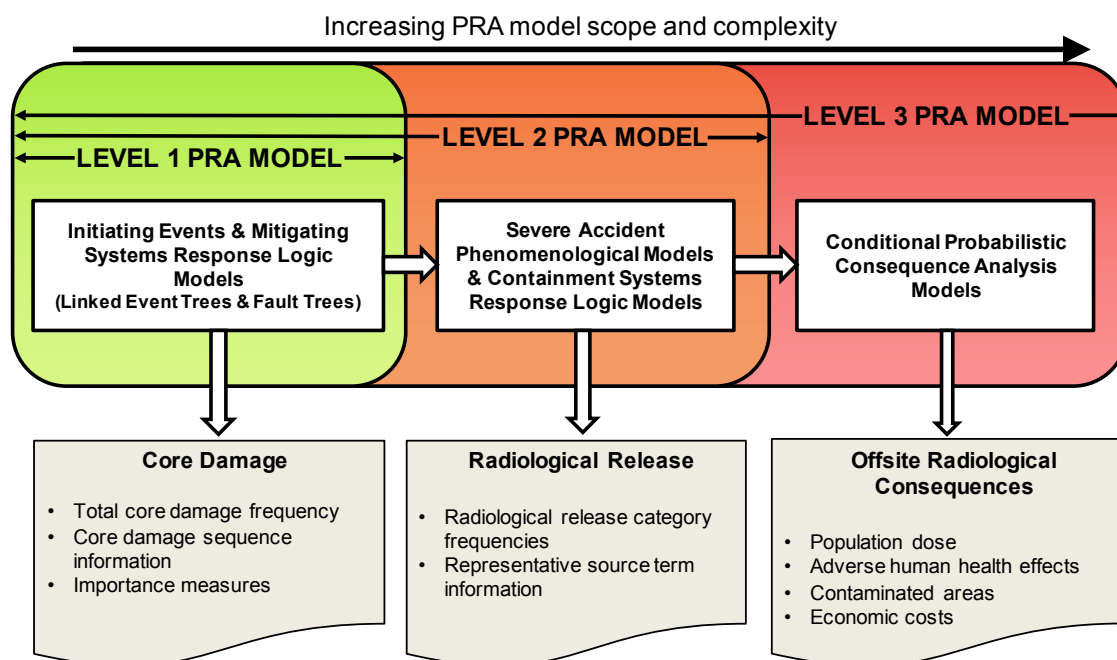
The NRC recognizes, however, that not all regulatory actions are amenable to a quantitative risk assessment and that certain evaluations may be based directly on engineering, regulatory judgment, or qualitative analysis. A more detailed description of the safety goal evaluation procedure is provided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

PREDECISIONAL

Text Box 2-1: Primer on Probabilistic Risk Assessment (PRA)

PRA is a subset of risk analysis techniques that can be used to support risk management, safety, or environmental decisions involving complex engineered systems. The traditional scenario-based approach to PRA involves systematic application of methods, models, data, and analytic tools to develop answers to three fundamental questions that underlie Kaplan and Garrick's widely accepted quantitative definition of risk: (1) *What can go wrong?* (2) *How likely is it to occur?* and (3) *If it does occur, what are the consequences?* In this framework, a *risk triplet* comprised of an accident scenario, its frequency, and its conditional consequences represents the risk attributed to a specified class of accident scenarios (Ref. 33). The set of risk triplets that encompasses a reasonably complete spectrum of possible accident scenarios is then assumed to represent the total risk attributed to accidents caused by failures within the modeled system.

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



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

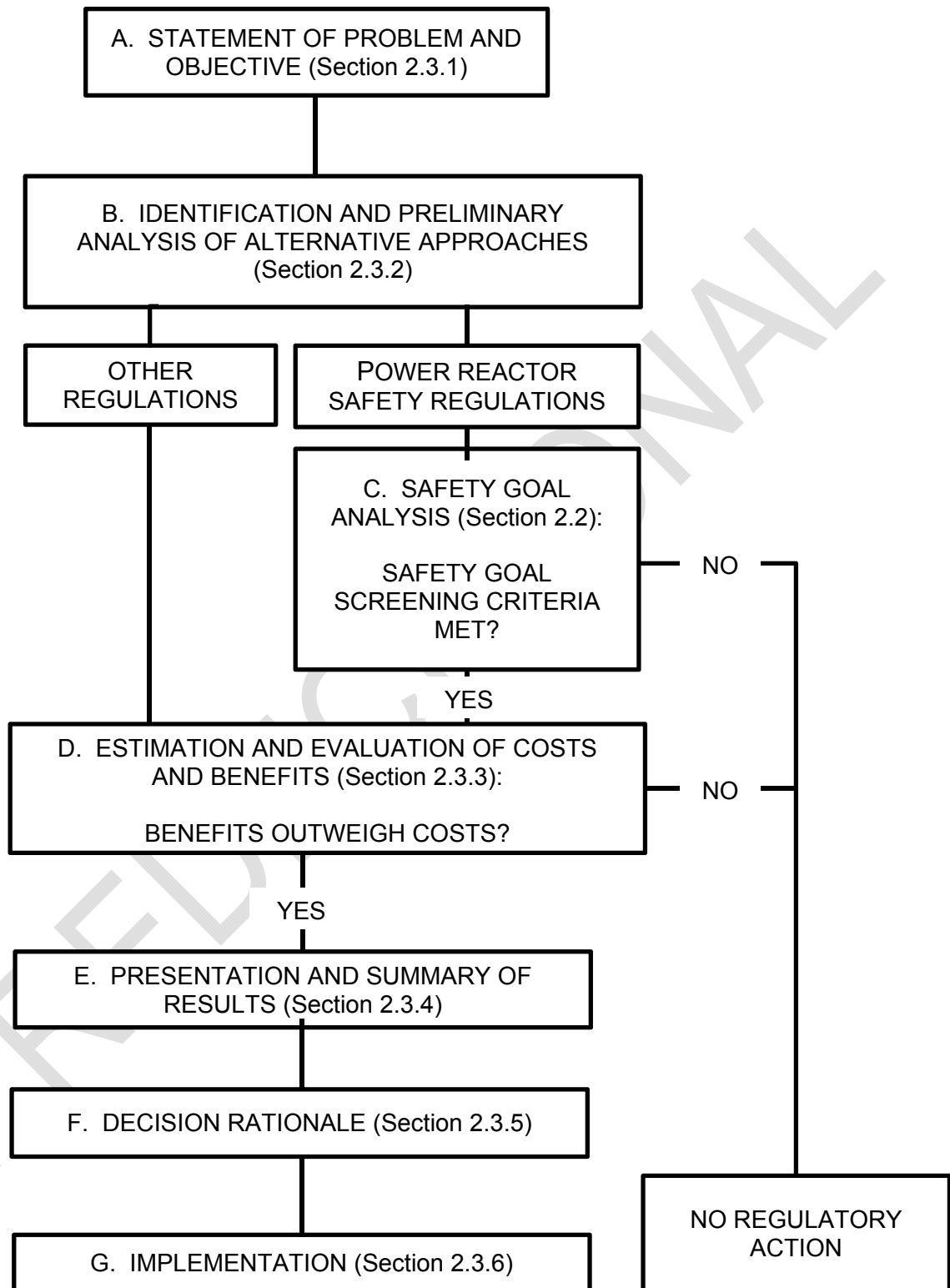


Figure 2-1 Elements of a Regulatory Analysis

2.3 Elements of a Regulatory Analysis

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

- (1) statement of the problem and objective
- (2) identification and preliminary analysis of alternative approaches
- (3) estimation and evaluation of costs and benefits (incorporating a safety goal evaluation in appropriate cases)
- (4) presentation and summary of results
- (5) decision rationale
- (6) implementation

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

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

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

Each of the six elements is addressed in detail below.

2.3.1 Statement of the Problem and Objective

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

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

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

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

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

Background of the Problem

The background discussion should include, as applicable:

- a brief history of the problem and the outcome of past efforts (if any) to resolve it
- any statutes or litigation³ that directly or indirectly addresses the problem
- whether existing requirements have created or contributed to the problem and whether these requirements can be modified to achieve the regulatory objective more effectively
- the extent to which the immediate problem is part of a larger problem
- the relationship of the problem to other ongoing studies or actions (e.g., NRC's generic safety issues [Ref. 35]).
- the objectives of the proposed new or revised requirement and the relationship of the objectives to NRC's legislative mandates and authority, safety goals for the operation of

³ Litigation records could come from court cases, decisions by an Atomic Safety and Licensing or Appeal Board, or Commission decisions in cases under litigation.

nuclear power plants, and policy and planning guidance (e.g., the NRC's Strategic Plan (Ref. 36).

- the relationship of the problem to formal positions adopted by national and international standards organizations
- the identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness
- any constraints or other cumulative impacts that pertain to the problem
- the draft papers in development or other underlying staff documents supporting the requirements or staff positions

2.3.2 Identification and Preliminary Analysis of Alternative Approaches

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

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

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

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

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

Using the rough estimates as well as 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 regarding whether a major or standard effort is needed to resolve the problem. 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 made in

performing the regulatory analysis. The significance of the problem will also help determine the priority assigned to its resolution.

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

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

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

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

When appropriate, the analyst should consider including specific rule provisions for the analyzed alternative. Adding the details allows the readers to track specific OMB supporting statements required by the Paperwork Reduction Act. Adding provision details also aids the OMB desk officer and stakeholders. This detail can be provided in the regulatory analysis.

2.3.3 Estimation and Evaluation of Costs and Benefits

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

Estimates are made for those attributes that lend themselves to quantification using standard techniques. Obtaining the appropriate data may be more complicated 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) (see Appendix B).

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

Depending 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 the usefulness of results and the amount of resources required. Uncertainty analyses should produce actual probability distributions for the overall results, based on assumed distributions for selected input parameters. Appendix C discusses the differences between sensitivity and uncertainty analyses and their respective roles in the cost-benefit analysis.

Complete the above steps for each alternative evaluated.

2.3.4 Presentation and Summary of Results

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

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

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

For alternatives projected to result in significantly different 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 should be assessed. These could include eliminating or creating a need for other programs; using limited NRC resources resulting in postponement or rescheduling of other programs; modifying accident probabilities resulting in changes to the priority of, or need for, other programs; or developing information with a bearing on other programs. Effects on other government agencies, if any, should also be assessed and reported.

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

The presentation provides a uniform format for recording the results of the evaluation of all quantitative attributes, plus a comments section to discuss other attributes and special considerations. It displays the results for the net-value measure.

All dollar measures should be present-valued and expressed in terms of the same year. This may require the conversion of some dollar values from the years in which they have been expressed to one common year. The gross domestic product (GDP) price inflation can be used to convert historical nominal dollars to dollars of one common year.

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

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

2.3.5 Decision Rationale

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

The net-benefit calculation is a compilation of all attributes that can be quantified in monetary terms. Certain attributes are generally quantified in other than monetary terms (e.g., public health (accident), which is measured in person-rem's of exposure) and converted to monetary terms with an established conversion factor (see Appendix H). These attributes are included in the net-benefit calculation. To aid the decisionmaker, the net benefit is to be computed for each alternative.

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

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

Nonquantifiable attributes can only be factored into the decision in a subjective way; the experience of the decisionmaker will strongly influence the weight that they are given. These attributes may be significant factors in regulatory decisions and should be considered.

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

proposed action on other existing and planned NRC programs and requirements is also necessary. This will ensure that there are no negative safety impacts in other areas, that NRC resources are being used responsibly, and that all actions are adequately planned and coordinated. Any other relevant criteria may be used with adequate documentation in the regulatory analysis.

2.3.6 Implementation

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

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

2.4 Safety Goal Evaluation for Operation of Nuclear Power Plants

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

When performing a safety goal evaluation, the analyst should be aware of any previous or ongoing safety improvements that have the potential to affect the status quo risks associated with the issues being addressed. Because there is no formal process for accounting for the potential dependencies between issues, the analyst should resort to a “best effort” approach in accounting for preexisting or concurrent impacts. The analyst should make a thorough effort to identify any previous or ongoing safety improvements that may affect the issue being evaluated. For example, an analyst addressing proposed improvements to diesel generator performance at power reactors should be aware of any diesel generator improvements already addressed in station blackout considerations. To the extent possible, the analyst should modify the risk equations of the representative plant to reflect the upgraded status quo from these other safety improvements. The analyst can then evaluate the difference between this new status quo and the proposed improvements being considered.

2.4.1 Implementation Guidance

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

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

The NRC's philosophy for safety goal evaluations involves the concept of defense-in-depth and a balance between prevention and mitigation (Ref. 9). This traditional defense-in-depth approach and the accident mitigation philosophy require the reliable performance of containment systems. The safety goal evaluation focuses on accident prevention; that is, on issues intended to reduce core damage frequency (CDF). However, to achieve a measure of balance between prevention and mitigation, the safety goal screening criteria established for these evaluations include a mechanism to use when relatively poor containment performance results in the need for greater consideration of issues and associated accident sequences.

2.4.1.1 Prevention of Core Damage Accidents – Comparison with Subsidiary Goal for Mean Core Damage Frequency of 10^{-4} per Reactor Year

For proposed regulatory actions to prevent or reduce the likelihood of sequences that can lead to core damage events, the change in the estimated CDF per reactor year needs to be evaluated and addressed in the regulatory analysis. CDF is defined as "the sum of the accident sequence frequencies of those accident sequences whose end state is core damage," where core damage is defined as "sufficient damage that could lead to a release of radioactive material from the core that could affect public health" (Ref. 41). The objective is to ensure that emphasis is placed on preventing core damage accidents.

This calculation should be computed on a generic basis for the class of affected plants. The resulting change in CDF should be representative for the affected class of plants. The selection of the PRA model (or models) and the associated data base should be identified and justified as representative of the class. For example, if the class of affected plants is a subset of boiling-water reactors (BWRs), one or more PRAs from individual plant examination (IPE) submittals or from those that have otherwise been conducted for the subset of BWRs should be selected. NUREG-1560, "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance," provides the NRC staff summary of all IPE submittals and NUREG-1742, "Perspectives Gained from the Individual Plant Examination of External Events (IPEEE) Program," provides a similar summary of all IPEEE submittals for external events. These references provide CDF and conditional containment failure probability information for the fleet of operating nuclear power plants in the 1990s. The top portion of Table 2-1 provides PRA-related information compiled from severe accident mitigation alternatives (SAMA) analyses that were conducted for nuclear power plant license renewal environmental reviews. This

information is documented in plant-specific supplements in NUREG-1437, Revision 1, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," for operating plants that have applied for license renewal.

NRC regulation 10 CFR Part 52 requires that a new reactor design certification applicant submit a description of the design-specific PRA and its results. The PRA is described in Chapter 19 of the design's Final Safety Analysis Report, and includes both a Level 1 and a Level 2 analysis. A Level 3 analysis that includes an assessment of offsite radiological consequences from postulated radiological releases is described in the design's Environmental Report. PRAs for new reactors have been developed by applicants and approved by the NRC for several new reactor designs including the following: advanced boiling water reactors (ABWR), AP1000, and economic simplified boiling water reactor (ESBWR) (Ref. 24). After a new reactor design has been constructed at a site and before operation begins, the PRA for that site-design combination is updated to reflect the as-built configuration of the plant.

The NRC has certified under 10 CFR Part 52 five reactor designs (see Appendices A through E of Part 52) where a description of the design-specific PRA and its results have been reviewed by the NRC staff. The bottom portion of Table 2-1 provides the key risk-related CDF and large release frequency (LRF) values for the three certified designs where an associated combined license to build and operate has also been issued by the NRC. Note that the ABWR design has two versions undergoing certification renewal, one ABWR version by General Electric – Hitachi (GEH) and a second ABWR version by Toshiba. Because of the unique process under Part 52 where PRAs have been applied as design tools, the related internal events CDFs for the Part 52 certified reactor designs as shown in Table 2-1 are less than the current operating reactors due to the removal of certain dominate accident sequences.

Analysts should use Table 2-1 data to perform a preliminary screening of the merit of the proposed new requirements for the appropriate class of nuclear power plants. This will result in identifying and assessing the range of reduction in CDF, as well as estimating the representative change for the class. Uncertainties and limitations should be addressed qualitatively and, to the extent practicable, quantitatively in the supporting documentation for the proposed regulatory action. This would include, for example, addressing plant-to-plant variability within a class of nuclear power plants. The analyst should consider that the internal events CDF entries capture only part of the total plant risk. The SAMA analyses documented in the NUREG-1437 supplements report external events multipliers in the range of 1.2 to 12 with an average value of 3.2 (based on the 51 of 57 supplements published between 1999 and 2016 that reported external events multipliers for 82 individual reactors). This means that the total CDF was estimated to be 1.2 to 12 times, with an average value of 3.2 times, the internal events CDF.

Table 2-1 PRA-Related Information for Use in Preliminary Screening Analyses

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

^a Source: CDF data from NUREG-1437 supplements

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

^c Pressurized water reactor (PWR)

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

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

^f Large release frequency (LRF): The Commission has not approved a formal definition of a large release or LRF. One informal definition for LRF is “the frequency of an unmitigated release of airborne fission products from the containment to the environment that is of sufficient magnitude to cause severe health effects, regardless of its timing.” The history of the use of the term “Large Release Frequency” is provided in SECY-13-0029. SOURCE: NUREG-2122, “Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking”

^g SOURCE: ABWR (GEH) data from NUREG-1503, July 1994

^h SOURCE: AP1000 data from NUREG-1793

ⁱ SOURCE: ESBWR data from NUREG-1966

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

- The analysis should explicitly define the class of affected plants and justify the use of specific PRAs to represent that class.
- The PRA should reflect the current state of PRA technology and include an analysis of uncertainties.

- The product of the analyses should be mean values and uncertainty estimates.
- The analysis should receive an independent review by staff knowledgeable and experienced in PRA, as well as reviews by the individual or group that identified the issue and the group that would be responsible for implementing the resolution.
- The analysis should be documented with sufficient detail to enable the analysis to be repeated. In addition, sufficient explanatory material should be provided to enable the reader to understand the significance of the calculations and to reconcile the various calculations with engineering judgment. Thus, the event or issue, its relationship to safety, the calculation approach, and all assumptions should be listed and justified, including, for example, choice of base PRA, choice of parameters, source of basic data, and any mathematical approximations used. The accident sequences affected should be described, and explanations of why they are affected should be provided.

The documentation should not present calculation results with more significant figures than are appropriate. More than one significant figure in the mantissa is not appropriate in most cases. Note, however, that if intermediate results are presented, a reader attempting to use these intermediate results in duplicating the calculation may not calculate exactly the same final results, due to rounding errors.

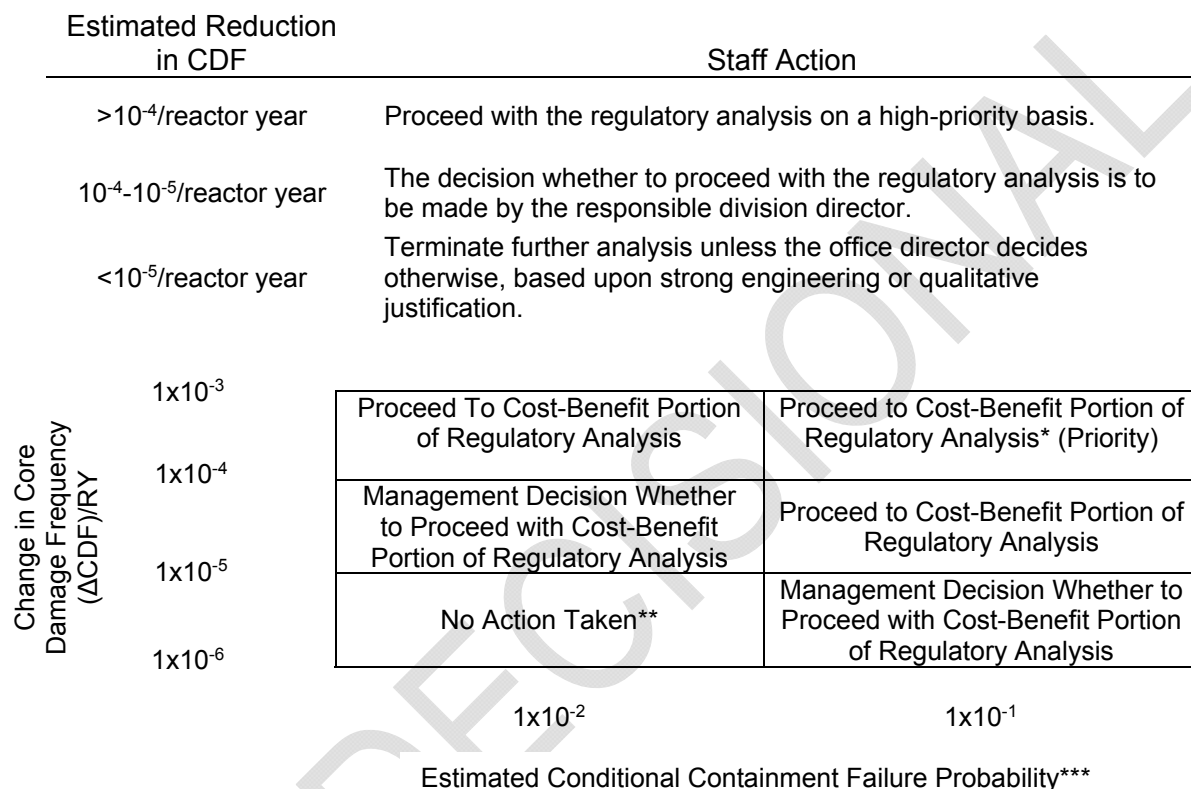
In comparing the estimated resulting change in CDF for the affected class of plants, contributions from both internal and external events should be considered to the extent that information is available and pertinent to the issue. However, the uncertainties associated with certain external event risk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

For the purpose of evaluating regulatory initiatives against safety goals, the magnitude of the change in CDF should be considered in concert with the determination of whether the substantial additional protection standard of the backfit rule is met. Specifically, a single common criterion is to be used for determining whether a regulatory initiative involving a reduction in CDF (1) meets the substantial additional protection standard identified in the backfit rule (Ref. 8) and (2) is appropriate, considering the subsidiary safety goal of 10^{-4} in mean CDF per reactor year (Ref. 32). This goal has been determined by the staff to be a useful benchmark but is not a Commission approved safety goal.

In light of the inherent uncertainties of PRA analysis, a reduction in CDF will be considered to be clearly substantial if the reduction is equal to or greater than 10^{-4} per reactor year. If the reduction in CDF is between 10^{-4} and 10^{-5} mean CDF per reactor year (i.e., 10 percent or more of the subsidiary safety goal of 10^{-4} in mean CDF per reactor year but less than 10^{-4}), consideration should be given to the probability of containment failure before a conclusion is reached on whether the reduction in CDF constitutes substantial additional protection. As illustrated in Figure 2-2, this means that, with certain exceptions, as discussed later in this guidance, regulatory initiatives involving new requirements to prevent core damage should result in a reduction of at least 1×10^{-5} in the estimated mean value CDF (i.e., the CDF before the proposed regulatory change should exceed the CDF after the change by at least 1×10^{-5}) to justify proceeding with further analyses. This safety goal screening criterion was selected to provide some assurance that the PRA and data limitations and uncertainties, as well as the variability among plants, will not eliminate issues warranting regulatory attention. This does not mean that, in all cases, a proposed safety enhancement of at least 1×10^{-5} will subsequently

prove to be justified for implementation after more detailed assessments are performed in accordance with Section 2.5, Relationship to Other Procedural Requirements, of this guidance. In this regard, the effect of uncertainties should be considered and discussed.

After the significance has been determined as measured by the estimated reduction in CDF of the proposed new requirement for the affected class of plants, guidance on further staff action is provided in Figure 2-2:



- * A determination is needed regarding adequate protection or compliance. The extent to which costs are considered is discussed in NUREG-1409.
- ** Unless an office director decides that the screening criteria do not apply (see Additional Consideration of Containment Performance)
- *** Conditional upon core damage accident that releases radionuclides into the containment (see Additional Consideration of Containment Performance)

Figure 2-2 Safety Goal Screening Criteria

The evaluation of CDF reduction provides a calibration on the significance of the proposed regulatory action. If the initiative results in a small change in CDF (less than 1×10^{-5} /reactor year), the regulatory analysis should, in general, proceed only if an alternative justification for the proposed new requirement can be formulated. A class of accident sequences involving the potential for early containment failure or containment bypass should receive further consideration, even if the reduction in CDF is less than 1×10^{-5} /reactor year. However, there may be other special circumstances that should be analyzed. The analyst should forward the issue (and include sufficient supporting information) for office director review.

If it is not possible to develop adequate quantitative supporting information for the proposed new requirement, a qualitative analysis and associated perspectives should be provided. To the

extent practicable, this information should be related to the safety goal screening criteria. For example, how does the proposed initiative affect the CDF and to what extent? How should the risk and the expected improvement be measured or estimated?

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

2.4.1.2 Additional Consideration of Containment Performance

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

CPCFB in this context is the conditional probability of early containment failure or bypass, given a core melt. In NUREG-1150, “Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants,” early containment failure is defined as “those containment failures occurring before or within a few minutes of reactor vessel breach for pressurized water reactors (PWRs) and those failures occurring before or within 2 hours of vessel breach for BWRs. Containment bypass failures (e.g., interfacing-system loss-of-coolant accidents) are categorized separately from early failures” (Ref. 47). The definition recognizes the impacts of early failure and uses that as a baseline from which to assess containment performance (e.g., CPCFB changes). In applying these screening criteria, the CPCFB definition may be extended, if appropriate, to up to 4 hours after vessel breach, to permit initiation of accident management and emergency preparedness actions. It is not a goal being sought because the staff recognizes the benefits of assuming prolonged containment failure in those scenarios that risk early failure.

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

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

- those involving core damage and release into an intact containment with early containment failure occurring
- those involving core damage and for which the containment system is breached as a result of accident phenomena either before or early in the core damage or melt progression
- those involving preexisting conditions that cause loss of containment integrity before core damage (e.g., large openings)

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

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

Furthermore, note that the safety goal screening criteria described in this guidance do not address issues that deal only with containment performance. Consequently, issues that have no impact on core damage frequency (Δ CDF of zero) cannot be addressed with the safety goal screening criteria. However, because release mitigating initiatives have been relatively few and infrequent compared with accident preventive initiatives, mitigating initiatives will be assessed on a case-by-case basis with regard to the safety goals. Given the very few proposed regulatory initiatives that involve mitigation, this should have little overall impact from a practical perspective on the usefulness of the safety goal screening criteria.

2.4.1.3 Summary of Safety Goal Screening Criteria Guidance

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

2.4.1.4 Regulatory Analysis

If the safety goal evaluation of the proposed regulatory action results in a favorable determination (i.e., any decision except no action), the analyst may presume the substantial additional protection standard of 10 CFR 50.109(a)(3) is achievable. The initiative should then be assessed in accordance with Section 2.4.1 of this guidance (see Figure 2-1). If the net value calculation required by Section 2.4.1 is not positive, further activities and analyses should be terminated unless there is a qualitative justification for proceeding further.

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 (Ref. 9). 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 as follows:

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

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

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

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

This guidance contains specific information implementing the quantitative objectives that the analyst should carefully follow.

This guidance states that a safety goal evaluation is needed for a proposed generic safety enhancement to nuclear power plants that is subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). Thus, proposals for a facility-specific backfit or for generic backfits within the exceptions at 10 CFR 50.109(a)(4)(i-ii) do not require a safety goal evaluation. This guidance also states that a safety goal evaluation is not needed for a proposed relaxation of a requirement affecting nuclear power plants.

This guidance states that a PRA should normally be used in performing a safety goal evaluation to quantify the risk reduction and corresponding values of a proposed new requirement. NRC's Final Policy Statement on the use of PRA methods in nuclear regulatory activities (Ref. 25) 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.

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

2.4.2 New Power Reactors under 10 CFR Part 52

When analyzing risks from severe accidents as part of the environmental review under 10 CFR Part 52 for an early site permit (ESP) or for a combined license (COL), as provided in NUREG-1555, the reviewer should compare the site-specific severe accident dose risks with the Commission's safety goals (Ref. 9). New reactor designs submitted for standard certification must comply with the PRA requirements in 10 CFR Part 52.

2.5 Relationship to Other Procedural Requirements

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

2.5.1 Paperwork Reduction Act

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

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

Agencies are required to obtain OMB approval for collections of information when under any of the following conditions: (1) the information collection involves 10 or more persons by means of identical questions or reporting or recordkeeping requirements, or (2) the collection is addressed to all or a substantial majority of an industry, even if that majority involves fewer than 10 persons (Ref. 50).

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

In the event that OMB disapproves an information collection, independent regulatory agencies, such as the NRC, may override the disapproval or stay of effectiveness of approval of a collection of information by a majority vote of the Commissioners. Procedures for Commission override of OMB disapproval are contained in NRC Management Directive (MD) 3.54.

2.5.2 Regulatory Flexibility Act

The Regulatory Flexibility Act requires Federal agencies to prepare a regulatory flexibility analysis to be made available for public comment, if a proposed rule will have a significant economic impact on a substantial number of small entities. The analysis is to describe the impact of the proposed rule on small entities (Ref. 51). The size standards used by the NRC to qualify a licensee as a small entity, codified at 10 CFR 2.810, are as follows:

- a small business that is a for-profit concern and is a concern that provides a service or a concern not engaged in manufacturing with average gross receipts of \$7.0 million or less over its last 3 completed fiscal years
- a manufacturing concern with an average number of 500 or fewer employees, based upon employment during each pay period for the preceding 12 calendar months
- a small organization that is a not-for-profit organization that is independently owned and operated and has annual gross receipts of \$7.0 million or less
- a small governmental jurisdiction that is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000
- a small educational institution that is (1) supported by a qualifying small government jurisdiction or (2) is not State or publicly supported and has 500 or fewer employees

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

2.5.3 National Environmental Policy Act

When a generic or programmatic EIS has been prepared under NEPA (see Appendix I) that provides the technical basis for a proposed regulatory action, a brief summary of the EIS will be an acceptable substitute for the information and analysis requirements identified in Sections 4.1-4.4 of this guidance. The EIS may be referenced at other appropriate points in the regulatory analysis to avoid duplicating existing written material.

When a regulatory analysis and an EIS or EA are being prepared for a proposed regulatory action, preparation of the two documents should be coordinated as much as possible. For

example, the alternatives evaluated in the regulatory analysis should correspond as much as possible to the alternatives evaluated in the EIS or EA.

2.5.4 Information Requests under 10 CFR 50.54(f)

Procedures for NRC information requests directed to production and utilization facility licensees appear at 10 CFR 50.54(f). The regulation requires the NRC to prepare a written statement justifying the reasons for the information request, except when the information is needed to verify licensee compliance with the current licensing basis for the facility. The written statement is to establish that the burden imposed on the licensee is justified in view of the potential safety significance of the issue. All justification statements must be approved by the EDO or his or her designee before issuance of the information request.

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

MD 8.4 discusses facility-specific information requests directed at individual nuclear power plants.

Written statements prepared according to the preceding requirements to justify information requests are not regulatory analyses within the scope of this guidance. Nevertheless, the written justification will have many of the elements of a regulatory analysis. The elements of a regulatory analysis discussed in Section 2.5 of this guidance can appropriately be included in an information request justification. An information request justification will normally be a more concise document than a regulatory analysis.

3. BACKFITTING AND ISSUE FINALITY

3.1 General

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

Backfitting is defined in 10 CFR 50.109 as the modification of or addition to SSCs, or the design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in Commission rules or the imposition of a regulatory staff position that is either new or different from a previously applicable staff position *and* effective after specific dates described in the backfit rule. For selected nuclear materials facilities, the backfitting definitions in 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 are slightly different⁴.

The term "backfit" is not normally used in discussions relevant to new power reactors; the concept of "issue finality" is used rather than "backfit." In this guidance, the NRC uses the terms "backfit" and "backfitting" to mean backfits as defined in 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76 and issue finality matters under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

3.2 Relationship of Regulatory Analysis to Backfitting

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

The regulatory analysis should account for the costs and averted costs of the type discussed in NUREG-1409, Backfitting Guidelines. The analyst should document the following factors in the regulatory analysis to support the preparation of the backfit analysis:

- a statement of the specific objective that the proposed backfit is designed to achieve
- a general description of the activity that would be required by the licensee or applicant to complete the backfit
- the potential for change in the risk to the public from the accidental offsite release of radioactive material
- the potential impact of radiological exposure to facility employees
- the installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay (i.e., resource burden on licensees)

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

- the potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements
- the estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources
- the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit
- a statement as to whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis

The backfit rule requires the NRC to consider the costs for improving public health and safety, which include facility downtime or construction delay as costs associated with the backfit.

Averted onsite costs can arise when it is estimated that the backfit will save money for licensees, such as by reducing forced outage rates. These savings are not treated as a benefit (safety enhancement). They are, however, considered as a negative cost, that is, an offset against other licensee costs. Averted offsite costs can result from an estimated decrease in accident frequency or severity. These reduce enhancement.

The backfit rule establishes a more difficult standard than the cost beneficial standard used in regulatory analysis. For backfitting, the analyst should first show that there is a substantial increase in the overall protection of public health and safety or the common defense and security to be derived from the backfit and then if that step is met, that “the direct and indirect costs of implementation for that facility are *justified* in view of this increased protection” (emphasis added) (Ref. 18). Qualitative factors can be considered (see Appendix A). Many of the factors to be addressed in the analysis may not be easily quantified, and the backfit rule permits consideration of other relevant and material factors including qualitative factors.

For generic backfits, the CRGR Charter provides guidance on what cost and benefit information is needed in the backfit analyses for CRGR review. One way of meeting these requirements is for the analyst to address each backfit analysis factor (which is specifically listed in the CRGR Charter) in the regulatory analyses. An example of this approach is provided in NUREG-1409.

4. NATIONAL ENVIRONMENTAL POLICY ACT

4.1 General

As previously discussed in Section 1.2.3, NEPA requires Federal agencies to prepare a detailed statement for major Federal actions significantly affecting the quality of the human environment (Ref. 27). This statement is defined by NRC regulations as an EIS (Ref. 28). A “major Federal action” is defined by the Council on Environmental Quality as an “action with effects that may be major and which are potentially subject to Federal control and responsibility” (Ref. 53). Many NRC licensing and regulatory actions meet this definition. NRC regulations implementing NEPA are in 10 CFR Part 51. The “essential purpose” of the Act is to ensure that the environmental effects of agency actions are considered along with other factors during the agency’s regulatory decisionmaking process (Ref. 30).

In some cases, EISs have been prepared to avoid duplicating the environmental reviews for similar licensing actions and allow reviewers to focus specifically on those environmental issues that are important to a specific regulatory action. The NRC calls these EISs generic environmental impact statements (GEIS). Site-specific environmental issues are then considered in a supplement to the GEIS, known as a supplemental EIS (SEIS). Operating reactor license renewal, reactor decommissioning, and in-situ recovery projects use the GEIS/SEIS model.

When a GEIS has been prepared that forms the basis for a proposed regulatory action, a brief summary of the EIS will be an acceptable substitute for the information and analysis requirements identified in Sections 2.3.1–2.3.3 of this guidance. The EIS may be referenced at other appropriate points in the regulatory analysis to avoid duplicating existing written material. When a regulatory analysis and an EIS or EA are being prepared for a proposed regulatory action, preparation of the two documents should be coordinated as much as possible. For example, the alternatives examined in the regulatory analysis should correspond as much as possible to the alternatives examined in the EIS or EA.

4.2 Cost-Benefit Analyses in 10 CFR Part 51

Under 10 CFR 51.71(d), the NRC staff is required, unless excepted in 10 CFR 51.71, “Draft Environmental Impact Statement,” or 10 CFR 51.75, “Draft Environmental Impact Statement—Construction Permit, Early Site Permit, or Combined License,” to include in the draft EIS a preliminary analysis that considers the economic, technical, and other benefits and costs of the proposed action and alternatives (Ref. 28). The following sections describe how cost-benefit analyses are conducted in NEPA reviews for NRC reactor and materials licensing actions.

4.2.1 Requirements

By regulation, applicants for NRC licenses are required to include the consideration of the economic, technical, and other benefits and costs of the proposed action and its alternatives in environmental reports (ERs). NRC regulation 10 CFR 51.45(c) states, “Except for an environmental report prepared at the early site permit stage, or an environmental report prepared at the license renewal stage under 10 CFR 51.53(c), the analysis in the environmental report should also include consideration of the economic, technical, and other benefits and costs of the proposed action and its alternatives. ERs prepared at the license renewal stage under 10 CFR 51.53(c) need not discuss the economic or technical benefits and costs of either

the proposed action or alternatives, except if these benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or relevant to mitigation” (Ref. 28).

This regulatory requirement does not apply to ERs prepared at the license renewal stage under 10 CFR 51.53(c), unless benefits and costs are either essential for a determination regarding the inclusion of an alternative in the range of alternatives considered or are relevant to mitigation (10 CFR 51.71(d)). For ESPs under 10 CFR Part 52, the draft EIS must not include an assessment of the economic, technical, or other benefits (for example, need for power) and costs of the proposed action or an evaluation of alternative energy sources, unless these matters are addressed in the ESP ER (10 CFR 51.75(b)). When cost-benefit analyses are required, they will, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, those considerations or factors will be discussed in qualitative terms. Environmental standard review plans (ESRPs) in NUREG-1555 provide guidance to the staff on the identification and tabulation of costs and benefits resulting from construction and operation of new nuclear power plants (see ESRP Chapter 10.4, “Benefit-Cost Balance,” and ESRP Chapters 10.4.1 and 10.4.2).

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

4.2.2 Costs and Benefits for the Proposed Action and Each Alternative

The discussion of costs and benefits will include both the costs of each alternative and a qualitative discussion of environmental impacts. Assumptions and uncertainties in the analyses should be provided and discussed.

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

- qualitative discussion of environmental enhancement or degradation (including air, water, soil, and biotic, as well as socioeconomic factors such as noise, traffic congestion, overuse of public works and facilities, and land access restrictions)
- changes to public health and safety
- capital costs or benefits of the proposed action and alternatives, including land and facilities

- operating and maintenance costs
- post-operation restoration (not applicable when the alternative is restoration)
- post-operation monitoring requirements
- other costs or benefits of the alternative (e.g., changes to tax revenue, recreational value, and impacts to transportation corridors, as appropriate)
- incremental changes in regional productivity
- changes to recreational values
- other costs or benefits

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

Qualitative environmental costs and benefits can be compared to the discussion of environmental impacts within the environmental report. Standard project costs can be reviewed using standard cost-estimating databases. Socioeconomic costs and benefits can be reviewed and compared against similar projects, as applicable. The reviewer should also verify that analyses were performed in accordance with appropriate cost-benefit guidance. Future costs and benefits should be discounted to present worth, as discussed in “Economic Analysis of Federal Regulations under Executive Order 12866.” The methods used for discounting should be explained and applied consistently to both costs and benefits. NUREG-1727, “NMSS Decommissioning Standard Review Plan,” provides guidance on determining costs and benefits for decommissioning projects, as well as providing guidance on determining what is deemed as low as reasonably achievable (ALARA) and prohibitive costs related to ALARA. The cost-benefit analysis provides input to determine the relative merits of various alternatives; however, the NRC should ultimately base its decision on public health and safety issues.

4.3 Environmental Justice

The Commission’s “Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions” (69 FR 52040; August 24, 2004), confirmed that NEPA is the legal basis for NRC’s analysis of environmental justice matters, including impacts of a proposed licensing or regulatory action on minority or low-income communities. The NRC supports the general goals of Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,” and the NRC will meet these goals through the normal and traditional NEPA review process.

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

- Office of Nuclear Reactor Regulation (NRR) Office Instruction LIC-203, Revision 3, "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues," dated "July 1, 2013
- NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," dated August 22, 2003
- "Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan" (NUREG-1555) dated October 1999
- "Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal" (NUREG-1555, Supplement 1, Revision 1) dated June 2013. (Refer to the NRC Regulations Handbook, NUREG/BR-0053, Rev. 6, issued September 2005).

4.4 Public and Occupational Health Impact Analyses

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

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

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

- major sources and levels of background radiation exposure, including natural and man-made sources; express levels in millisieverts/yr (mrem/yr)
- current sources and levels of exposure to radioactive materials
- major sources and levels of chemical exposure; express levels in appropriate units
- historical exposures to radioactive materials
- occupational injury rates and occupational fatality rates
- summary of health effects studies

4.4.1 Reactors – SAMA/SAMDA Analyses

Severe nuclear accidents are those that could result in substantial damage to the reactor core, whether or not there are serious offsite consequences. In the license renewal GEIS and in COL EISs, the staff assesses the impacts of severe accidents, using the results of existing analyses and site specific information to conservatively predict the environmental impacts of severe

accidents for each nuclear power plant. In addition, an evaluation of SAMA for the plant is required. Severe accident mitigation design alternatives (SAMDA) are a subset of the SAMA review. The purpose of the evaluation of SAMA is to determine whether there are SAMDAs or procedural modifications or training activities that can be justified to further reduce the risks of severe accidents.

4.4.1.1 Severe Accident Mitigation Alternatives

In accordance with 10 CFR 51.53(c)(3)(ii)(L), license renewal applicants are to consider alternatives to mitigate severe accidents if the staff has not previously evaluated SAMA for the applicant's plant in an EIS or related supplement or in an EA. The purpose of this consideration is to ensure that changes at nuclear power plants before and during the license renewal term (e.g., hardware, procedures, and training) with the potential for improving the severe accident safety performance are identified and evaluated. Section 4.4.1.2 discusses the use of SAMA for new reactor applications.

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

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

The NRC staff reviews the SAMA analysis prepared by the applicant and determines whether the methods used and the implementation of those methods follow the guidance of Nuclear Energy Institute (NEI) 05-01.

4.4.1.2 Severe Accident Mitigation Design Alternatives

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

In an ER submitted as part of a DC application, an applicant identifies candidate SAMDA based on a review of alternatives for other plant designs, including those considered in license renewal ERs, and on consideration of facility-specific enhancements. The alternatives are then screened to identify candidates for detailed evaluation.

After screening, the DC applicant calculates the maximum attainable benefit associated with completely eliminating all risk for the design under review. This methodology involves determining the net value for a SAMDA according to the following formula:

$$\text{Net Value} = (\text{APE} + \text{AOC} + \text{AOE} + \text{AOSC}) - \text{COE}$$

where:

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

If the net value of a SAMDA is negative, the cost of implementing the SAMDA is larger than the benefit associated with the SAMDA, and it is not considered to be cost beneficial. To assess the risk reduction potential for SAMDAs, the applicant assumes that each design alternative would work perfectly to completely eliminate all severe accident risk from the events that are evaluated. This assumption is conservative, because it maximizes the benefit of each design alternative. The applicant estimates the public exposure benefits for the design alternative on the basis of the reduction of risk expressed in terms of whole body person-rem per year received by the total population within a 50-mile radius of the generic reactor site.

In 10 CFR 52.47(a)(27), the NRC requires that an applicant for a DC perform either a facility-specific or site-specific PRA. The aim of this PRA is to seek improvements in the reliability of core and containment heat removal systems that are significant and practicable. The set of potential design improvements considered for the proposed DC includes those from generic, technology-appropriate, reactor SAMA reports.

The NRC staff evaluates the risk reduction potential of design improvements for proposed designs based on risk-reduction estimates for screened design alternatives, in conjunction with an assessment of the potential impact of uncertainties on the results. The NRC staff performs averted cost estimates using two sets of parameters (best estimate and high estimate) when calculating the occupational dose after an accident and during decontamination and cleanup,

and for the replacement power costs. The NRC staff's maximum estimate is based on the use of "high or upper bound" estimated parameters and the proposed design's power rating.

4.4.2 Materials

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

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

The analyst should identify the list of reasonably foreseeable (i.e., credible) accidents, which have the potential for releases to the environment and analyze the dose consequences from these accidents. For example, design-basis events for licenses under 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste;" and credible consequence events for licenses under 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

5. DETAILS OF A COST-BENEFIT ANALYSIS

5.1 General

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

A cost-benefit analysis can do the following:

- help the analyst and decisionmaker define the problem
- provide a logical structure for the combination of issues contributing to a decision
- describe beneficial and detrimental aspects of a decision
- provide a record of the decision rationale to provide documentation, defensibility, and reproducibility
- focus discussions on the specific issues of contention to assist in resolution
- provide a framework for the sensitivity testing of data and assumptions
- consider all factors affecting an issue
- clarify results in the face of closely valued alternatives and large uncertainties

5.1.1 Methods

As stated earlier, the regulatory analysis process is comprised of six steps. These steps are as follows:

- (1) a statement of the problem and NRC objectives for the proposed regulatory action
- (2) identification and preliminary analysis of alternative approaches to address the problem
- (3) estimation and evaluation of the costs and benefits for selected alternatives, including consideration of the uncertainties affecting the estimates
- (4) the conclusion of the evaluation of costs and benefits and, when appropriate, the safety-goal evaluation
- (5) the decision rationale for selecting the proposed regulatory action
- (6) a tentative implementation schedule and implementation instrument for the proposed regulatory action

The cost-benefit portion of a regulatory analysis encompasses the third and fourth steps of the process. Cost-benefit analysis identifies and estimates the relevant costs and benefits likely to

result from a proposed NRC action. The methodology is a systematic definition and evaluation of those costs and benefits.

Attributes are the principal components of a cost-benefit assessment that are used to characterize the consequences of a proposed 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 costs or benefits, can have either positive or negative algebraic signs, depending on whether the proposed action has a favorable or adverse effect. The sign conventions are as follows: favorable results are positive; adverse results are negative. Each attribute measures the change from the existing condition due to the proposed action. Attributes are discussed in detail in Sections 5.2 and 5.3.

To the extent possible, all attributes, whether a cost or benefit, are quantified in monetary terms and added together to obtain the net value in dollars. The net value calculation is generally favored over other measures, such as a cost-benefit ratio or an internal rate of return.

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

Significant differences may exist between the recipients of benefits and those who incur costs. The distribution of costs and benefits on various groups should be presented and discussed.

To calculate a net value, all attributes should be expressed in dollars. For instance, person-rem of averted exposure, a measure of safety value, is converted to dollars using a dollar per person-rem conversion factor.

5.1.2 Attribute Considerations for Materials Licensees

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

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

The quantification of these attributes may involve both frequencies and population doses associated with accident scenarios. Nonreactor facilities tend to be much simpler in system configuration than power reactors, and the potential consequences to the public from accidents compared to power reactors is much smaller. This simplifies the scope of the accident analysis and accident frequency and population dose data; however, there are fewer data available than for power reactors. See Appendix H for additional guidance.

5.2 Identification of Attributes

For every cost-benefit analysis to be performed, those attributes that could be affected by the proposed action should be identified. Once identified, the attributes may be quantified using the techniques presented in Appendix B.

5.2.1 Public Health (Accident)

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

In most cases, the effect of the proposed action would be on public exposure. A decrease in public exposure (given in person-rem) 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-rem) assumes a negative sign. When this increase is multiplied by the monetary conversion factor (\$/person-rem), the resulting monetary term is interpreted as negative.

5.2.2 Public Health (Routine)

This attribute accounts for changes in radiation exposures to the public during normal facility operations (i.e., nonaccident situations). It is expected that this attribute would not be affected as often in reactor regulatory analyses as in nonreactor 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.

5.2.3 Occupational Health (Accident)

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

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

5.2.4 Occupational Health (Routine)

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

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

5.2.5 Economic Consequences (Offsite Property)

This attribute measures the expected total monetary effects on offsite property resulting from the proposed action. Changes to economic consequences 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 economic consequences is taken as positive; an increase in economic consequences is considered negative.

5.2.6 Onsite Property

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

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

5.2.7 Industry Implementation

This attribute is an impact that 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. Additional costs above the status quo are considered negative; cost savings would be considered positive.

5.2.8 Industry Operation

This attribute measures the projected net economic effect due to routine and recurring activities required by the proposed action on all affected licensees. If applicable, 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.

5.2.9 NRC Implementation

This attribute measures the projected net economic effect on the NRC to place the proposed action into operation. Costs already incurred, including all predecisional 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.

5.2.10 NRC Operation

This attribute measures the projected net economic effect on the NRC after the proposed action is implemented. Additional inspection, evaluation, or enforcement activities would be examples of such costs. 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.

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.

5.2.11 Other Government Entities

This attribute measures the net economic effect of the proposed action on the Federal Government (other than the NRC) and State and local governments resulting from the action’s implementation or operation. Additional costs above the status quo are taken to be negative; cost savings are taken to be positive.

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.

5.2.12 General Public

This attribute accounts for direct, out-of-pocket costs paid by members of the general public as a result of implementation or operation of a proposed action. Examples of these costs could include items such as increased cleaning costs 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 economic consequences 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 that are reimbursed by the applicant or licensee should be accounted for here and not duplicated under industry costs.

5.2.13 Improvements in Knowledge

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

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

5.2.14 Regulatory Efficiency

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

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

5.2.15 Safeguards and Security Considerations

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

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

5.2.16 Environmental Considerations

NEPA Section 102(2) requires Federal agencies to take various steps to enhance environmental decisionmaking. NRC's procedures for implementing NEPA are set forth in 10 CFR Part 51. Many of the NRC's regulatory actions are handled through the use of a generic or programmatic EIS, EA, or categorical exclusion. If these processes are used, no further cost-benefit analysis is necessary, because such analyses are part of the NEPA process. However, a summary of the salient results of the environmental analysis should be included in the regulatory analysis document. NEPA reviews are handled separately from the cost-benefit analysis described in this guidance. It could be the case that mitigation or other measures resulting from the environmental review may result in cost increases that should be accounted for in the cost-benefit analysis. Alternatives examined in an EIS or EA should correspond as closely as possible to the alternatives examined in the corresponding cost-benefit analysis.

5.2.17 Other Considerations

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

5.3 Quantification of Attributes

The following sections provide specific guidance in estimating the values of each attribute. However, before looking at specific attributes, there are several generic concepts that need to be explored.

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

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

5.3.1 Treatment of Industry Initiatives

Industry initiatives are typically actions performed by licensees that either form the bases for continued compliance with the regulations or obviate the need for new regulations. Industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, without compromising facility safety or reducing the NRC's commitment to safety and sound regulation.

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

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

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

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

- costs associated with the industry initiative (i.e., if the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal, it is more likely the industry initiative will continue in the future)
- the extent to which written commitments exist (i.e., if written commitments exist, it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative)

- the degree to which the industry initiative is noncontroversial and standard industry practice (i.e., if the industry initiative is noncontroversial and standard industry practice, as a function of consistency with provisions of industry codes and standards, the participation rate among relevant licensees, the length of time the program has been operating, or its effectiveness, the more likely it will continue without the rule change)
- the scope and schedule for industry initiatives that are still pending (i.e., for industry initiatives that are still works in progress, the more well defined the scope and the sooner the initiative is expected to be in place, the more likely it will be available in the future)

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

Ordinarily, voluntary actions are not included in the cost estimate for backfit analyses. The backfit rule applies to actions that impose positions or requirements on licensees; it does not apply to requested actions that are optional or voluntary. The term "voluntary" as it applies to "voluntary actions" or "voluntary relaxations" is distinct from "mandatory actions" or "mandatory relaxations." The concept of "voluntary action" versus "mandatory action" is best illustrated in the following example.

Consider a situation where the regulation or guidance provides a new alternative that may be voluntarily adopted by the licensee or an extension of what was previously addressed in the regulation, such as the Risk-Informed Treatment Rule in 10 CFR 50.69 or the Thermal Annealing Rule in 10 CFR 50.66. These two rule changes are voluntary relaxations in which the licensee could continue to comply with its current design procedures or practices and still be in compliance with the new, relaxed requirement. In contrast, if the licensee should change its design, procedures, or practices to be in compliance with a new relaxed requirement, then the new requirement would be a "mandatory relaxation" and would be considered in the estimated costs for the regulatory change.

5.3.2 Attributes Valuation

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

Based on OMB's guidance in Circular A-94, a 7-percent real (i.e., inflation adjusted) discount rate should be used for a best estimate. For sensitivity analysis, a 3-percent discount rate should be used. However, for certain regulatory actions involving a timeframe exceeding 100 years (e.g., decommissioning and waste disposal issues), OMB Circular A-94 stipulates the following:

The regulatory analysis should display results to the decision-maker in two ways. First, on a present worth basis using a 3 percent real rate, and second, by displaying the cost and benefits at the time in which they are incurred with no present worth conversion. In this latter case, no calculation of the resulting net value should be made.

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

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

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

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

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

To estimate values for the accident-related attributes in a regulatory analysis, the analyst can draw from detailed risk/reliability assessments or statistically based analyses.

However, the analyst will sometimes find limited factual data or information sufficiently applicable only for providing a quantitative perspective, possibly requiring extrapolation. These may often involve nonreactor licensees, because detailed risk assessments, reliability assessments, or statistically based analyses are less common than for power reactor licensees. Two examples illustrate this type of quantitative evaluation.

In 1992, the NRC performed a regulatory analysis for the adoption of a proposed rule (57 FR 56287; November 27, 1992) concerning air gaps to avert radiation exposure resulting from NRC-licensed users of industrial gauges. The NRC found insufficient data to determine the averted radiation exposure. To estimate the reduction in radiation exposure should the rule be adopted, the NRC assumed a source strength of one curie for a device with a large air gap, which produces 1.3 rem per hour at a distance of 20 inches from a cesium (Cs)-137 source. Assuming half this dose rate would be produced, on average, in the air gap, and that a worker is within the air gap for 4 hours annually, the NRC estimated the worker would receive 2.6 rem per year. The NRC estimated that adopting the proposed air-gap rule would be cost effective if 347 person-rem per year were saved. At the estimated average savings of 2.6 person-rem per year for each gauge licensee, incidents involving at least 133 gauges would have to be eliminated. Given the roughly 3,000 gauges currently used by these licensees, the proposed rule would only have to reduce the incident rate by roughly 4 percent, a value the NRC believed to be easily achievable. As a result, the NRC staff recommended adoption of the air gap rule.

In 1992, the NRC responded to a petition from General Electric (GE) and Westinghouse for a rulemaking to allow self-guarantee as an additional means for compliance with decommissioning regulations. An NRC contractor estimated the default risks of various types of financial assurance mechanisms, including the proposed self-guarantee. The contractor had to collect data on failure rates of firms of different sizes and of banks, savings and loans, and other suppliers of financial assurance mechanisms. The contractor estimated a default risk of 0.13 percent annually for the GE-Westinghouse proposal, with a maximum default risk of only 0.055 percent annually for third-party guarantors; specifically, a small savings and loan issuing a letter of credit. Based on these findings, the NRC initiated a proposed rulemaking that would allow self-guarantee for certain licensees. The final rule was issued December 29, 1993 (58 FR 68726).

5.3.2.1 Public Health (Accident)

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

- (1) Estimate the reduction in accident frequency per facility (see Appendix H).
- (2) Estimate the reduction in public health (accident) risk per facility.
- (3) Convert the value of public health (accident) risk avoided (person-rem) per facility to the monetary equivalent (dollars) via the monetary valuation of health effects.

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

where Z_{PHA} = monetary value of public health (accident) risk avoided per facility-year before discounting (\$/facility-year)
 D_{PA} = avoided public dose per facility-year (person-rem/facility-year)

R = monetary equivalent of unit dose (\$/person-rem)

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

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

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

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

If individual facility values rather than generic values are used, the formulations can be replaced with

$$V_{PHA} = \sum_i N_i W_{PHAi}$$

where i = facility (or group of facilities) index.

5.3.2.1.1 Estimation of Accident-Related Health Effects

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

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

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

Tables 5-1 and 5-2 provide screening information from NUREG-1150 that can be used for performing standard analyses.

Table 5-1 Expected Population Doses for Power Reactor Release Categories

Plant Type	Release Category	Accident Progression Characteristics						Population Dose	
		CF Time	PDS	SP Bypass	RB Bypass	CCI	CF Mode	Total (Person-Rem)	% Long Term
PWR	RSUR1	CFatVB	LOSP	Not Applicable		Dry	Rupture	6.15 x 10 ⁶	63
	RSUR2	Late CF					Leak	2.30 x 10 ⁶	88
	RSUR3	No CF					No CF	2.50 x 10 ²	67

Plant Type	Release Category	Accident Progression Characteristics						Population Dose	
		CF Time	PDS	SP Bypass	RB Bypass	CCI	CF Mode	Total (Person-Rem)	% Long Term
	RSUR4	Bypass	Bypass				Bypass	4.29 x 10 ⁶	80
	RZ1	CFatVB	LOCA			Shallow	Rupture	5.77 x 10 ⁶	65
	RZ2	Late CF				Flooded	Leak	1.31 x 10 ⁵	38
	RZ3	No CF					No CF	3.31 x 10 ²	67
	RZ4	Bypass	Bypass			Dry	Bypass	4.80 x 10 ⁶	76
	RSEQ1	CFdurCD	LOSP			Dry	CatRup	1.31 x 10 ⁷	50
	RSEQ2	CFatVB						5.77 x 10 ⁶	56
	RSEQ3	Late CF	LOCA			Flooded	Rupture	1.33 x 10 ⁵	42
	RSEQ4	No CF					No CF	4.06 x 10 ²	71
	RSEQ5	Bypass	Bypass			Dry	Bypass	4.94 x 10 ⁶	76
BWR	RPB1	CFatVB	LOSP	Early/Late	Sm/None	Dry	DWMth	5.25 x 10 ⁶	80
	RPB2		ATWS					5.32 x 10 ⁶	
	RPB3	CFdurCD		None	Large		WWvent	3.26 x 10 ⁶	84
	RPB4	Late CF		LOSP			Early/Late		DWRup
	RPB5	No CF	None		Sm/None	Shallow	No CF	8.27 x 10 ³	62
	RPB6	CFatVB	Early/Late		Large	Dry	DWMth	1.11 x 10 ⁷	
	RLAS1	CFdurCD	Tran	Early/Late	Sm/None	Dry	WWawrup	5.25 x 10 ⁶	80
	RLAS2	CFatVB				Shallow	WWaw-lk	3.21 x 10 ⁶	81
	RLAS3						DWRup	4.66 x 10 ⁶	82
	RLAS4	CFdurCD			Sm/None	Dry	WWvent	5.92 x 10 ⁶	73
	RLAS5	Late CF				Shallow		1.75 x 10 ⁶	82
	RLAS6				Large	Dry	CF-Ped	4.18 x 10 ⁶	73
	RLAS7	No CF		None	None	Shallow	No CF	3.33 x 10 ²	65
	RGG1	CFatVB	STSB	Early/Late	Early/Late	Flooded	Rupture	5.77 x 10 ⁶	75
	RGG2	CFdurCD		None	None			2.74 x 10 ⁶	90
	RGG3	Late CF		Late Only	Late Only			2.35 x 10 ⁶	80
	RGG4	CFdurCD		Early/Late	Early/Late	2.70 x 10 ⁶		93	
	RGG5	No CF		None	None	No CCI	No CF	1.18 x 10 ²	59

Note: The initials RSUR, RZ, and RSEQ refer to Surry, Zion, and Sequoyah release categories respectively, followed by the release category number.

The initials RPB, RLAS, and RGG refer to Peach Bottom, LaSalle, and Grand Gulf release categories respectively, followed by the release category number.

Key:

CF Time	=	containment failure (CF time)
CFatVB	=	CF at vessel breach (VB)
CFdurCD	=	CF during core damage (before VB, if it occurs)
LateCF	=	CF during core concentration interactions (CCI)
No CF	=	no CF
Bypass	=	bypass of containment (usually throughout duration of accident)
PDS	=	plant damage state (PDS)
LOSP	=	loss of offsite power

Plant Type	Release Category	Accident Progression Characteristics						Population Dose	
		CF Time	PDS	SP Bypass	RB Bypass	CCI	CF Mode	Total (Person-Rem)	% Long Term
	LOCA	=	loss-of-coolant accident						
	Bypass	=	bypass of containment (interfacing systems LOCA or steam generator tube rupture)						
	ATWS	=	anticipated transient without scram						
	Tran	=	transient						
	STSB	=	short-term station blackout						
	CCI	=	type of molten core-concrete interactions (CCI)						
	Dry	=	CCI occurs in a dry cavity						
	Shallow	=	CCI occurs in a wet cavity (nominally 5 ft. of water)						
	Flooded	=	CCI occurs in a deeply flooded cavity (nominally 14 ft. of water)						
	No CCI	=	there is no CCI (the debris is coolable with replenishable water or no VB)						
	CF Mode	=	containment failure mode						
	CatRup	=	catastrophic rupture failure						
	Rupture	=	rupture failure of containment						
	Bypass	=	bypass of containment						
	Leak	=	leak failure of containment						
	NoCF	=	no CF						
	WWawrup	=	rupture above the wetwell water level						
	WWaw-lk	=	leak above the wetwell water level						
	DWRup	=	rupture in the drywell						
	WWvent	=	venting of the wetwell						
	CF-Ped	=	rupture in the drywell wall, caused by late failure of the reactor pedestal						
	DWMth	=	melt-through of the drywell wall by direct contact of the molten core						
	SP Bypass	=	suppression pool (SP) bypass						
	Early/Late	=	SP is bypassed from the time of VB throughout the accident						
	None	=	SP is never bypassed						
	Late Only	=	SP is only bypassed late in the accident (during CCI)						
	RB Bypass	=	reactor building (RB) bypass						
	Sm/None	=	nominal or small leakage from the RB						
	Large	=	large leakage from the RB or bypass of the RB (for Grand Gulf, all containment failures were assumed to be above the RB)						

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

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

Mubayi et al. (1995) have calculated population doses weighted by the frequencies of the accident-release categories for the five power reactors analyzed in NUREG-1150. These are

listed in Table 5.4, based on Version 1.5.11.1 of the MELCOR Accident Consequence Code System (MACCS) computer code (Chanin et al., 1993). The population doses have been calculated as the sum of those for emergency response and long-term protective action, defined as follows:

- For early consequences, an effective emergency response plan consisted of evacuation of all but 0.5 percent of the population within a 10-mile radius at a specified speed and delay time following notification of the emergency.
- For long-term relocation and banning of agricultural products, the interdiction criterion was 4 rem to an individual over 5 years (2 rem in year one, followed by 0.5 rem each successive year).

For regulatory analyses involving nuclear power plants, doses should be estimated over a 50-mile radius from the site (see Section 5.2.1). Doses for other distances can be considered in sensitivity analyses or special cases and are available in NUREG/CR-6349. Alternatively, the analysis can be conducted for individual facilities or groups of similar facilities, using site-specific information and cost information modeled in much greater detail.

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

$$\begin{aligned} \text{Avoided Public Dose} = & \sum_{\text{Release Categories}} [\text{Release Category Frequency} \times \text{Category Population Dose Factor}]_{\text{Status Quo}} \\ & - \sum_{\text{Release Categories}} [\text{Release Category Frequency} \times \text{Category Population Dose Factor}]_{\text{After Action}} \end{aligned}$$

or

$$\begin{aligned} \text{Avoided Public Dose} = & [\text{Accident Frequency} \times \text{Population Dose Factor}]_{\text{Status Quo}} \\ & - [\text{Accident Frequency} \times \text{Population Dose Factor}]_{\text{After Action}} \end{aligned}$$

Table 5-2 Weighted Population Dose Factors for the Five NUREG-1150 Power Reactors

Reactor	Type	Person-rem within 50 miles of the Plant
Zion	PWR	1.95x10 ⁵
Surry	PWR	1.60 x10 ⁵
Sequoyah	PWR	2.46 x10 ⁵
Peach Bottom	BWR	2.00 x10 ⁶
Grand Gulf	BWR	1.93 x10 ⁵
Average		1.99 x10 ⁵

In parallel with the more involved effort to identify and quantify affected parameters in appropriate accident sequences would be an equivalent effort to quantify population dose factors and possibly even specific health effects. Such effort at the consequence end of the risk calculation would increase the likelihood of obtaining representative results. Nonrepresentative results can arise through the use of inappropriate or inapplicable dose calculations just as readily as through inappropriate logic models and failure data.

Several computer codes exist for estimating population dose. Most for reactor applications have been combined under MACCS (Ref. 71 and Ref. 72). Three codes for nonreactor applications are GENII (Napier, 2012), CAP-88 PC (Rosnick, 2013), and COMPLY (EPA, 1989). There have also been upgrades to MELCOR for modeling severe accidents in light-water reactors (LWRs), including an estimation of severe accident source terms and their sensitivities or uncertainties (Ref. 76).

The GENII code package determines individual and population radiation doses on an annual basis, as dose commitments, and as accumulated from acute or chronic radionuclide releases to air or water. It has an additional capability to predict very-long-term doses from waste management operations for periods up to 10,000 years.

The CAP-88-PC code package is used at the U.S. Department of Energy (DOE) facilities to demonstrate compliance with radionuclide air emission standards, where the maximally exposed offsite individual is more than 3 kilometers (km) from the source (40 CFR 61.93(a)). The code contains modules to estimate dose and risk to individuals and populations from radionuclides released to the air. It comes with a library of radionuclide-specific data and provides the most flexibility of the U.S. Environmental Protection Agency (EPA) air compliance codes in terms of ability to input site-specific data.

The COMPLY code is a screening model intended primarily for use by NRC licensees and Federal agencies other than DOE facilities. It is approved for use by DOE facilities where the maximally exposed offsite individual is less than 3 km from the emissions source (Ref. 77). The code consists of four screening levels, each of which requires increasingly detailed site-specific data to produce a more realistic (and less conservative) dose estimate. COMPLY runs on a personal computer and does not require extensive site-specific data.

5.3.2.1.2 Monetary Valuation of Accident-Related Health Effects

Mortality Effects

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

Morbidity Effects

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

Non-fatal health effects risk valuation differs from that of mortality risk valuation in that the values depend on the type of illness, each with its own unique severity, duration, and effect on quality of life. As with VSL estimates, willingness-to-pay (WTP) to reduce the risk of experiencing an illness is the theoretically preferred approach to valuing morbidity effects. From WTP estimates, the value of statistical illness (VSI) for cancer could be derived and combined with the non-fatal portion of the total cancer risk coefficient (i.e. cancer incidence minus fatality) to provide a comparable dollar per person-rem value for morbidity. However, many of the illnesses of concern have been the subject of few or no valuation studies and therefore lack existing WTP and VSI estimates (Ref. 78). Some methods that may be used to estimate these values include cost-of-illness (COI), averting behavior, and contingent valuation.

There are several other methods to value morbidity that do not estimate WTP, but may be used to inform the analysis, such as risk-risk tradeoffs and health-state indexes. One such method, the quality-adjusted life-year (QALY), is a measure of the value of health outcomes that considers both life years saved with the quality of the life years when a person experiences disease. It is a type of health-state index most commonly applied in cost-effectiveness or cost-utility analyses to estimate the ratio between the cost of a health-related intervention and the benefit it produces in terms of the number of years lived and the quality of those years. An Institute of Medicine panel commissioned by the EPA with support from OMB discouraged the practice of monetizing QALYs because WTP and health-related quality of life indexes have been developed out of two differing, and not entirely compatible, frameworks (Ref. 79). As such, they should not be used for deriving monetary estimates for use in cost-benefit analyses, although there is evidence that components of these indices may still be useful in a benefit-transfer context (Ref. 80). Appendix K discusses these valuation methods in further detail.

Psychosocial Effects

Psychosocial health effects are defined as post-accident stress and potential long-term psychological consequences (e.g., mental anguish, depression, post-traumatic stress) provoked by an accident or by population evacuation and emergency phase relocation, the fear of contracting diseases, or general stress on a sector of a society or on the society as a whole. This psychosocial impact may depend on the perceived quality of the emergency response, competence of the authorities, or feelings of powerlessness. Psychosocial effects may require medical treatment and may cause direct and indirect (e.g. workdays lost) costs to the society. If

these effects are causally related to the accident and not included in another attribute, the analysis should consider these costs.

Following the Three Mile Island – Unit 2 (TMI-2) accident, psychosocial effects appear to have comprised the main health effect of the accident on the people living in the region of Three Mile Island (TMI) and on the workers at TMI. Mental stress (short-lived mental distress) resulting from the accident was found to be the primary effect, especially among those living within five miles of TMI and in families with preschool children or in families who left the area. Also, workers at TMI experienced more distress than workers at another plant studied for comparison purposes. This distress was higher among the nonsupervisory employees and continued in the months following the accident (Ref. 81). Even ten years after the 1979 TMI-2 accident, worries about personal and children's health were still elevated among residents who had lived within 10 miles of the plant prior to the accident (Ref. 82), despite the fact that radioactive releases from that accident were small. These effects were reported even though the TMI-2 accident caused no injuries, and numerous epidemiological studies conducted since 1981 have found no discernible direct health effects to the population in the vicinity of the plant.

Psychosocial effects were documented in populations affected by the 1986 Chernobyl accident. Danzer and Danzer (2014) analyzed a population sample consisting of adults who were not relocated out of the areas contaminated by the accident. They used survey and economic data to estimate the increase in national income that would be needed to compensate the affected population for the impact of the accident on life satisfaction. The International Atomic Energy Agency (IAEA) Chernobyl Forum (2016) concluded that many people were traumatized by the relocation, the breakdown in social contacts, fear, and anxiety about what health effects might result. As a result, affected people reported high levels of anxiety and stress-related symptoms and were more subject to unexplained physical symptoms and subjective poor health. Masunaga et al. (2014) found that even well-educated people born after the Chernobyl accident in areas that were only modestly contaminated had anxiety about their radiation exposures, which has affected their mental health.

The Fukushima Dai-ichi accident produced considerable psychosocial stresses within populations in the Fukushima Prefecture over the past four years, even in areas where radiation levels are deemed by regulators to be acceptable for habitation. A study found that radiation anxiety, insomnia, and alcohol misuse were significantly elevated three years after the accident (Ref. 86). Increased incidences of mental health problems and suicidal thoughts were also observed among residents forced to live in long-term shelters after the accident (Ref. 87). Complex psychosocial effects were also observed, including discordance within families over perceptions of radiation risk, between families over unequal compensatory treatments, and between evacuees and their host communities (Ref. 88). The National Academy of Science review of the Fukushima Dai-ichi accident also highlighted the psychosocial effects of the accident on society (Ref. 89).

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

5.3.2.1.3 Discounting Monetized Value of Accident-Related Health Effects

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

$$W_{PHA} = C \times Z_{PHA}$$

where W_{PHA} = monetary value of public health (accident) risk avoided per facility after discounting (\$/facility)
 $C = [\exp(-rt_i) - \exp(-rt_f)]/r$
 t_f = years remaining until end of facility life
 t_i = years before facility begins operating
 Z_{PHA} = monetary value of public health (accident) risk avoided per facility-year before discounting (\$/facility-year).

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

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

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

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

5.3.2.2 Public Health (Routine)

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

The steps are as follows:

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

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

$$G_{PRI} = RD_{PRI}$$

$$G_{PRO} = RD_{PRO}$$

where G_{PRI} = monetary value of per-facility reduction in routine public dose required to implement the proposed action, before discounting (\$/facility)

G_{PRO} = monetary value of annual per-facility reduction in routine public dose to operate following implementation of the proposed action, before discounting (\$/facility-year)

D_{PRI} = per-facility reduction in routine public dose required to implement the proposed action (person-rem/facility)

D_{PRO} = annual per-facility reduction in routine public dose to operate following implementation of the proposed action (person-rem/facility-year)

R = monetary equivalent of unit dose (\$/person-rem)

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

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

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

where V_{PHR} = discounted monetary value of reduction in public health (routine) risk for all affected facilities (\$)

H_{PRI} = monetary value of per-facility reduction in routine public dose required to implement the proposed action, after discounting (\$/facility)

H_{PRO} = monetary value of per-facility reduction in routine public dose to operate following implementation of the proposed action, after discounting (\$/facility)

N = number of affected facilities.

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

If individual facility values rather than generic values are used, the formulations can be replaced with

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

where i = facility (or group of facilities) index.

5.3.2.2.1 Estimation of Change in Routine Exposure

A proposed NRC action can affect routine public exposures in two ways. It may cause a one-time increase in routine dose due to implementation of the action (e.g., installing a retrofit). It may also cause a change (either an increase or a decrease) in the recurring routine exposures after the action is implemented. The equations included in this revision apply a discounting term to doses associated with both implementation and operational impacts. In practice, the implementation dose may be of such short duration that discounting is not necessary. Its inclusion here is in recognition that, in some cases, implementation may extend over a longer period than 1 year.

For the standard analysis, the analyst may attempt to make exposure estimates or obtain at least a sample of industry or community data for a validation of the estimates developed. Baker (1995) provides estimates of population and individual dose commitments for reported radionuclide releases from commercial power reactors operated during 1991. Tichler et al. (1995) have compiled and reported releases of radioactive materials in airborne and liquid effluents from commercial LWRs during 1993. Data on solid waste shipments are also included. This report is updated annually.

5.3.2.2.2 Monetary Valuation of Routine Exposure

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

5.3.2.3 Occupational Health (Accident)

Evaluating the effect on occupational health from a change in accident frequency due to proposed regulatory actions is a multistep process. Reduction in occupational risk is algebraically positive; increase is negative (viewed as a negative reduction).

The steps are as follows:

- (1) Estimate reduction in accident frequency per facility
- (2) Estimate reduction in occupational health (accident) risk per facility, due to the following:
 - “immediate” doses
 - long-term doses
- (3) Per facility, convert value of occupational health (accident) risk avoided (person-rem) to monetary equivalent (dollars) via monetary evaluation of health effects, due to the following (see Occupational Health (Accident)) (Ref. 64):
 - “immediate” doses $Z_{IO} = RY_{IO}$
 - long-term doses $Z_{LTO} = RY_{LTO}$

where Z_{IO} = monetary value of occupational health (accident) risk avoided per facility-year due to “immediate” doses, before discounting (\$/facility-year)

Z_{LTO} = monetary value of occupational health (accident) risk avoided per facility-year due to long-term doses, before discounting (\$/facility-year)

Y_{IO} = avoided occupational "immediate" dose per facility-year (person-rem/facility-year)

Y_{LTO} = avoided occupational long-term dose per facility-year (person-rem/facility-year)

R = monetary equivalent of unit dose (\$/person-rem).

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

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

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

where V_{OHA} = discounted monetary value of occupational health (accident) risk avoided for all affected facilities

W_{IO} = monetary value of occupational health (accident) risk avoided per facility due to "immediate" doses, after discounting (\$/facility)

W_{LTO} = monetary value of occupational health (accident) risk avoided per facility due to long-term doses, after discounting (\$/facility)

N = number of affected facilities.

If individual facility values rather than generic values are used, the formulations can be replaced with

$$V_{OHA} = \sum_i N (W_{IO_i} + W_{LTO_i})$$

where i = facility (or group of facilities) index.

5.3.2.4 Occupational Health (Routine)

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

The steps are as follows:

- (1) Estimate reductions in occupational health (routine) risk per facility for implementation (D_{OR1}) and operation (D_{ORO}).
- (2) Convert each reduction in occupational health (routine) risk per facility from person-rem to dollars via monetary evaluation of health effects:

$$G_{ORI} = RD_{ORI}$$

$$G_{ORO} = RD_{ORO}$$

where G_{ORI} = monetary value of per-facility reduction in routine occupational dose to implement the proposed action, before discounting (\$/facility)

G_{ORO} = monetary value of annual per-facility reduction in routine occupational dose to operate following implementation of the proposed action, before discounting (\$/facility-year)

D_{ORI} = per-facility reduction in routine occupational dose to implement the proposed action (person-rem/facility)

D_{ORO} = annual per-facility reduction in routine occupational dose to operate following implementation of the proposed action (person-rem/facility-year)

R = monetary equivalent of unit dose (\$/person-rem).

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

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

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

where V_{OHR} = discounted monetary value of reduction in occupational health (routine) risk for all affected facilities (\$)

H_{ORI} = monetary value of per-facility reduction in routine occupational dose required to implement the proposed action, after discounting (\$/facility)

H_{ORO} = monetary value of per-facility reduction in routine occupational dose to operate following implementation of the proposed action, after discounting (\$/facility)

N = number of affected facilities.

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

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

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

where i = facility (or group of facilities) index.

5.3.2.4.1 Estimation of Change in Routine Exposure

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

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

General estimates of radiation fields can be obtained from a number of sources. For power reactors, Chapter 12 of the FSAR for the plant will contain a partitioning of the power plant into estimated radiation zones. Both summary tables and plant layout drawings are usually provided. Some FSARs provide exposure estimates for specific operational activities. The analyst should be cautioned that the FSAR values are calculated, not measured. Actual data from operating facilities, as might be obtained from facility surveys, would have greater accuracy. Generic estimates of dose rates for work on specific PWR and BWR systems and components are provided by Beal et al. (1987). These are used by Sciacca in NUREG/CR-4627, "Generic Cost Estimates," along with labor hours and occupational exposure estimates for specific repair and modification activities.

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

- (1) height (i.e., work conducted at elevations such as on ladders or scaffolds) = 10 to 20 percent of basic time duration
- (2) respiratory protection = 25 to 50 percent of basic time duration
- (3) radiation protection = 10 to 40 percent of basic time duration
- (4) protective clothing = 30 percent of adjusted time duration
- (5) work breaks = 8.33 percent of total adjusted time duration.

Sciacca (1992) provides information from which to estimate relevant labor productivity factors, whose values can vary with the status of the plant and work environment at the time of the action.

Keeping these factors in mind, the analyst can proceed with the estimation of implementation and operational doses. The implementation dose would be:

$$D_{ORI} = -F_R \times W_I$$

where D_{ORI} = per-facility reduction in routine occupational dose required to implement the proposed action (person-rem/facility-year)

F_R = radiation field in area of activity (rem/hour)

W_I = work force required for implementation (labor-hours/facility).

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

The operational dose is the change from the current level; its formulation is:

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

where D_{ORO} = annual per-facility reduction in routine occupational dose to operate following implementation of the proposed action (person-rem/facility-year)

F_R = radiation field in area of activity (rem/hour)

W_O = work force required for activity (labor-hours/facility-activity)

A_F = number of activities (e.g., maintenance, tests, inspections) per year (activities/year)

S = status quo (current conditions)

A = after implementation of proposed action.

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

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

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

5.3.2.4.2. Monetary Valuation of Routine Exposure

Mortality Effects

The analyst should use the dollar per person-rem conversion factor discussed in Revision 1 of NUREG-1530 for the monetary valuation of the cancer mortality risk resulting from routine exposures to radiation.

Morbidity Effects

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

Psychosocial Effects

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

Public perceptions of nuclear power (aesthetic effects) were analyzed for the 1996 GEIS for the license renewal of nuclear plants (Ref. 40). The analysis consisted of seven case studies on the public perception of nuclear power, a survey of academic literature, and a review of newspaper and magazine articles. Based on the analysis, the NRC staff found that license renewal would not likely alter existing perceptions of nuclear power. It is well understood that some people perceive the use of nuclear power and nuclear material negatively. Most of these negative perceptions are based on environmental and safety concerns, fear of accidents and acts of terrorism, or an anti-nuclear orientation. Whatever the consideration, the NRC believes that for these people their lives have been affected by the presence of a nuclear power plant or some other nuclear facility.

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

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

5.3.2.4.3 Nonradiological Occupational Costs

In some cases, it will be possible to identify nonradiological occupational costs associated with a proposed action. When possible, these should be identified and included in the regulatory analysis. One source of data on the incidence of occupational injuries for various industries is the “Injuries, Illnesses, and Fatalities” program website maintained by the U.S. Department of

Labor's Bureau of Labor Statistics (BLS) (Ref. 95).

Occupational injury data should be converted to a dollar valuation. The value of an injury should include medical costs and the value of lost production (Regulatory Working Group 1996, Section 5). The value of lost production is normally estimated using employee wage rates. Pain and suffering costs attributable to occupational injury can be identified qualitatively but would not normally be quantified in dollar terms. Potential information sources for occupational injury valuation data are the National Center for Health Statistics (<http://www.cdc.gov/nchs/index.htm>) and the publication, "Injury Facts," published annually by the National Safety Council, based in Itaska, IL.

5.3.2.5 Offsite Property

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

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

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

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

It is possible that the proposed action mitigates the consequences of an accident instead of, or as well as, reducing the accident frequency. In that event, the value of the action is

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

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

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

The computer code MACCS has been developed to estimate power reactor accident consequences using currently available information. MACCS was employed for the consequence analyses in NUREG-1150.

Cost values within 50 miles are to be used in the regulatory analysis: Alternative values reflecting shorter and longer distances from the plan may be used for sensitivity analyses or special cases.

The present value for offsite property damage can be calculated as

$$D = C \times B$$

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

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

$$C = [1 - \exp(-rt_f)] / r$$

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

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

At a more detailed level but still within the scope of a standard analysis, the analyst can identify the affected facilities, then calculate the proper sum effect, rather than relying on generic values. The following steps are required:

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

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

Burke et al. (1984) examined the offsite economic consequences of severe LWR accidents, developing cost models for the following:

- population evacuation and temporary sheltering, including food, lodging, and transportation
- emergency phase relocation, including food, housing, transportation, and income losses
- intermediate phase relocation, beginning immediately after the emergency phase
- long-term protective actions, including decontamination of land and property and land area interdiction
- health effects, including the two basic approaches (human capital and willingness to pay).

5.3.2.6 Onsite Property

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

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

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

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

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

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

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

Cleanup and Decontamination

Cleanup and decontamination of a nuclear facility, especially a power reactor, following a medium or severe accident can be extremely expensive. In particular, decontamination of the damaged unit required several years of extended planning and analysis, which allowed for selecting the most appropriate equipment for clean-up. The TMI-2 was the first commercial nuclear power plant accident and that many tools had to be specifically designed and manufactured to perform the work. This had an impact on the time needed and the relative costs for decontamination and for fuel removal and transportation. Radioactive material, rubble and melted core debris are stored at the Idaho National Laboratory. The final decommissioning

of TMI-2 will be undertaken at the time of decommissioning of the other nuclear unit at the TMI site.

According to official figures, the clean-up of the damaged TMI-2 nuclear reactor started in 1979 and officially ended in 1993, with a publicly announced cost of about \$975 million. However, these costs do not take into account some aspects of decommissioning and nuclear waste management that will make the total cost higher. In particular, the cesium present in the cooling water migrated into the concrete walls, making the decommissioning of TMI-2 more complex and therefore more expensive. Also, the melted core and other highly radioactive debris are currently stored at the Idaho National Laboratory and should be properly managed and disposed of.

Costs for onsite property damage from both reactor and non-reactor accidents are provided in Appendix G, "Historical Data." Some of these costs are given as combined offsite and onsite damage costs.

Long-Term Replacement Power

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

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

Historical estimates for long-term replacement power costs based on simulations of production costs and capacity expansion for representative pools of utility systems are provided in Appendix G, "Historical Data."

Repair and Refurbishment

In the event of an accident where the facility is recoverable (e.g., a reactor event in which plant safety systems function as intended, some fuel cladding ruptures, but no fuel melts, the containment building is moderately contaminated, but there is minimal physical damage), the licensee will incur costs to repair or replace damaged components before the damaged facility can be returned to operation. For these events, Burke et al. (1984) proposed a method for estimating equipment repair costs based on outage duration. Using this approximation method and data from outages of varying durations at reactors, the authors suggest that an upper bound estimate of these repair and refurbishment costs are roughly 20 percent of the long-term replacement power costs for a single event. This method may be used when a quick estimate is needed, few details are available or cost data are unavailable, the cost estimate will be used to support what-if analyses, or when approximating the cost for a noncontroversial amendment to an existing rule or regulation.

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

Onsite Property Damage Costs Following a Severe Accident

Any severe facility accident is expected to cause such extensive damage that resuming operations may be impossible. The facility involved may have to be permanently shut down and dismantled. However, depending on the onsite contamination levels and on decisions from government agencies and the licensee following the accident, other undamaged facilities onsite could be temporarily or permanently shut down as a consequence of the accident. For example, if an accident occurs at a nuclear power plant site hosting multiple units, there are three possible outcomes with respect to the undamaged units: (1) continue operation of the undamaged units or restart shortly after the accident, (2) resume operation of non-affected units after a certain time, or (3) permanent shutdown of all the units at the site.

In the case of the TMI and the Chernobyl accidents, the undamaged onsite units resumed operations, either immediately or sometime after the accident. The TMI-1 reactor, which was shutdown for refueling at the time of the TMI-2 accident, had its license suspended by the NRC. The NRC permitted the TMI-1 reactor to restart in October 1985, five and half years after the accident, following some modifications in the plant. The TMI-1 unit is currently in operation and the license has been extended until April 2034. At Chernobyl, the three undamaged units continued operation after the accident due to the energy shortages in the country. The Chernobyl units were permanently shutdown in 1991, 1996, and 2000, respectively. On the other hand, all six units at Fukushima Dai-ichi site, including the undamaged units 5 and 6, have been permanently shutdown following the nuclear accident.

The total costs are assumed to consist of cleanup and decontamination costs and replacement power costs. Repair and refurbishment costs are not applicable for a non-repairable unit. The total onsite property costs is defined as:

. . . risk-based cost, the discounted net present value of the risk over the remaining life of the plant, which is proportional to the accident frequency [F]. . .

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

Power Reactor Severe Accident Example

An example is provided below for a hypothetical 910 MWe reactor, which is assumed to have a remaining lifetime of 24 years. The estimates for total risk-based costs attributed to regulatory actions that occur in 1993, assuming a 7 percent annual discount rate, for this example are as follows:

Table 5-3 Reactor Example: Onsite Property Cost Estimate following a Severe Accident at a Hypothetical 910 MWe reactor

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

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

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

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

5.3.2.7 Industry Implementation

This section provides procedures for computing estimates of the industry's incremental costs to implement the proposed action. Estimating incremental costs during the operational phase that follows the implementation phase is discussed in Section 5.3.2.8. Incremental implementation costs measure the additional costs to industry imposed by the regulation; they are costs that would not have been incurred in the absence of that regulation. Reduction in the net cost (i.e., cost savings) is algebraically positive; increase (i.e., cost accrual) is negative (viewed as negative cost savings). Both the NRC and Agreement State licensees should be addressed, as appropriate.

In general, there are three steps that the analyst should follow to estimate industry implementation costs:

- (1) Estimate the amount and types of equipment, materials, and labor that will be affected by the proposed action.
- (2) Estimate the costs associated with implementation.
- (3) If appropriate, discount the implementation costs and then sum.

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

- land and land-use rights
- structures
- hydraulic, pneumatic, and electrical equipment
- radioactive waste disposal
- health physics
- monitoring equipment

- personnel construction facilities, equipment, and services
- engineering services
- recordkeeping
- procedural changes
- license modifications
- staff training/retraining
- administration
- facility shutdown and restart
- replacement power (power reactors only)
- reactor fuel and fuel services (power reactors only)
- items for averting illness or injury (e.g., bottled water or job safety equipment)

Note that transfer payments should not be included.

For the standard analysis, the analyst should use consolidated information to estimate the cost to industry for implementing the action.

Step 1 - Estimate the amounts and types of equipment, materials, and labor that will be affected by the proposed action, including not only physical equipment and craft labor but professional staff labor for design, engineering, quality assurance, and licensing associated with the action. If the action requires work in a radiation zone, the analyst should account for the extra labor required by radiation exposure limits and low worker efficiency due to awkward radiation protection gear and tight quarters.

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

Step 2 - Estimate the costs associated with implementation, both direct and indirect. Direct costs include materials, equipment, and labor used for the construction and initial operation of the facility during the implementation phase. Indirect costs include required services. The analyst should identify any significant secondary costs that may arise. One-time-component replacement costs and associated labor costs should be accounted for here. Additional information on cost categories, especially for reactor facilities, is available at the following references: Schulte et al. (1978) and United Engineers and Constructors, Inc. (Refs. 103, 104, and 105).

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

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

For a major effort beyond the standard analysis, the analyst should obtain very detailed information, in terms of the cost categories and the costs themselves. The analyst should seek guidance from NRC contractors or industry sources experienced in this area (e.g., architect engineering firms). The incremental costs of the action should be defined at a finer level of detail. The analyst should refer to the code of accounts in the Energy Economic Data Base (Ref. 105) or Schulte et al. (1978) to prepare a detailed account of implementation costs.

5.3.2.7.1 Short-Term Replacement Power

For power reactors, the possibility that implementation of the proposed action may result in the need for short-term replacement power should be incorporated into a regulatory analysis. Unlike the long-term costs associated with severe power reactor accidents discussed in Section 5.3.2.6 and in Appendix G, the replacement power costs associated with industry implementation of a regulatory action would be short-term.

Typical short-term replacement power cost estimates are provided in Appendix G to this guidance.

5.3.2.7.2 Premature Facility Closing

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

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

Thus, a plant closed 20 years early will incur an additional cost of \$20 million using a 7 percent real discount rate.

5.3.2.8 Industry Operation

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

In general there are three steps that the analyst should follow to estimate industry operation

costs:

- (1) Estimate the amount and types of equipment, materials, and/or labor that will be affected by the proposed action.
- (2) Estimate the associated costs.
- (3) Discount the costs over the remaining lifetimes of the affected facilities, then sum.

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

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

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

- (1) Estimate the amount and types of equipment, materials, and labor that will be affected by the proposed regulation, including professional staff time associated with reporting requirements and compliance activities. Possible costs on a facility's capacity factor should be considered. The analyst may consult with engineering and costing experts, as needed. The analyst could seek guidance from NRC contractors, architect-engineering firms, or utilities.
- (2) Estimate the associated operation and maintenance costs. The analyst should consider direct and indirect effects of the action; for example, the action could have an impact on labor, which, in turn, could affect administrative costs.
- (3) Discount the total costs over the remaining lifetime of the affected facilities.

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

For a major effort beyond the standard analysis, the analyst should seek specific guidance from contractor or industry sources experienced in this area. The user may wish to use contractors who have developed explicit methodologies for estimating operating and maintenance costs. The following references can provide useful information for industry operation costs: Budwani (1969); Carlson et al. (1977); Clark and Chockie (1979); Eisenhauer et al. (1982); NUS Corporation (1969); Phung (1978); Roberts et al. (1980); Stevenson (1981), and United Engineers and Constructors, Inc. (Refs. 103, 104, and 105).

5.3.2.9 NRC Implementation

Once a proposed action is defined and the Commission endorses its application, the NRC will incur costs to implement the action. Implementation costs refer to those “front-end” costs necessary for the proposed action. All costs associated with predecisional activities by the NRC are viewed as “sunk” costs and are excluded from the NRC implementation costs. Reduction in the net cost (i.e., cost savings) is algebraically positive; increase (i.e., cost accrual) is negative (viewed as negative cost savings).

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

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

NRC implementation costs include only the incremental costs resulting from adoption of the proposed action. Examples of these costs are as follows:

- developing guidelines for interpreting the proposed action and developing enforcement procedures
- preparing handbooks for use by the NRC staff responsible for enforcement and handbooks for use by others responsible for compliance
- supporting and reviewing a licensee’s change in technical specifications
- conducting initial inspections to validate implementation

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

Three steps are necessary for estimating NRC implementation costs:

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

Implementation is likely to affect a number of NRC branches and offices. For example, the Office of Nuclear Regulatory Research (RES) may develop a regulatory guide, NRR may review any licensee submissions, and the NRC regional offices may inspect against some portion of the guide in operating facilities. In developing estimates for the implementation costs, the analyst is encouraged to contact all of the NRC components likely to be affected by the

proposed action.

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

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

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

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

5.3.2.10 NRC Operation

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

There are three steps for estimating NRC operating costs:

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

In determining the required post implementation activities, the analyst should carefully examine the proposed action, asking such questions as the following:

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

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

For the standard analysis, the analyst should obtain estimates of the number of full-time equivalent professional NRC staff person-hours that would be required to ensure compliance with the proposed rule. The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR 4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses."

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

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

5.3.2.11 Other Government Entities

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

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

Three steps are needed to estimate the other government implementation costs:

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

Implementation is likely to affect a number of government branches and offices. In developing estimates for the implementation costs, the analyst is encouraged to contact all of the government components likely to be affected by the proposed action.

For the standard analysis, the analyst should identify the major tasks that should be performed to get the proposed rule implemented, major pieces of equipment (if any) that should be acquired, and major costs of materials. Major tasks are then assessed to estimate the approximate level of effort (in professional staff person-hours) necessary to complete them. The number of person-hours for each task is multiplied by the appropriate labor rate and then summed over all of the tasks.

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

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

The three steps for estimating the other government operating costs are

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

In determining the required post-implementation activities, the analyst should carefully examine the proposed action, asking such questions as the following:

- Does compliance with the proposed action require non-NRC cooperation?
- Is periodic review of industry performance required beyond that of the NRC?

- What is an appropriate schedule for such a review?
- Does this action affect ongoing government programs, and, if so, will it affect the costs of those programs?

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

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

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

5.3.2.12 General Public

This attribute measures costs incurred by members of the general public, other than additional taxes, as a result of implementation of a proposed action. Taxes are viewed simply as transfer payments with no real resource commitment from a societal perspective. Reduction in the net cost (i.e., cost savings) is algebraically positive; increase (i.e., cost accrual) is negative (viewed as negative cost savings).

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

The two steps to estimate costs to the general public are as follows:

- (1) Identify the adverse impacts incurred by the general public to implement the proposed action.
- (2) Estimate the costs associated with these adverse impacts, discount if appropriate, then sum.

This attribute is not expected to be one commonly affected by regulatory actions. However, if relevant, the standard analysis would require the analyst to identify the major activities to implement the proposed action that will result in adverse impacts to the general public. Public records or analogous experience from other communities could be used as information sources to estimate the costs to the general public.

5.3.2.13 Improvements in Knowledge

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

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

To the extent that the effects of regulatory actions can be quantified, they should be treated under the appropriate quantitative attributes. On the other hand, if the effects from the assessments are not easily quantified, the analyst still has the burden of justifying the effort and providing some indication of its effect. If necessary, this justification would be expressed qualitatively under this attribute. An effort should be made to identify the types of costs and benefits that are likely to accrue and to whom.

Consider the following statement:

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

While this statement describes why the proposed assessment is needed, no information is provided for evaluating the merits of the proposed assessment.

Providing answers to the following questions would help to fill this information gap:

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

The above questions are specific to a particular topic. For the broader problem of providing a cost-benefit analysis of an assessment proposal, it is recommended that the analyst be responsive to the following list of more general questions:

- What are the objectives?

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

5.3.2.14 Regulatory Efficiency

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

If necessary, this justification would be expressed qualitatively under this attribute. An effort should be made to identify the types and recipients of cost and benefits likely to accrue. If the proposed NRC action is expected to have major effects on regulatory efficiency, then a proper evaluation of these effects may require a level of effort commensurate with their magnitude. This may mean expending resources to obtain the judgments of experts outside of the NRC if the necessary expertise is not available in-house.

Whether the assessment is performed by a panel of experts or by the analyst, the following are questions that might be considered to focus on that assessment:

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

5.3.2.15 Safeguards and Security Considerations

Safeguards and security considerations include protection of the common defense and security

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

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

While quantification of safeguards and security changes may be difficult, the analyst should attempt quantification when feasible. If this process is impossible, the analyst may proceed with a qualitative analysis under this attribute.

5.3.2.16 Environmental Considerations

NEPA Section 102 requires Federal agencies to consider environmental impacts in the performance of their regulatory missions. NRC's regulations implementing NEPA are in 10 CFR Part 51. Any documentation prepared to satisfy NEPA and 10 CFR Part 51 should be coordinated with any regulatory analysis documentation covering the same or similar subject matter as much as possible.

Environmental impacts can have monetary effects (e.g., environmental degradation, mitigation measures, environmental enhancements), which could render potential alternative actions unacceptable or less desirable than others. Therefore, at a minimum, such effects should be factored into the cost-benefit analysis, at least to the extent of including a summary of the results of the environmental analysis.

Many of the NRC's regulatory actions are subject to categorical exclusions, as set forth in 10 CFR 51.22, "Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review." In these cases, detailed environmental analyses are not performed, and there will be no environmental consideration to factor into the regulatory analysis. In some cases, a generic or programmatic EIS is prepared. If such is the case, portions of the EIS may be referenced in lieu of performing certain elements of the regulatory analysis. In the remaining cases, it may be that the regulatory analysis alternative being considered will initiate the requirement for review of environmental effects. For purposes of the regulatory analysis document, the preferred approach to be used in this situation is to perform a preliminary environmental analysis, identifying, in general terms, anticipated environmental consequences and potential mitigation measures. The results of this preliminary analysis should be quantified under the appropriate quantitative attributes, if possible, or addressed qualitatively under this attribute, if not quantified.

5.3.2.17 Other Considerations

There may be other considerations associated with a particular proposed action that are not captured in the preceding descriptions. Possible examples might include the way in which the proposed action meets specific requirements of the Commission, the EDO, or an NRC office director that requested the regulatory analysis; the way in which the proposed action would help

achieve NRC policy; or advantages or detriments that the proposed action would have for other NRC programs and actions. If quantifiable, the effect should be included in essentially the same way as in the quantitative attributes. Because such considerations would be expected to be unusual, some additional discussion in the regulatory analysis document should be provided.

The analyst needs to give thoughtful consideration to the possible effects of the proposed action. Some of the effects may not be immediately obvious. The analyst may wish to consult with other knowledgeable individuals to aid in identifying all significant effects. These considerations need to be presented clearly to facilitate the reader's understanding of the issues.

When quantification of effects is not feasible, the analyst may still be able to provide some indication of the magnitude to facilitate comparison among alternatives, as well as comparison with quantifiable attributes. Comparative language (greater than, less than, about equal to) can be very helpful in achieving this objective, as the analyst can make the necessary judgments. Consultation with experts or other knowledgeable individuals may be required.

5.4 Labor Rates

When determining the appropriate industry labor rates, the analyst should use data from the National Wage Data available on the BLS Web site (www.bls.gov). Depending on the industry and the occupation (e.g., manufacturing, health and safety), an appropriate mean hourly labor rate should be selected. The labor rate should be increased using a multiplier of 1.5 to account for benefits (e.g., pension, insurance premiums, and legally required benefits). Because exact hourly rates may be difficult to obtain and may not be sufficiently recent, nationwide mean hourly rates should be used.

The NRC's labor rates are determined using the methodology in Abstract 5.2, "NRC Labor Rates," of NUREG/CR-4627. This methodology considers only variable costs (including salary and benefits) that are directly related to the implementation, operation, and maintenance of the amendments. The NRC's labor rates are distributed annually.

5.5 Economic Discounting and Calculation of Present Value

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

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

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

A method known as "discounting" is used to compare amounts of money expended at different times. The result of discounting is called the "present value," the amount of money that should

be invested today to achieve a specified sum in the future. To perform the discounting procedure, the analyst should know three parameters:

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

5.6 Discount Rate

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

When the time horizon associated with a regulatory action exceeds 100 years, the 7-percent real discount rate should not be used. Instead the net value should be calculated using the 3-percent real discount rate. In addition, the results should be displayed showing the costs and benefits at the time they are incurred with no discounting (Ref. 15).

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

5.7 Discrete Discounting

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

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

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

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

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

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

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

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

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

For example, if the increase in annual industry costs is \$1,000, due to increased maintenance expenses, with a 7-percent real discount rate for 20 years, starting at the present time, the present value of these costs is:

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

In most cases, operating costs will start to be incurred at some date in the future, after which the real costs will be constant on an annual basis for the remaining life of the facility. To discount the costs in this situation, a combination of the above two methods or formulas is needed. For example, given the same \$1,000 annual cost for a 20-year period at a 7-percent real discount rate, but starting 5 years in the future, the formula to calculate the PV is:

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

where:

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

Therefore,

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

Additional background on discrete discounting can be found in the EPRI Technical Assessment Guide (1986), DOE Cost Guide (1982), and Wright (1973).

5.8 Continuous Discounting

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

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

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

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

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

The monetized values for the reductions in public and occupational dose due to accidents, as well as the avoided onsite and offsite property damage costs, require continuous discounting. To calculate the present value for the public health (accident) and offsite property attributes, when the monetary value or cost C_o can occur with a frequency f, Strip (1982) provides the following formula:

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

where: t_i = time of onset of accident risk
 t_f = time of end of accident risk.

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

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

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

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

To calculate present values for the occupational health (accident) and onsite property attributes, the continuous discounting formula should be modified. The modifications account for two items. First, some components of severe accident costs are not represented by constant annual charges as noted in Section 5.7. Secondly, the single-event present values should be reintegrated, because the accident costs and risks would be spread over a period of time (e.g., over the remaining plant life-time for replacement power costs and over the estimated 10 years for cleanup and decontamination following a severe accident, for onsite property damage). Section 5.3.2.1.3 and Appendix G ("Total Onsite Property Damage Costs") address these modifications and provide estimation guidelines for regulatory initiatives that affect accident frequencies in current and future years.

6. CONCLUSION

NUREG/BR-0058, Revision 5 accomplishes the three objectives that the staff sought to accomplish through this update. Specifically, the revision consolidates the NRC cost-benefit analysis guidance of NUREG/BR-0058, Revision 4, and NUREG/BR-0184, into one document, which allows for efficiencies in obtaining the guidance to support their regulatory analyses reviews. Second, this revision incorporates improvements in methods for assessing factors that are difficult to quantify and includes relevant best practices identified in GAO-09-3SP as well as recommendations from GAO-15-98. Finally, this revision incorporates NRC experience and improvements in uncertainty analysis, as well as Commission direction on cost-benefit analysis since the last revision of these documents.

7. REFERENCES

1. U.S. Nuclear Regulatory Commission (NRC). 1977. SECY-77-388A, "Value-Impact Guidelines," ADAMS Accession No. ML12234B122.
2. 46 FR 13193. February 17, 1981. "Executive Order 12291: Federal Regulation." *Federal Register*, Office of the President, Washington, D.C. Accessed at <http://www.archives.gov/federal-register/codification/executive-order/12291.html>.
3. U.S. Nuclear Regulatory Commission (NRC). 1983a. "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058, Washington, D.C. ADAMS Accession No. ML15027A412. Accessed at <http://pbadupws.nrc.gov/docs/ML1502/ML15027A412.pdf>.
4. U.S. Nuclear Regulatory Commission (NRC). 1983b. "A Handbook for Value-Impact Assessment." NUREG/CR-3568, Washington, D.C. ADAMS Accession No. ML062830096. Accessed at <http://pbadupws.nrc.gov/docs/ML0628/ML062830096.pdf>.
5. U.S. Nuclear Regulatory Commission (NRC). 1984. "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058, Revision 1, Washington, D.C. ADAMS Accession No. ML15027A413.
6. 58 FR 51735. October 4, 1993. "Executive Order 12866: Regulatory Planning and Review." *Federal Register*, Office of the President, Washington, D.C. Accessed at <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>.
7. U.S. Nuclear Regulatory Commission (NRC). 1995b. "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058, Revision 2, Washington, D.C. ADAMS Accession No. ML15141A076.
8. 10 CFR Part 50. *Code of Federal Regulations*, Title 10, *Energy*, Part 50, "Domestic Licensing of Production and Utilization Facilities." Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/>.
9. U.S. Nuclear Regulatory Commission (NRC). 1986. 51 FR 30028 (August 21, 1986). "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement, Republication." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/commission/policy/51fr30028.pdf>.
10. U.S. Office of Management and Budget (OMB). 1993. "Regulatory Impact Analysis Guidance, Appendix V. in Regulatory Program of the United States Government: April 1, 1992 – March 31, 1993." Document No. S/N 041-001-00388-6, U.S. Government Printing Office, Washington, D.C.
11. U.S. Nuclear Regulatory Commission (NRC). 2011. "The Charter for Committee to Review Generic Requirements." Revision 8, Washington, D.C. ADAMS Accession No. ML110620618. Accessed at <http://pbadupws.nrc.gov/docs/ML1106/ML110620618.pdf>.

12. U.S. Nuclear Regulatory Commission (NRC). 1997. "Regulatory Analysis Technical Evaluation Handbook: Final Report." NUREG/BR-0184, Washington, D.C. ADAMS Accession No. ML050190193. Accessed at <http://pbadupws.nrc.gov/docs/ML0501/ML050190193.pdf>.
13. U.S. Nuclear Regulatory Commission (NRC). 2000. "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058, Revision 3, Washington, D.C. ADAMS Accession No. ML023290519. Accessed at <http://pbadupws.nrc.gov/docs/ML0232/ML023290519.pdf>.
14. U.S. Nuclear Regulatory Commission (NRC). 2004. "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." NUREG/BR-0058, Revision 4, Washington, D.C. ADAMS Accession Number ML042820192.
15. U.S. Office of Management and Budget (OMB). 2003. "Regulatory Analysis," Circular No. A-4. September 17, 2003. Accessed at https://www.whitehouse.gov/omb/circulars_a004_a-4/.
16. U.S. Nuclear Regulatory Commission (NRC). 2012a. SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework." ADAMS Accession No. ML12173A478. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2012/2012-0110scy.pdf>.
17. U.S. Nuclear Regulatory Commission (NRC). 2013b. Staff Requirements Memorandum to SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," ADAMS Accession No. ML13079A055.
18. U.S. Nuclear Regulatory Commission (NRC). 1990. "Backfitting Guidelines." NUREG-1409, Washington, D.C. ADAMS Accession No. ML032230247. Accessed at <http://pbadupws.nrc.gov/docs/ML0322/ML032230247.pdf>.
19. U.S. Government Accountability Office (GAO). 2009. "GAO Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Capital Program Costs." GAO-09-3SP, Washington, D.C. Accessed at <http://www.gao.gov/assets/80/77175.pdf>.
20. U.S. Government Accountability Office (GAO). 2014. Report to Congressional Requesters, "Nuclear Regulatory Commission—NRC Needs to Improve Its Cost Estimates by Incorporating More Best Practices." GAO-15-98, Washington, D.C. Accessed at <http://www.gao.gov/assets/670/667501.pdf>.
21. 10 CFR Part 70. *Code of Federal Regulations*, Title 10, *Energy*, Part 70, "Domestic Licensing of Special Nuclear Material." Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part070/>.
22. 10 CFR Part 72. *Code of Federal Regulations*, Title 10, *Energy*, Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste."

- Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part072/>.
23. 10 CFR Part 76. *Code of Federal Regulations*, Title 10, *Energy*, Part 76, "Certification of Gaseous Diffusion Plants." Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part076/>.
 24. 10 CFR Part 52. *Code of Federal Regulations*, Title 10, *Energy*, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Washington, D.C.
 25. U.S. Nuclear Regulatory Commission (NRC). 1995. 60 FR 42622 (August 16, 1995). "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, Final Policy Statement." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C. Accessed at <http://www.gpo.gov/fdsys/pkg/FR-1995-08-16/pdf/95-20237.pdf>.
 26. U.S. Nuclear Regulatory Commission (NRC). 1998. Staff Requirements Memorandum to SECY-98-185 - Proposed Rulemaking, "Revised Requirements for the Domestic Licensing of Special Nuclear Material," ADAMS Accession No. ML991880012.
 27. 42 U.S.C. 4332 et seq. National Environmental Policy Act of 1989, as amended. Accessed at <http://ceq.eh.doe/nepa/regs/nepa/nepaeqia.htm>.
 28. 10 CFR Part 51. *Code of Federal Regulations*, Title 10, *Energy*, Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." Washington, D.C.
 29. Spensley, J.W. Esq., 1997. "National Environmental Policy Act," *Environmental Law Handbook*, 14th ed., (Thomas F.P. Sullivan ed., 1997).
 30. U.S. Nuclear Regulatory Commission (NRC). 2005. "U.S. Nuclear Regulatory Commission Regulations Handbook." NUREG/BR-0053, Revision 6, Washington, D.C. ADAMS Accession No. ML052720461. Accessed at <http://pbadupws.nrc.gov/docs/ML0527/ML052720461.pdf>.
 31. Chilk, S. 1993. Staff Requirements Memorandum to the Office of the Executive Director for Operations, J.M. Taylor and W.C. Parker, "SECY-93-086-Backfit Considerations," ADAMS Accession No. ML003760758.
 32. U.S. Nuclear Regulatory Commission (NRC). 1990. Staff Requirements Memorandum to SECY-89-102, "Implementation of the Safety Goals," ADAMS Accession Number ML003707881. Accessed at <http://pbadupws.nrc.gov/docs/ML0037/ML003707881.pdf>.
 33. Kaplan, S. and Garrick, B. J. 1981. On The Quantitative Definition of Risk. *Risk Analysis* 1(1), 11–27.
 34. U.S. Nuclear Regulatory Commission (NRC). 2002. 67 FR 61695 (October 1, 2002). "NRC Information Quality Guidelines." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C. Accessed at <http://www.nrc.gov/public-involve/info-quality/fr67p61695.html>.

35. U.S. Nuclear Regulatory Commission (NRC). 2011. "A Prioritization of Generic Safety Issues." NUREG-0933 and supplements, Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0933/>.
36. U.S. Nuclear Regulatory Commission (NRC). 2004. "U.S. NRC Strategic Plan: FY2004-FY2009." NUREG-1614, Vol. 3, Washington, D.C. ADAMS Accession No. ML042230185. Accessed at <http://pbadupws.nrc.gov/docs/ML0422/ML042230185.pdf>.
37. 44 U.S.C. 3501 et seq. Paperwork Reduction Act of 1980, as amended. Accessed at <http://www.reginfo.gov/public/reginfo/prs.pdf>.
38. U.S. Nuclear Regulatory Commission (NRC). 1997. "Individual Plant Examination Program: Perspectives on Reactor Safety and Plant Performance." NUREG-1560, Washington, D.C.
39. U.S. Nuclear Regulatory Commission (NRC). 2002. "Perspectives Gained From the Individual Plant Examination of External Events (IPEEE) Program." NUREG-1742, Washington, D.C.
40. U.S. Nuclear Regulatory Commission (NRC). 2013. "Generic Environmental Impact Statement for License Renewal of Nuclear Plants." NUREG-1437, Washington, D.C.
41. U.S. Nuclear Regulatory Commission (NRC). 2013. "Glossary of Risk-Related Terms in Support of Risk-Informed Decisionmaking - NUREG-2122." Washington, D.C. Accessed at <http://www.nrc.gov/docs/ML1331/ML13311A353.pdf>.
42. U.S. Nuclear Regulatory Commission (NRC). 2013. SECY-13-0029, "History of the Use and Consideration of the Large Release Frequency Metric by the U.S. Nuclear Regulatory Commission."
43. U.S. Nuclear Regulatory Commission (NRC). 1994. "Final Safety Evaluation Report Related to the Certification of the Advanced Boiling Water Reactor Design, Main Report." NUREG-1503, Washington, D.C. ADAMS Accession No. ML080670592.
44. U.S. Nuclear Regulatory Commission (NRC). 2004. "Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design." NUREG-1793, Washington, D.C.
45. U.S. Nuclear Regulatory Commission (NRC). 2014. "Final Safety Evaluation Report Related to the Certification of the Economic Simplified Boiling-Water Reactor Standard Design." NUREG-1966, Washington, D.C. ADAMS Accession No. ML14100A304.
46. U.S. Nuclear Regulatory Commission (NRC). 1990. "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." NUREG-1150, Washington, D.C.
47. U.S. Nuclear Regulatory Commission (NRC). 2013. "Management of Facility-Specific Backfitting and Information Collection." NRC Management Directive 8.4, Washington, D.C.

48. 5 U.S.C. 601 et seq. Regulatory Flexibility Act of 1980, as amended. Accessed at http://www.nmfs.noaa.gov/sfa/laws_policies/economic_social/rfa_revised_through_2010_jobs_act.pdf.
49. U.S. Nuclear Regulatory Commission (NRC). 2016. "NRC Information Collections Program." NRC Management Directive 3.54, Washington, D.C. ADAMS Accession No. ML15239A370. Accessed at <http://www.nrc.gov/docs/ML1523/ML15239A370.pdf>.
50. 5 CFR Part 1320. *Code of Federal Regulations*, Title 5, *Administration*, Part 1320, "Controlling Paperwork Burdens on the Public." Washington, D.C.
51. 5 U.S.C. 603, Public access to budget data, (1974).
52. 10 CFR Part 2. *Code of Federal Regulations*, Title 10, *Energy*, Part 2, "Agency Rules of Practice and Procedure." Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/cfr/part002/part002-0810.html>.
53. U.S. Nuclear Regulatory Commission (NRC). 2007. "Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan for New Site/Plant Applications." NUREG-1555, Revised Sections, Washington, D.C. Accessed at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1555/>.
54. U.S. Nuclear Regulatory Commission (NRC). 1999. "Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Volume 2." NUREG-1555, Washington, D.C. ADAMS Accession No. ML003701937.
55. U.S. Nuclear Regulatory Commission (NRC). 2000. "NMSS Decommissioning Standard Review Plan." NUREG-1727, Washington, D.C. ADAMS Accession No. ML003761169. Accessed at <http://pbadupws.nrc.gov/docs/ML0037/ML003761169.pdf>.
56. U.S. Nuclear Regulatory Commission (NRC). 2004. 69 FR 52040 (August 24, 2004) "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions." *Federal Register*, U.S. Nuclear Regulatory Commission, Washington, D.C.
57. 59 FR 32. February 11, 1994. "Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations." *Federal Register*, Office of the President, Washington, D.C. Accessed at <http://www.archives.gov/federal-register/executive-orders/pdf/12898.pdf>.
58. U.S. Nuclear Regulatory Commission (NRC). 2013. "Procedural Guidance for Preparing Environmental Assessments and Considering Environmental Issues." Office of Nuclear Reactor Regulation LIC-203, Revision 3, ADAMS Accession No. ML12234A708.
59. U.S. Nuclear Regulatory Commission (NRC). 2003. "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs." NUREG-1748, Final Report, Washington, D.C. ADAMS Accession No. ML032450279.

60. U.S. Nuclear Regulatory Commission (NRC). 2013. "Standard Review Plans for Environmental Reviews for Nuclear Power Plants, Supplement 1: Operating License Renewal." NUREG-1555, Supplement 1, Revision 1, Washington, D.C. ADAMS Accession No. ML13106A246.
61. 10 CFR Part 54. *Code of Federal Regulations*, Title 10, *Energy*, Part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants." Washington, D.C.
62. Nuclear Energy Institute (NEI). 2005. "Severe Accident Mitigation Alternatives (SAMA) Analysis: Guidance Document." NEI 05-0, Revision A, Washington, D.C. ADAMS Accession No. ML060530203. Accessed at <http://pbadupws.nrc.gov/docs/ML0605/ML060530203.pdf>.
63. 10 CFR Part 20. *Code of Federal Regulations*, Title 10, *Energy*, Part 20, "Standards for Protection against Radiation." Washington, D.C.
64. U.S. Nuclear Regulatory Commission (NRC). 2015. "Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy." NUREG-1530, Revision 1, Draft for Comment, Washington, DC. ADAMS Accession No. ML15237A211. Accessed at <http://pbadupws.nrc.gov/docs/ML1523/ML15237A211.pdf>.
65. 42 USC 2011 et seq. Atomic Energy Act of 1954, as amended.
66. U.S. Office of Management and Budget (OMB). 1992. "Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs: Guidelines and Discounts," Circular No. A-94. October 29, 1992. Accessed at <https://www.whitehouse.gov/omb/circulars/a094/>.
67. 57 FR 56287. November 27, 1992. "Requirements Concerning the Accessible Air Gap for Generally Licensed Devices." *Federal Register*.
68. 58 FR 68726. December 29, 1993. "Self Guarantee as an Additional Financial Assurance Mechanism." *Federal Register*.
69. Mubayi, V., et al. 1995. "Cost-Benefit Considerations in Regulatory Analysis." NUREG/CR-6349, Brookhaven National Laboratory, Upton, NY.
70. Chanin, D., et al. 1993. "MAACS Version 1.5.11.1: A Maintenance Release of the Code." NUREG/CR-6059, Sandia National Laboratories, Albuquerque, NM.
71. Chanin, D., et al. 1990. "MELCOR Accident Consequence Code Systems (MACCS); User's Guide." NUREG/CR-4691, Sandia National Laboratories, Albuquerque, NM.
72. Chanin, D. and M.L. Young. 1997. "Code Manual for MACCS2 User's Guide." NUREG/CR-6613, SAND97-0594, Sandia National Laboratories, Albuquerque, NM.
73. Napier, B.A. 2012. "GENII Version 2 Users' Guide." PNNL-14583, Rev. 4, Pacific Northwest National Laboratory, Richland, WA.

74. Rosnick, R. 2013. "CAP88-PC Version 3.0 User Guide." Trinity Engineering Associates, Inc., Cincinnati, OH. Accessed at <https://www.epa.gov/radiation/cap-88-and-cap-88-pc-resources>.
75. U.S. Environmental Protection Agency (EPA). 1989. "User's Guide for the COMPLY Code." EPA/520/1-89-003, Rev. 2, U.S. Environmental Protection Agency, Washington, D.C. Accessed at <https://www.epa.gov/radiation/comply>.
76. Humphries, L.L., et al. 2015. "MELCOR Computer Code Manuals: Primer and User's Guide Version 2.1.6840 2015." SAND2015-6691 R, Vol. 1, Sandia National Laboratories, Albuquerque, NM. ADAMS Accession No. ML15300A479.
77. 40 CFR Part 61. *Code of Federal Regulations*, Title 40, *Protection of Environment*, Part 61, "National Emission Standards for Hazardous Air Pollutants." Washington, D.C.
78. U.S. Environmental Protection Agency (EPA). 2010. "Guidelines for Preparing Economic Analyses." U.S. Environmental Protection Agency, Washington, D.C. Accessed at [https://yosemite.epa.gov/ee/epa/erm.nsf/vwAN/EE-0568-50.pdf/\\$file/EE-0568-50.pdfhttps://www.epa.gov/radiation/comply](https://yosemite.epa.gov/ee/epa/erm.nsf/vwAN/EE-0568-50.pdf/$file/EE-0568-50.pdfhttps://www.epa.gov/radiation/comply).
79. Institute of Medicine. 2006. "Valuing Health for Regulatory Cost-Effectiveness Analysis." Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation, Washington, DC.
80. Van Houtven et al. 2006. "Valuing avoided morbidity using meta-regression analysis: what can health status measures and QALYs tell us about WTP?"
81. Kemeny, J.G., et al. 1979. "Report of the President's Commission on the Accident at the Three Mile Island, The Need for Change: The Legacy of TMI," Available at: <http://www.threemileisland.org/downloads/188.pdf>.
82. Bromet, E. J., and L. Litcher-Kelly. 2002. "Psychological response of mothers of young children to the Three Mile Island and Chernobyl Nuclear Plant accidents one decade later." In J. Havenaar, J. Cwikel, and E. Bromet (Eds.), *Toxic Turmoil: Psychological and Societal Consequences of Ecological Disasters* (pp. 69-84). New York: Springer Science+Business Media LLC/Springer US.
83. Danzer, A. M., and N. Danzer. 2014. "The Long-Run Consequences of Chernobyl: Evidence on Subjective Well-Being, Mental Health and Welfare." University of Munich, Munich Discussion Paper No. 2014-25. Accessed at <http://epub.ub.uni-muenchen.de/20969>.
84. IAEA. 2006. "Environmental consequences of the Chernobyl accident and their remediation: twenty years of experience." Report of the Chernobyl Forum Expert Group Environment. IAEA Publication 1239, 2006, IAEA, Vienna. Accessed at: http://www-pub.iaea.org/mtcd/publications/pdf/pub1239_web.pdf.
85. Masunaga, T., A. Kozlovsky, A. Lyzikov, N. Takamura, and S. Yamashit. 2014. "Mental health status among younger generation around Chernobyl." *Archives of Medical Science* 9(6): 1114-1116.

86. Karz, A., J. Reichstein, R. Yanagisawa, and C. L. Katz. 2014. Ongoing mental health concerns in post-3/11 Japan. *Annals of Global Health* 80(2): 108-114
87. Amagai, M., N. Kobayashi, M. Nitta, M. Takahashi, I. Takada, Y. Takeuch, Y. Sawada, and M. Hiroshima. 2014. "Factors related to the mental health and suicidal thoughts of adults living in shelters for a protracted period following a large-scale disaster." *Academic Journal of Interdisciplinary Studies* 3(3): 11-16.
88. Hasegawa, A., K. Tanigawa, A. Ohtsuru, H. Yabe, M. Maeda, J. Shigemura, T. Ohira, T. Tominaga, M. Akashi, N. Hirohashi, T. Ishikawa, K. Kamiya, K. Shibuya, S. Yamashita, and R. K. Chhem. 2015. "Health effects of radiation and other health problems in the aftermath of nuclear accidents, with an emphasis on Fukushima." *The Lancet* 386(9992): 479-488.
89. National Research Council (US) Committee. 2008. "Estimating Mortality Risk Reduction Benefits from Decreasing Tropospheric Ozone Exposure." National Academies Press (US), Washington, D.C.
90. Baker, D. 1995. "Dose Commitments Due to Radionuclide Release from Nuclear Power Plant Sites in 1991." NUREG/CR-2850 Vol. 13, Pacific Northwest National Laboratory, Richland, WA.
91. Tichler, J., et al. 1995. "Radioactive Materials Released from Nuclear Power Plants. Annual Report 1993." NUREG/CR-2907 Vol. 14, Brookhaven National Laboratory, Upton, NY.
92. Beal, S., et al. 1987. "Data Base of System-Average Dose Rates at Nuclear Power Plants." NUREG/CR-5035, Science and Engineering Associates, Inc., Albuquerque, NM.
93. Sciacca, F. 1992. "Generic Cost Estimates." NUREG/CR-4627, Revision 2, Science and Engineering Associates, Inc., Albuquerque, NM.
94. LaGuardia, T., et al. 1986. "Guidelines for Producing Commercial Nuclear Power Plant Decommissioning Cost Estimates." AIF/NESP-036, Atomic Industrial Forum, Washington, D.C.
95. U.S. Bureau of Labor Statistics (BLS). "Injuries, Illnesses, and Fatalities" program website. Retrieval at <http://www.bls.gov/iif/>.
96. Regulatory Working Group (RWG). 1996. Economic Analysis of Federal Regulations Under Executive Order No. 12866, (Online Report). Accessed at https://www.whitehouse.gov/omb/inforeg_riaguide/.
97. National Safety Council. "Injury Facts." National Safety Council, Statistics Division, University of Michigan. Retrieval at <http://www.nsc.org/pages/home.aspx>.
98. Strip, D. 1982. "Estimates of the Financial Risks of Nuclear Power Reactor Accidents." NUREG/CR-2723, Sandia National Laboratories, Albuquerque, NM.

99. Burke, R., et al. 1984. "Economic Risks of Nuclear Power Reactor Accidents." NUREG/CR-3673, Sandia National Laboratories, Albuquerque, NM.
100. Robert Snow Means Co., Inc. 1995. "Building Construction Cost Data 1996." 54th annual edition, Robert Snow Means Co, Inc., Kingston, MA.
101. Electric Power Research Institute (EPRI). 1986. "Technical Assessment Guide." EPRI-P-4463-SR, Electric Power Research Institute, Palo Alto, CA.
102. Schulte, S., et al. 1978. "Fusion Reactor Design Studies – Standard Accounts for Cost Estimates." PNL-2648, Pacific Northwest National Laboratory, Richland, WA.
103. United Engineers and Constructors, Inc. 1986. "Energy Economic Data Base (EEDB) – Phase VIII, Complete CONCISE Printouts for Model 148 Pressurized Water Reactor (Median Experience Basis) and Model 205 BWR (ME) Mark II, 1195 MWe Boiling Water Reactor." United Engineers and Constructors, Inc., Philadelphia, PA.
104. United Engineers and Constructors, Inc. 1988a. "Phase IX Update (1987) Report for the Energy Economic Data Base (EEDB) Program EEDB-1X." DOE/NE-0091, U.S. Department of Energy, Washington, D.C.
105. United Engineers and Constructors, Inc. 1988b. "Technical Reference Book for the Energy Economic Data Base Program EEDB Phase IX (1987)." DOE/NE-002, United Engineers and Constructors, Inc., Philadelphia, PA.
106. Budwani, R. 1969. "Power Plant Capital Cost Analysis." Power Engineering, 84(5)62-70.
107. Carlson, W., et al. 1977. "Analysis of Coal Option. Vol. II of Comparative Study of Coal and Nuclear Generating Options for the Pacific National Northwest." WPPSS FTS-058-II, Fuel and Technical Studies Department, Washington Power Supply System, Richland, WA.
108. Clark, L., and Chockie, A. 1979. "Fuel Cycle Cost Projections." NUREG/CR-1041, Pacific Northwest National Laboratory, Richland, WA.
109. Eisenhower, J., et al. 1982. "Electric Energy Supply Systems Comparison and Choices Volume I: Technology Description Report." PNL-3277, Pacific Northwest National Laboratory, Richland, WA.
110. NUS Corporation. 1969. "Guide for Economic Evaluation of Nuclear Reactor Plant Designs." NUS-531, NUS Corporation, Rockville, MD.
111. Phung, D. 1978. "A Method for Estimating Escalation and Interest During Construction (EDC and IDC)." ORAU IEA-78-7(M), Institute for Energy Analysis, Oak Ridge Associated Universities, Oak Ridge, TN.
112. Roberts, J., et al. 1980. "Treatment of Inflation in the Development of Discount Rates and Levelized Costs in NEPA Analyses for the Electric Utility Industry." NUREG-0607, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C.

113. Stevenson, J. 1981. "Evaluation of the Cost Effects on Nuclear Power Plant Construction Resulting from the Increase in Seismic Design Level." NUREG/CR-1508, Structural Mechanics Associates, Woodward-Clyde Consultants, Cleveland, OH.
114. U.S. Department of Energy (DOE). 1982. "Cost Guide, Volume 2: Standard Procedures for Determining Revenue Requirements (Product Cost)." DOE/MA-0063 (Vol. 2), U.S. Department of Energy, Washington, D.C.
115. Wright, M. 1973. "Discounted Cash Flow." McGraw-Hill, London, England.

PREDECISIONAL

APPENDIX A

QUALITATIVE FACTORS ASSESSMENT TOOLS

PREDECISIONAL

APPENDIX B
COST ESTIMATING AND BEST PRACTICES

PREDECISIONAL

1

APPENDIX C

2

TREATMENT OF UNCERTAINTY

3

PREDECISIONAL

1
2
3
4

APPENDIX D
GUIDANCE ON REGULATORY ANALYSES RELATED TO ASME CODE
CHANGES

PREDECISIONAL

1

APPENDIX E

2

SPECIAL CIRCUMSTANCES

3

PREDECISIONAL

1

APPENDIX F

2

DATA SOURCES

3

PREDECISIONAL

1

APPENDIX G

2

HISTORICAL DATA

3

PREDECISIONAL

1

APPENDIX H

2

SEVERE ACCIDENT CONSEQUENCE ANALYSIS

3

PREDECISIONAL

1
2
3
4

APPENDIX I
NATIONAL ENVIRONMENTAL POLICY ACT COST-BENEFIT
ANALYSIS

PREDECISIONAL

1

APPENDIX J

2

BACKFITTING PROCEDURES

3

PREDECISIONAL

1

APPENDIX K

2

MORBIDITY

PREDECISIONAL

1

APPENDIX L

2

REPLACEMENT POWER COSTS

3

PREDECISIONAL