Attachment 2

Draft Revision of NUREG/BR-0058, Revision 4
"REGULATORY ANALYSIS GUIDELINES OF THE U.S. NUCLEAR REGULATORY COMMISSION"

Section 4 and 6

4 ELEMENTS OF A REGULATORY ANALYSIS

This section presents the specific elements to be included in a regulatory analysis document. The intent of these Guidelines is to ensure uniformity in the elements included in a regulatory analysis. These elements include the following:

- A statement of the problem and NRC objectives for the proposed regulatory action.
- Identification and preliminary analysis of alternative approaches to the problem.
- Estimation and evaluation of the values and impacts for selected alternatives, including consideration of the uncertainties affecting the estimates.
- The conclusions of the evaluation of values and impacts and, when appropriate, the safety goal evaluation.
- The decision rationale for selection of the proposed regulatory action.
- A tentative implementation schedule and implementation instrument for the proposed regulatory action.

A regulatory analysis should address each of these elements and should also include an executive summary, a list of acronyms, and an identification of the references used. More detailed guidance for the preparation of regulatory analysis documents is in the Handbook. The Handbook includes methodological tools and generic estimates for the quantification of selected attributes that are typically included in NRC regulatory analyses, as well as an extensive bibliography.

Regulatory analyses are reviewed within the NRC and made publicly available. Reviewers include NRC technical staff and managers and formal groups such as the CRGR, the Advisory Committee on Reactor Safeguards (ACRS), and the Advisory Committee on Nuclear Waste. 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 ~~this review, as well as~~ review by those outside the NRC, the staff should generally post the analysis, with all the supporting documents, on the internet so the public can review the findings. A good analysis should be transparent and its results be reproducible. One should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. ~~carefully document both the assumptions made and the sources of information used in preparing the regulatory analysis.~~ Information obtained from outside the NRC, including any from parties interested in a proposed regulatory action, may be used in the regulatory analysis after the staff has been assured of the reasonableness of the information.

Because of its influential nature and its specific role in the rulemaking process, it is appropriate to set minimum quality standards for a regulatory analysis. The staff should provide documentation that the analysis is based on the best reasonably attainable scientific, technical, and economic information available. To achieve this, the staff should rely on peer-reviewed literature, where available, and provide the source for all original information. The staff is encouraged to

have the regulatory analysis peer-reviewed, and be able to attest that the regulatory analysis satisfies the NRC's Information Quality Guidelines.[13]

The appropriate level of detail to be included in a regulatory analysis can vary, 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 values and impacts;

3. The relative amount by which projected values exceed impacts;[14]

4. The immediacy of the need for a regulatory action and time constraints imposed by legislation or court decisions; and

5. Any supplemental direction provided by the Commission, the Office of the EDO, or an NRC Office Director.

The emphasis in implementing the Guidelines 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 must be sufficiently clear and contain sufficient detail to enable NRC decision makers and other interested parties to easily recognize—

- 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 requirement was appropriate and justified,

- The sources and magnitude of uncertainties that might affect the conclusions and the proposed new requirement, and

- The sensitivity of the conclusions to changes in underlying assumptions and considerations.

In theory, 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 guidelines). This might be the case, when, for example, the regulatory initiative is a "significant regulatory action" as defined in E.O. 12866 (see footnote 5), or of such policy import that a major controversy is likely to ensue. In OMB Circular A-4 (Ref. 14), additional regulatory analysis guidance is provided for such initiatives. Among other things, this additional guidance includes the use of a standardized accounting statement, cost effectiveness analysis, incremental analyses of values and impacts, and the calculation of internal rates of return. In addition, it calls for both a more expansive

[13]U.S. Nuclear Regulatory Commission, "NRC Information Quality Guidelines," Federal Register, Vol. 67, October 1, 2002, pp. 61695-61699.

[14]Proposed actions with values and impacts that are estimated to differ by a relatively small amount should normally be analyzed in greater detail than actions with values and impacts that differ by a substantial amount.

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 alternative health and safety measures that consider quality adjusted life years, equivalent lives, and non-fatal risks.[15] NRC initiatives rarely meet the high economic and policy thresholds of Circular A-4. Therefore, for most NRC regulatory analyses, this level of analysis would not be required nor justified due to the increased level of effort involved. Thus, rather than provide this more detailed guidance here, analysts are referred to Circular A-4 when a specific regulatory action satisfies OMB's high threshold standards.

4.1 Statement of the Problem and Objective

The statement of the problem should be a concise summary of the problems or concerns that need to be remedied, defined within the context of the existing regulatory framework. The statement should provide the reader with a clear understanding of exactly what the problem is and why it exists, the extent of the problem and where it exists, and why it requires action. In this context, a measure of its safety importance needs to be presented on either a qualitative or quantitative basis. The focus of this section is to clearly demonstrate that the problem requires action and to demonstrate the implications of taking no action.

Many NRC regulatory initiatives are pursued because existing regulations are deemed insufficient to protect the public health and safety. Therefore, relating the action to these concerns is important when defining the problem and objectives. However, from OMB's perspective, for many such regulatory initiatives, the underlying causative factor for governmental action is market failure, and OMB encourages acknowledging such a relationship when it is relevant. For the NRC, requirements that focus on health and safety improvements, including environmental improvements, can typically be attributed to a failure of private markets to account for externalities, which are uncompensated values or impacts that one party's actions impose on another party. Examples are when a licensee's operations may impose uncompensated residual risks and/or environmental damages on the public.

For certain regulatory issues there may be existing NRC or Agreement State regulatory requirements or guidance, industry programs, or voluntary efforts by licensees directed at the same or similar problem. These activities, and any variations in industry practice and commitments among licensees, should be identified and discussed to the extent practicable. The need for regulatory action must be justified within the context of what would prevail if regulatory action were not taken. This justification requires assumptions as to whether, and to what degree, voluntary practices may change in the future. In general, the no action alternative or base case is central to the estimation of incremental values and impacts. Additional discussion is included in Section 4.3.

The problem statement should identify the specific class or classes of licensees,

[15] It is worth noting that NRC's $2000 per person-rem conversion factor does in fact rely on the willingness to pay method and, in addition, accounts for non-fatal risks.

reactors, or other facilities affected by the problem, as appropriate. Any distinctions between impacted licensees (e.g., NRC and Agreement State) should be noted, as well as any differences in facility type, age, design, or other relevant considerations.

4.1.1 Background of the Problem

A background discussion of the problem should be included. The background discussion should cover the following, as applicable:

- A brief history of the problem and the outcome of past efforts (if any) to alleviate it;
- Any legislation or litigation[16] 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 (if any) to which the immediate problem is part of a larger problem;
- The relationship of the problem to other ongoing studies or actions;[17]
- The objectives of the proposed new requirement and the relationship of the objectives to NRC's legislative mandates and authority, safety goals for the operation of nuclear power plants, and policy and planning guidance (e.g., NRC's Five-Year Plan);
- The relationship of the problem to formal positions adopted by national and international standards organizations;
- Identification of any existing or proposed NRC (or Agreement State) regulatory actions that address the problem and their estimated effectiveness;
- Constraints or other cumulative impacts that work against solutions to the problem; and
- Draft papers or other underlying staff documents supporting the requirements or staff positions.

4.1.2 Backfit Rule Concerns

For problems or concerns within the scope of the backfit rule (10 CFR 50.109), the type of backfit needs to be identified. Depending on whether the action is being initiated for adequate protection or compliance and not as a safety enhancement, a regulatory analysis may not be needed or its scope or focus could be markedly different (see Section 2.3). Thus, the analyst needs to address this issue early in the regulatory analysis process. For any single action, more than one type of backfit may be involved. Under these circumstances, plants should be assessed for each type of backfit on a case-by-case basis.

4.2 Identification and Preliminary Analysis of Alternative Approaches

Once the need for action has been identified, the regulatory analysis should

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

[17] Reviewing issues associated with the problem in the context of other issues that apply to the same problem is important. These other issues may be among NRC's prioritized generic safety issues (NUREG-0933) (Ref. 12) or other identified safety issues meriting NRC's attention.

focus on identifying reasonable alternatives that have a high likelihood of resolving the problems and concerns and meeting the objectives identified in Section 4.1.1. The initial list of alternatives should be identified and analyzed as early in the regulatory analysis process as possible. For certain rulemakings, an options paper may be needed to identify and delineate substantive issues and to facilitate early consensus on the resolution of those issues. This analysis forces early consideration and documentation of alternatives and identifies an initially preferred option.

The list of alternatives should be reasonably comprehensive to ensure that the range of all potentially reasonable and practical approaches to the problem are considered. The no-action alternative will normally serve as the base case for analysis. In essence, it functions as a default approach that will occur if none of the action alternatives is justified. Its primary value is to establish the baseline condition from which all incremental values and impacts can be calculated. If applicable, the list of alternatives should include alternatives to direct regulation such as providing economic incentives to encourage the desired behavior, for example, user fees or marketable permits or licenses, or providing information upon which choices can be made by the public or licensees.

Alternatives generally focus on or explore various ways to answer a series of hypothetical questions: what, who, how, and when. When applicable in defining alternatives, consider the following issues:

- What action should be taken? — It may be appropriate to identify alternative ways to resolve the problem. Viable alternatives could be based on variability in the physical and technical requirements needed to address the problem at hand. Alternatives could also include varying the scope of requirements and the number of licensees affected.

- Whose responsibility should it be to take action? — Different entities may be capable, and therefore, could assume responsibility for resolving the problem. For example, initiatives by licensees and industry support groups may constitute a viable alternative to some NRC initiatives.

- How should it be done? — The various mechanisms (e.g., generic letter, rule, policy statement) available to the NRC to accomplish the change should be considered.

- When should it become effective? — Alternative implementation schedules and compliance dates may be appropriate.

The selection of alternatives for any given regulatory analysis will largely depend on the specific circumstances at hand. For some regulatory analyses, alternatives covering the full range of considerations may be appropriate. For others, circumstances may dictate that the alternatives be confined to only one of the categories previously listed. For example, Congressional actions or court rulings could prescribe an NRC action with such specificity that the only alternatives open to the NRC are implementation mechanisms.

If the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirement should merely specify the objective or result to be attained rather than prescribe to the licensee how

the objective or result is to be attained. In other words, requirements should be performance-based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary.

After the initial list of alternatives is identified, a preliminary analysis of the feasibility, values, and impacts of each alternative usually eliminates some alternative approaches. The elimination of alternatives from further analysis can be based on such factors as (1) clearly exorbitant impacts in relation to values, (2) technological impracticality, or (3) severe implementation difficulties. As information is generated as part of the preliminary analysis of alternatives, the initial set of alternatives should be refined. For each alternative that survives the preliminary screening, a general description of the activities required of licensees and the NRC to implement the alternative should be provided. In certain circumstances, this preliminary screening of alternatives may eliminate most of the alternatives being considered. In such cases, the regulatory analysis need only address the limited set of alternatives that remains.

The alternatives section of the regulatory analysis document should list all significant alternatives considered by the staff. A brief explanation of the reason for elimination should be included for alternatives not selected for further study.

4.3 Estimation and Evaluation of Values and Impacts

The alternatives that survive the screening process of Section 4.2 should be analyzed in the section of the regulatory analysis document covering the estimation and evaluation of values and impacts. The level of detail need not be equivalent for all alternatives. For example, less detail is needed when one alternative can be shown to be clearly superior to the others. Nevertheless, this section will often be the longest and most complex portion of the document.

For the purpose of these Guidelines, the definitions of values and impacts shown below are adopted. These definitions are largely derived from Section 6(a)(3)(C) of EO 12866.

Values 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 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 staff should consult the Handbook and any relevant NRC reports or documents issued subsequently to these Guidelines and the Handbook for additional guidance on estimating and evaluating values and

impacts. General principles to be followed are discussed in this section.

Categories of groups affected by the proposed regulatory action should be identified. Groups may include (but are not limited to) the general public, units of State and local government, Indian tribes, licensees of the NRC and/or Agreement States, employees of licensees, contractors and vendors, the NRC, and other Federal agencies. Within each affected group, further differentiation, for example, licensee suppliers or contractors, may be necessary if the proposed action affects segments of the group differently. Under these circumstances, separate estimates and evaluations of values and impacts should be made for each distinct category. Such estimates and evaluations should include transfer payments (see Section 4.3.3). The categorization of licensees may be appropriate for a variety of reasons. For example, the effects of a new requirement can be markedly different between newer facilities that have had safety features installed during construction and older facilities.

For each affected group, the attributes that characterize the consequences of the proposed action should be identified. The Guidelines (especially Sections 4.3.2 and 4.3.3) and the Handbook should be reviewed before selecting appropriate attributes.

Value and impact estimates are to be incremental best estimates relative to the baseline case, which is normally the no-action alternative.[18] The baseline is not to be confused necessarily with the status quo, because the baseline should reflect how the world would look absent the proposed action. Thus, if it is reasonable to assume a maturation of existing programs or other regulatory changes, the baseline should reflect the effects of these changes. Because this can raise uncertainty, when more than one baseline is reasonable and the choice of a baseline will significantly affect estimated values and impacts, measuring consequences against alternative baselines should be considered. This approach is specifically recommended in treating industry initiatives and is discussed in detail in Section 4.3.1.

When possible, best estimates should be made in terms of the "mean" or "expected value." However, depending upon the level of detail available from the data sources employed in the regulatory analysis, acceptable estimates could include other point estimates such as the median. However, the rationale for use of estimates other than mean values should be provided. The definition of the baseline case requires specific attention to ensure against double counting of either the values or impacts in the regulatory analysis. For example, in evaluating a new requirement for existing plants, the staff should assume that all existing NRC and Agreement State requirements have been implemented. Consequently the values and impacts associated with these requirements are not part of the incremental values or impacts associated with the regulatory action under consideration. Similarly, insofar as new regulatory requirements may affect future plants, the reference point for these plants should also be the existing regulatory requirements. To ensure against double counting of either the values or impacts in the regulatory analysis, the staff should be aware of values and impacts associated with other formally proposed regulatory

[18]Procedures for making best estimates are discussed in the Handbook.

actions related to the subject action that are likely to be implemented.

Uncertainties are important to consider in developing a regulatory analysis. The sources and magnitudes of uncertainties in value and impact estimates and the methods used to quantify uncertainty estimates should be discussed in all regulatory analyses. Hypothetical best- and worst-case values and impacts can be estimated for sensitivity analyses. Sensitivity analysis can be used in addition to or in lieu of formal uncertainty analysis; the former option should be exercised when uncertainty analysis is impractical or exceedingly complicated and costly. Additional information on incorporating uncertainties and sensitivities in a regulatory analysis is in the Handbook. The Handbook also discusses the distinction between them.

Values and impacts should be estimated by year for the entire period that groups will be affected by the proposed regulatory action. For licensed facilities, estimates should be made for the remainder of the operating license or projected useful life of the facility (i.e., extended into the license renewal period). For nuclear power reactors, separate estimates for a license renewal term should be made if the analyst judges that the results of the regulatory analysis could be significantly affected by the inclusion of such a renewal term. If not, the basis for the judgment or conclusion that there would not be a significant effect should be stated for future reference.
Estimated values and impacts should be expressed in monetary terms whenever possible and expressed in constant dollars from the most recent year for which price adjustment data are available.
Consequences that cannot be expressed in monetary terms should be described and quantified in appropriate units to the extent possible. In this regard, many regulatory actions, such as those affecting non-power reactor and materials licensees, may not be supported by available PRA analysis, and probabilistic analysis techniques may not be practical for some actions. However, the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective and useful trends concerning the value of the proposed action. Even inexact quantification with large uncertainties is preferable to no quantification, provided the uncertainties are appropriately considered.

The staff should use care to verify that neither values nor impacts are double counted. Values and impacts that are determined to be unquantifiable should be identified and discussed qualitatively. An attribute should not be omitted from a regulatory analysis document simply because it is determined to be unquantifiable.

4.3.1 Treatment of Industry Initiatives in Estimation of Values and Impacts

Industry initiatives are typically actions performed by licensees that form the bases for either continued compliance with the regulations or obviate the need for new regulations. It must be clear to the public that substituting industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, will in no way compromise plant safety, and does not represent a reduction in NRC’s commitment to safety and sound regulation. The NRC and the industry are jointly responsible for the long term success of using industry initiatives as substitutes for NRC regulatory action. Licensees must effectively manage and implement their commitments associated with these industry initiatives

and the NRC must provide a credible and predictable regulatory response if licensees fail to satisfy these commitments.

Industry initiatives can generally be put into one of the following 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 values and impacts and, as such, its treatment in the regulatory analysis must be explicitly considered. All consequences of a proposed regulatory change are measured relative to the baseline, which is how things would be if the proposed regulation were not imposed. If industry initiatives which complement or substitute for a proposed regulatory action exist, the future role of these industry initiatives must be determined. This determination would affect the baseline, which in turn would affect the calculation of incremental values and impacts. For example, if “full credit” is given to industry initiatives, (i.e., it is assumed that comple-mentary 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 purposes of the regulatory analysis, value-impact results are to be calculated based, to the extent practicable, on varied assumptions concerning the future role of industry initiatives. Initially, two sets of value-impact estimates are to be derived: one based on “no credit” and the other based on “full credit” for industry initia-tives. 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 value-impact 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 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:

- costs associated with the industry initiative (if the dominant costs are fixed costs that have already been expended or

the future recurring costs to maintain the industry initiative are minimal it is more likely the industry initiative will continue in the future);

- the extent to which written commitments exist (if written commitments exist it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative);

- the degree to which the industry initiative is noncontroversial and standard industry practice, the more likely it will continue without the rule change. This may be a function of consistency with provisions of industry codes and standards, the participation rate among relevant licensees, how long the program has been operating, and its effectiveness; and

- the scope and schedule for industry initiatives that are still pending (for industry initiatives that are still work-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 would contain, to the extent practicable, a best estimate of the values and impacts 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. This is because risk estimates from PRAs are based on existing conditions which 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 assure that these changes are properly reflected in the details of the PRA model.

4.3.2 Estimation of Values

Relevant value attributes should be identified and assessed for each alternative. These assessments should reflect best estimates, preferably mean values, which would account for differences in the likelihood and effectiveness of each alternative's ability to solve the problem. To the extent applicable, value attributes to be assessed include—

- Reductions in public and occupational radiation exposure,

- Enhancements to health, safety, or the natural environment,

- Averted onsite impacts,

- Averted offsite property[19] damage,

- Savings to licensees,

- Savings to the NRC,

- Savings to State, local, or tribal governments,

- Improved plant availability,
- Promotion of the efficient functioning of the economy, and

- Reductions in safeguards risks.

Particular care should be taken in estimating dollar savings deriving from averted onsite costs and improved plant availability because (1) values for these attributes are difficult to accurately estimate

[19]Offsite property refers to property that is not owned or leased by a licensee.

and (2) estimated values can potentially significantly outweigh other values and impacts associated with an alternative. In those instances where the exclusion of averted onsite costs and improved plant availability would be expected to result in a different or significantly altered conclusion, the staff should also display the results with these elements excluded for sensitivity analysis purposes and to help clarify the basis for the regulatory decision.

In the case of nuclear power plants, changes in public health and safety from radiation exposure and offsite property impacts should be examined over a 50-mile[20] distance from the plant site. The appropriate distance for other types of licensed facilities should be determined on a case-by-case basis. Care must be taken to ensure that changes in health risks associated with each alternative account for potential changes in plant or operational complexity. All changes in risk to the public and to workers should be estimated and discussed. When appropriate, health risks should be estimated for both routine operations and accidents.

The analyst should be aware that alternatives may have both positive and negative components for a particular attribute. For example, a requirement for new equipment within areas where radiation is present will result in increased occupational exposure during installation of the equipment. However, this requirement may reduce occupational exposure during routine operation and in the event of an accident.

[20]While the NRC's metrication policy statement (57 FR 46202; October 7, 1992) calls for the use of dual units, it also states that "all event reporting and emergency response communications between licensees, the NRC, and State and local authorities will be in the English system of measurement." Hence, the use of the English unit, "miles", in this case.

The ability to assess risks can vary dramatically, depending on the data and information available that is directly pertinent to the particular regulatory action being considered. Generally, the extent of any supporting detailed information will allow one of three types of regulatory analyses to be developed:

1. Detailed PRA or statistics-based analyses are available or can be developed to support the quantification of values.

2. Some factual information or data are available that can provide a quantitative perspective, but may involve considerable extrapolation of data. Thus, the resulting analysis may be quite uncertain and lack completeness or precision.

3. Extremely few data or accepted models exist to support a quantitative type analysis. As a result, the analysis must be qualitative. Once this situation is understood and the nature or type of the analysis is determined, the analyst should proceed as outlined below.

Typically, the most detailed and specific value assessment will involve regulatory initiatives impacting nuclear power reactors for which PRA analyses can be applied. The PRA can be used to generate a fairly detailed and comprehensive quantification of the expected risk reduction expressed in changes in core melt frequency or in person-cSv (person-rem) averted. This value is then quantified in dollars based on a dollar per person-cSv (person-rem) conversion factor.

The next level of quantification supporting regulatory initiatives concerns situations in

which PRAs are not available and other data and analyses must be used to justify the anticipated regulatory burden. Although no unique formula or algorithm can be postulated, the generally recommended approach is to utilize whatever data may be available within a simplified model to provide some quantitative perspective or insight on the nature and absolute or relative magnitude of the risk, as well as any discernable trends in the data. Typically, this approach will generate results that are subject to significant levels of uncertainty. The uncertainties will, in turn, require explicit disclosure of the simplifying assumptions embedded in the model as well as the data limitations. Typically, a sensitivity analysis that shows the variability in the derived risk as a function of key assumptions should be developed. The level of effort in terms of model development and data collection is dictated by the same factors that are utilized by the staff in determining the level of detail for the overall regulatory analysis.

The third level or type of regulatory analysis involves regulatory initiatives that for one reason or another cannot be quantified with meaningful limits on uncertainty. Certain issues, such as those involving emergency preparedness, security, and personnel requirements, tend to fall into this category. In these instances, the analyst must provide a qualitative basis and a clear description of how the regulatory action is justified. The analyst is cautioned that this type of regulatory analysis is subject to a higher level of scrutiny by the decision maker because of the degree of judgement involved. Reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have proven unsuccessful.

4.3.3 Estimation of Impacts

The number of potential impact attributes is very large. What constitutes an appropriate impact is highly dependent on the specific circumstances of the alternative under consideration. To the extent applicable, impacts to be assessed include the following six items:

1. Costs to licensees,

2. Costs to the NRC,

3. Costs to State, local, or tribal governments,

4. Adverse effects on health, safety, or the natural environment,

5. Adverse effects on regulatory efficiency or scientific knowledge needed for regulatory purposes, and

6. Adverse effects on the efficient functioning of the economy and private markets.

Impact estimates should be included for incremental impacts associated with each alternative. When applicable, the estimation of impacts should include information on both installation and continuing costs, including the cost of facility downtime or the cost of construction delay. Sunk costs may be identified but should not be included in the evaluation of impacts or the presentation of the results of the evaluation. Impacts should be estimated from society’s perspective. Transfer payments such as insurance payments and taxes should not be included as impacts because they do not involve consumptive use of real resources (Refs. 7, 13). However, if a proposed action being analyzed has as its major impact, a requirement that would produce additional costs for items generally considered

transfer payments, the regulatory analysis needs to consider values and impacts from a sectoral perspective and, in this context, these costs should be identified and included in the regulatory analysis. (An example would be a regulatory action whose sole impact would be to require licensees to carry additional insurance.) Information on identifying transfer payments is included in the Handbook. In addition, depreciation is an accounting concept that should not be included as an impact.

In analyzing impacts, the staff also has to be sensitive to the true impact (cost) to licensees. For example, the practice of allocating no replacement energy costs by claiming that the requirement can be accomplished during a regularly scheduled outage is not always practical or reasonable. In reality, the cumulative effect of all new requirements can add incremental downtime, and therefore, analysts should attribute appropriate replacement energy cost penalties to their respective regulatory actions, if appropriate. Further, for new requirements that have extremely high implementation costs or that will greatly increase operating costs, the analyst needs to consider the possibility that the imposition of these impacts may result in some facilities no longer being economical to operate and, thus, having to terminate operations. The Handbook should be consulted for additional information related to potential premature facility closures.

4.3.4 Evaluation of Values and Impacts

The evaluation of quantified estimates of the values and impacts associated with a proposed regulatory action involving NRC licensees generally involves expressing values and impacts on a common basis, for example, constant dollars from a reference year. Because the values and impacts need to be estimated for the entire period that members of society will be affected by the proposed regulatory action, a present-worth basis is normally used to allow meaningful summations and comparisons. Although this approach provides a rational basis for evaluating values and impacts, it has a number of complexities and controversies.

In order to place all values and impacts on a common basis, a conversion factor is needed that reflects the monetary worth of a unit of radiation exposure. The currently recommended value for this dollar conversion factor is $2000 per person-rem.[21] This dollar value only captures the health effects attributable to radiological exposure. In select regulatory applications, such as certain severe power reactor accident scenarios, a radiological release could also result in offsite property consequences whose monetary consequences would need to be addressed separately and treated as an additive factor in the overall value-impact assessment. The basis for the NRC's new conversion factor policy is provided in "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy," NUREG-1530. Guidance on how the dollar per person-rem conversion factor is to be applied as well as guidance on valuing offsite property consequences is included in the Handbook.

To provide meaningful summations, consistent with OMB guidance, all values and impacts, including public health and safety, are to be expressed on a present-

[21]The $2000 per person-rem conversion factor will be subject to periodic review by the NRC based on changes to the underlying assumptions. The dollar per person-rem conversion factor will only be adjusted if changes in the underlying parameters cause the base conversion factor (when rounded to the nearest thousand dollars) to shift up or down by a thousand dollars or more. Any future change in the dollar per person-rem conversion factor will be noted in subsequent revisions to the Handbook.

worth basis. The principle for regulatory analysis is that future health effects should be valued the same as current effects and present-worth techniques achieve this. For example, based on a given conversion factor, health and safety consequences are consistently valued at a fixed dollar value per person-cSv (person-rem). Thus, the monetary worth of a person-cSv (person-rem) averted is assigned a fixed value (in constant dollars) regardless of when the consequences occur in time. The present-worth calculation is simply determining how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future to avert a person-cSv (person-rem). By using present-worth, the health and safety effects, that is, person-cSv (person-rem), regardless of when averted in time, are valued equally.

Based on OMB guidance, present-worth calculations should be presented using both 3-percent and 7-percent real discount rates (Ref. 14). The 3-percent rate approximates the real rate of return on long-term Government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary affect of the regulation is on private consumption. Alternatively, the ~~re to use the recommended discount rate specified in the latest version of OMB Circular A-94. This circular was most recently updated in October 1992 (Ref. 13) and specifies the use of a 7-percent real discount rate. OMB's~~ 7-percent rate approximates the marginal pre-tax real rate of return on an average investment in the private sector ~~in recent years.~~ and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. Because the distribution of regulatory impacts on capital and consumption are not always well known, two sets of base case estimates should be developed and presented: one at 3 percent and one at 7 percent. The use of alternative discount rates as a further sensitivity analysis, is appropriate as long as sufficient justification is provided for use of that rate. ~~An alternative analysis, using a 3-percent real discount rate, should also be prepared for sensitivity analysis purposes. The base case, using for example OMB's currently recommended 7-percent rate, reflects recent economic conditions, yet NRC actions typically involve a 30- to 60-year time horizon. Given that uncertainties expand as one attempts to project further into the future, it is considered prudent to examine the result of assuming a lower rate as part of a sensitivity analysis. There are also theoretical arguments in the economics literature that support the use of lower rates (Ref. 14). A 3-percent rate is proposed for the alternative case because it approximates the long-term risk-free real rate of return on investment based on historical data. If the alternative rate does not alter the bottom-line result, simply indicating this conclusion is sufficient. If there is a different conclusion or if the net value determination is significantly altered, this result should be discussed and placed in perspective for the decision maker.~~

For certain regulatory actions, such as those involving decommissioning and waste disposal issues, the regulatory analysis may have to consider consequences that can occur over hundreds or even thousands of years. OMB recognizes that special considerations arise when comparing benefits and costs across generations. Under these circumstances, OMB continues to see value in applying discount rates of 3 and 7 percent. However, ethical and technical arguments can also support the use of lower discount rates. Thus, if a rule will have important intergenerational consequences, one

should consider supplementing the analysis with an explicit discussion of the intergenerational concerns, such as how future generations will be affected by the regulatory decision. Additionally, supplemental information could include a presentation of
~~For these reasons, and based on the technical literature, extended-time horizons make the appropriateness of using a relatively high interest rate for present-worth calculations questionable. When the timeframe exceeds 100 years, the analyst should avoid the use of a 7-percent real interest rate. In these instances, 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~~ the values and impacts at the time in which they are incurred with no present-worth conversion. In ~~the latter~~ this case, no calculation of the resulting net value or value-impact ratio should be made. ~~Further, the analyst may select another real rate as an additional option as long as sufficient justification is provided for use of that rate.~~Also, one should consider a sensitivity analysis using a lower but positive discount rate.

Finally, as a general principle, sensitivity or uncertainty analysis, or both, should be performed whenever the values of key attributes can range widely. A sensitivity analysis would consider the effect of varying the values of the attributes one at a time to measure each attribute's effect upon the overall result. Uncertainty analysis typically would require computer simulations, while sensitivity analysis could be performed in an analytic manner. Should the sensitivity or uncertainty analysis indicate that the preference among alternatives depends significantly on the variation in one or more key attributes, additional investigation to reduce this dependence may be appropriate. The extent to which sensitivity or uncertainty analyses are performed should reflect the magnitude and likelihood of values and impacts and their associated variability.

4.4 Presentation of Results

For each alternative considered, a net value calculation (summation of positive and negative attributes), as prescribed by OMB (Refs. 7, 13), should be computed and displayed. The net value calculation requires, to the extent possible, that all values and impacts be quantified in present-worth monetary terms and added together (with the appropriate algebraic signs) to obtain the net value in dollars. In addition, the analyst may choose to display the results based on the ratio of values to impacts. This method of display is supplemental, however, and not a replacement for the net value method. Under the ratio method, the numerator reflects the sum of all quantifiable present-worth estimates classified as values, while the denominator does likewise for impacts. Considerable care is required in calculating the ratio because statistical bias and differing results can occur, depending on the calculational approach employed. Although both presentation procedures may be used to clarify the results, the net value method is generally preferred because it provides an absolute measure of the aggregate net effect of the proposed action. Selecting the alternative with the largest net value is consistent with obtaining the largest societal gain from among the alternatives analyzed. The ratio, on the other hand, is a relative measure, particularly useful for prioritizing a large collection of proposed actions in the presence of a cost constraint. Under a cost constraint, independent actions are optimally selected by the largest ratios,

continuing to add actions in descending order, until the cost constraint is obtained. The ACRS endorsed the view that the net value and ratio measures should both be a part of the decision process (Ref. 15).

OMB maintains that the regulatory analysis should select the regulatory alternative that achieves the greatest present value–the discounted monetized value of expected net benefits (i.e., benefits minus costs) (Ref. 13). OMB also notes that the ratio has characteristics that make its results potentially misleading.

> Benefit-cost ratios, if used at all, must be used with care to avoid a common pitfall. It is a mistake to choose among mutually exclusive alternatives by selecting the alternative with the highest ratio of benefits to costs. An alternative with a lower benefit-cost ratio than another may have the higher net benefits (Ref. 7).

Tabular and graphic displays of results and associated uncertainties should be included if their use will facilitate comparison of alternatives. The values and impacts of attributes that are quantified in other than monetary terms should be displayed in a manner that facilitates comparison of alternatives. Values and impacts not quantified in the regulatory analysis should be discussed and compared among alternatives.

Further, in those instances when nonquantified values or impacts are a dominant consideration (e.g., an enhancement to safeguards requirements), the analyst should consider conducting a threshold analysis to help decision makers to understand the significance of these factors to the overall analysis. The threshold analysis answers the question: How small could the value of the nonquantified benefit be (or how large would the nonquantified costs need to be) before the proposed action would yield zero net benefits?

For alternatives projected to result in significantly different values and impacts for different categories of licensees, separate evaluations of values and impacts should be made for each distinct category. In addition, if significant differences exist between recipients of values and those who incur impacts, the distribution of values and impacts on various groups should be presented and discussed.

For certain proposed regulatory actions, the regulatory analysis may consist of only a cost effectiveness analysis. For example, the NRC may be required to initiate a requirement and achieve a certain level of value based on court or Congressional mandates, or NRC may require compliance or adequate protection actions. Under these circumstances, the issue is not to determine whether the impacts of the new requirement are justified, but rather to ensure that the requirement achieves the necessary level of value in an efficient and cost effective manner given the other implementing mechanisms available. Similarly, there may be proposed actions with important values that cannot be assigned monetary values or with uncertainties that are substantial. If the alternatives yield similar values, cost-effectiveness analysis can be used to choose the most efficient alternative.

The effect of each alternative on other NRC programs and requirements should be discussed. Effects on programs of other Federal agencies or State, local, or tribal governments should also be discussed. The extent to which the effects are

discussed should be in proportion to their significance.

For those proposed regulatory actions subject to a safety goal evaluation (see Section 3), the results of that analysis should appear in this section of the regulatory analysis. A satisfactory finding relative to the proposed safety goal screening criteria is considered a prerequisite for achieving the substantial additional protection criteria of the backfit standard in 10 CFR 50.109(a)(3). Proposed actions subject to the backfit rule [except for backfits falling within the three exception categories of 10 CFR 50.109(a)(4) (see Section 2.3)], are required by 10 CFR 50.109(a)(3) to show that there is a substantial increase in the overall protection of the public health and safety and that the costs of implementation are justified in view of this increased protection. A clearly positive finding with respect to the net value or value-impact ratio would normally satisfy this standard.

4.5 Decision Rationale for Selection of the Proposed Action

This section of the regulatory analysis should explain why the proposed action is recommended over the other alternatives considered. Taking no action should be considered an alternative except when the action has been mandated by legislation or a court decision. The decision criteria for the selection of the proposed action should be identified. The criteria should include, but are not necessarily limited to the following:

- The net value and value-impact computations,
- The relative importance of attributes that are quantified in other than monetary terms,
- The relative importance of nonquantifiable attributes,
- The relationship and consistency of the proposed alternatives with the NRC's legislative mandates, safety goals, and policy and planning guidance that are in effect at the time the proposed alternative is recommended, and
- The impact of the proposed action on existing or planned NRC programs and requirements.

This section of the regulatory analysis document should also include—

- A statement of the proposed generic requirement or staff position as it is proposed to be sent to licensees,
- A statement of the sponsoring office's position as to whether the proposed action would increase or relax (or reduce) existing requirements or staff positions, and
- A statement on whether the proposed action is interim or final, and if interim, the justification for imposing the proposed requirement on an interim basis.

4.6 Implementation

The regulatory analysis should identify how and when the proposed action is to be implemented. The proposed NRC instrument for implementing the proposed action should be identified (e.g., rule, regulatory guide) and the reasons for selecting the proposed instrument discussed. A specific date for implementation should also be identified and discussed.

A schedule should be prepared showing the steps needed to implement the proposed action. The action should be prioritized and scheduled in view of other ongoing regulatory activities affecting the facilities and their safety significance. If possible, a summary of the current backlog of existing related requirements awaiting implementation should be included. Regulatory actions should generally be scheduled in the order of their safety significance even if this means deferring the implementation of regulatory actions approved at an earlier date. An explanatory section should be included in the implementation section of the regulatory analysis document when the analysis recommends that the proposed action receive a higher implementation priority than actions previously approved. Any other information that may be considered appropriate with regard to priority, schedule, or cumulative impact should also be included.

The proposed implementation schedule should be realistic and allow sufficient time for such factors as needed analyses, approvals, procurement, installation and testing, training, and resources needed by licensees to implement other NRC and Agreement State requirements. Regulatory analyses should identify related regulatory and industry actions, even though it may be very difficult to properly characterize and account for all actions. Although regulatory actions generally are to be implemented in a timely manner, implementation schedules should be sufficiently flexible to minimize the cumulative burdens imposed on licensees by multiple regulatory requirements. When appropriate, alternative schedules should be prepared.

NRC staff actions as well as actions that will be needed by others (e.g., Agreement States and licensees) should be identified. In this regard, this section should describe the magnitude and availability of NRC resources to facilitate implementation of the proposed action.

6 REFERENCES

14. Office of Management and Budget, “Regulatory Analysis,” Circular A-4, September 17, 2003. (http//www.whitehouse.gov/omb/circulars/index.html) and O. H. Paananen and P. L. Hendrickson, "Selection of a Discount Rate for Use in Regulatory Analyses Prepared by the U. S. Nuclear Regulatory Commission and Application of Discount Rates to Future Averted Health Affects," PNL-8970, Pacific Northwest Laboratory, Richland, Washington, January 1993.