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Regulatory Analysis Technical Evaluation Handbook

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1 Introduction

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

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

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

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

1.1 Purpose

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

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

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

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

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

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

1.2 Regulatory Analysis Overview

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

1.2.1 Key Terms and Concepts

Backfitting. Backfitting is defined at 10 CFR 50.109(a)(1) as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the

4 Regulatory Analysis Methods and Supporting Information

A regulatory analysis consists of six elements:

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

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

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

4.1 Statement of the Problem and Objective

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

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

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

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Executive Summary

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

References

Appendixes (as needed)

Figure 4.1 Standard format and content of regulatory analyses

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

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

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

4.2 Identification and Preliminary Analysis of Alternative Approaches

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

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

The initial set of alternatives should be broad and comprehensive, but should also be sufficiently different to provide meaningful comparison and to represent the spectrum of reasonable possibilities. Alternatives that are minor variations of each other should be avoided. Table 4.1 contains a list of potential alternatives that may be used to begin identification of alternatives; however, the analyst should recognize that this generic list cannot envision every possibility associated with specific issues. Taking no action should be viewed as a viable alternative except in cases where action has been mandated by legislation or a court decision. If a viable new alternative is identified after analysis has begun, it should be added to the list of alternatives and treated in the same manner as the original alternatives.

Table 4.1 List of potential alternative actions

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

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

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

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

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

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

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

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

Once a broad and comprehensive list of alternatives has been developed, a preliminary analysis of the feasibility, values, and impacts of each alternative is performed. Some alternatives usually can be eliminated based on clearly exorbitant impacts in relation to values, technological infeasibility, severe enforcement or implementation problems, or other fairly obvious considerations. Reduction of the list of alternatives at this point in the analysis will reduce the resources needed to perform detailed evaluation of values and impacts. The regulatory analysis document should list all alternatives identified and considered, and provide a brief explanation of the reasons for eliminating certain alternatives during the preliminary analysis.

The level of analytical detail in the preliminary screening of alternatives need not be the same for all alternatives, particularly when one alternative can be shown to be clearly inferior or superior to the others. Rough estimates of values and impacts should be made using very simple analyses (in many cases, judgement may suffice). If several alternative actions are considered, comparison can be based on the "expected-value" of each.

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

Alternative regulatory documents which could be used to address regulatory concerns should also be identified at this time.[3] The most common forms of documents include regulations, policy statements, orders, generic letters, and

regulatory guides. Alternatives could include issuance of new documents or revision or deletion of existing ones. Other implementation means should be considered when appropriate (e.g., submission of proposed legislation to Congress).

Regulatory document alternatives should only be subjected to detailed value-impact analysis if preliminary assessment indicates significant differences in the values or impacts among such alternatives. Otherwise, the means of implementing the proposed action should be discussed in the section of the regulatory analysis document covering implementation (see Section 4.6).

For alternatives that survive preliminary screening and that require a backfit analysis according to 10 CFR 50.109(a)(3), a general description of the activities that would be required by the licensee or license applicant to complete the backfit should be prepared at this point in the regulatory analysis process. Preparation of this information will satisfy the requirements at 10 CFR 50.109(c)(2) and Section IV.B(vii)(b) of the CRGR Charter.

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

4.3 Estimation and Evaluation of Values and Impacts

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

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

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

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

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

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

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

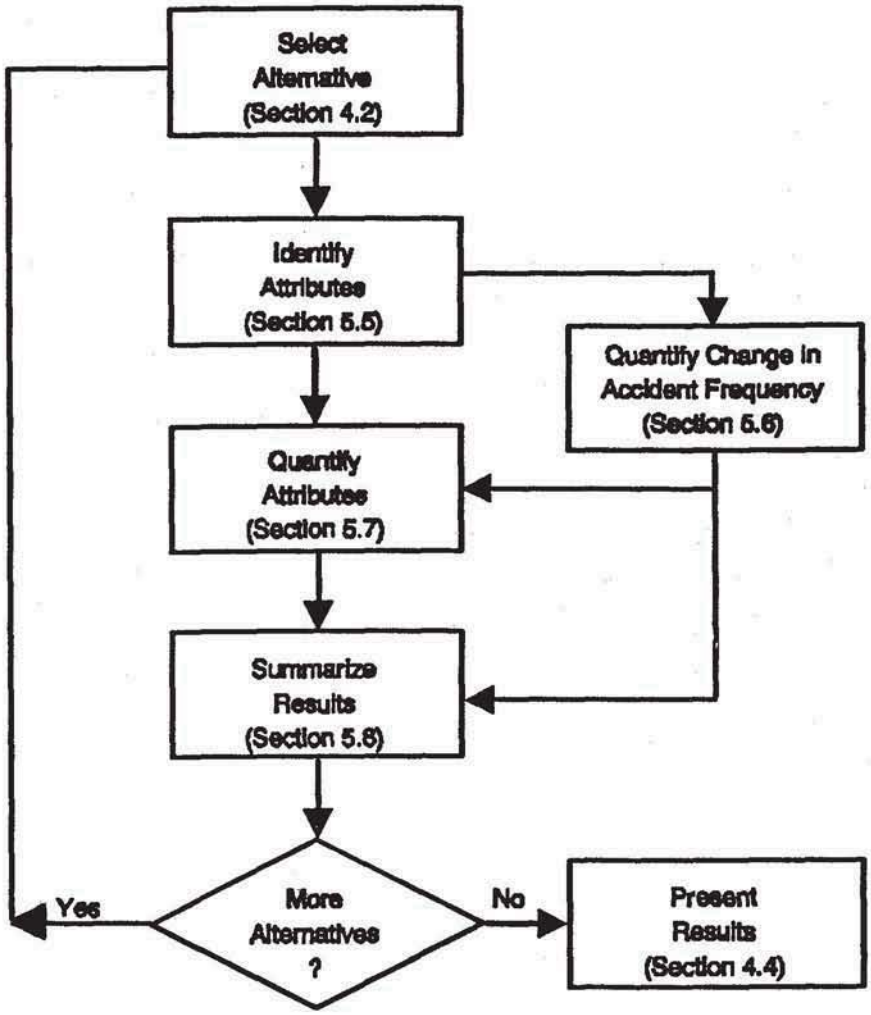

Figure 4.2 Steps in a value-impact analysis

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

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

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

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

Estimates are made for those attributes which lend themselves to quantification using standard techniques. Obtaining the appropriate data may be more complicated when a major effort is being undertaken. In cases where a proposed action would result in significantly different attribute measures for different categories of licensees, separate estimates and evaluations should be made for each distinct category (e.g., older plants vs. newer plants). In backfit regulatory analyses, it is also required that the potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit be evaluated [10 CFR 50.109(c)(8)].

Section 4.3 of the Guidelines identifies the need to consider attributes in terms of the different groups that may be affected by a proposed action. This Handbook accommodates this need by the way that the suggested attributes are defined (e.g., impacts on the industry, the NRC, and other governmental units). If appropriate, qualitative considerations may also be evaluated. While these may be difficult to compare with the quantitative attributes, a consistent approach in their evaluation can result in a useful comparison among competing alternatives.

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

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

Depending upon the level of effort, either sensitivity or uncertainty analyses should be performed while quantifying the attributes to estimate the effect upon the results of variations in input parameters. Hypothetical best- and worst-case consequences may be estimated for sensitivity analyses. The output from the sensitivity analyses is used to determine the importance of various parameters and to approximate the uncertainties associated with the results. Actual uncertainty analyses should be more rigorous. A number of techniques are available, each with differences in usefulness of results and the amount of resources required. Uncertainty analyses should produce actual probability distributions for the overall results based on assumed distributions for selected input parameters. The differences between sensitivity and uncertainty analyses and their respective roles in regulatory analysis are discussed in Section 5.4.

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

4.4 Presentation of Results

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

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

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

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

The effects of the proposed action on other NRC programs need to be assessed. These could include eliminating or creating a need for other programs; use of limited NRC resources resulting in postponement or rescheduling of other programs; modifying accident probabilities resulting in changes to priority of, or need for, other programs; or developing information with a bearing on other programs. Effects on other government agencies, if any, should also be assessed and reported.

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

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

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

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

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

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

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

4.5 Decision Rationale

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

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

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

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

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

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

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

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

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

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

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

4.6 Implementation

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

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

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

4.7 Endnotes for Chapter 4

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

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

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

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