POLICY ISSUE
NOTATION VOTE

March 17, 2004 SECY-04-0045

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL CRITERIA FOR THE TREATMENT OF INDIVIDUAL REQUIREMENTS IN A REGULATORY ANALYSIS

PURPOSE:

To obtain Commission approval of final criteria for the treatment of individual requirements in a regulatory analysis as stated in the attached *Federal Register* Notice (FRN) (Attachment 1), and to incorporate and publish these criteria in Revision 4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission" (Guidelines).

To obtain Commission approval of conforming changes to Sections 4 and 6 of the revised Guidelines based on the Office of Management and Budget's (OMB's) recent Circular A-4, "Regulatory Analysis" (Attachment 2).

BACKGROUND:

On December 27, 2002, the staff submitted SECY-02-0225, "Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis," and sought Commission approval to publish the criteria for public comment. In a March 23, 2003, staff requirements memorandum, the Commission approved the staff's request. The criteria were subsequently published in the *Federal Register* on April 18, 2003 (68 FR 19162). Two sets of comments were submitted in response to the publication. The Nuclear Energy Institute (NEI) submitted one set, and the Nuclear Regulatory Services Group (NRSG) submitted the other. A full response to each of these comments is provided in the attached FRN.

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On July 10, 2003, the staff's proposed final criteria were presented to the Advisory Committee on Reactor Safeguards (ACRS). In a July 17, 2003, letter to the Chairman of the Nuclear Regulatory Commission (NRC), from the Chairman of the ACRS, the ACRS concluded that ?the proposed criteria are responsive to the Commission's Staff Requirements Memorandum (SRM) dated December 31, 2001."

Subsequently, OMB issued Circular A-4 on September 17, 2003 (68 FR 54023). The OMB circular, which replaced Circular A-94 as OMB's regulatory analysis guidance document, provides guidance to Federal agencies on the development of regulatory analyses as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review." As an independent agency, the NRC's analyses are not subject to OMB oversight and conformance with OMB guidance is not mandatory. However, because OMB's views constitute the latest thinking on this subject and OMB is responsible for providing guidance to all executive agencies in the Federal Government, the NRC has consistently attached importance to OMB's positions and has previously made selective conforming changes in response to OMB's updates. The staff has reviewed the document and made conforming changes to be included in the revised Guidelines.

Lastly, in COMSECY-02-0037, ?Proposed NRC Information Quality Guidelines," dated July 7, 2002, the staff recommended minor revisions to the Guidelines to make NRC's regulatory analysis guidance conform more closely to the treatment of uncertainties as prescribed in OMB's Information Quality Guidelines. On July 31, 2002, the Commission approved the staff's general proposal, including a staff recommendation that these changes be implemented when the criteria for individual requirements were completed. For efficiency purposes, the staff decided to formally incorporate these changes into the Guidelines when other changes under development were completed.

DISCUSSION:

NEI submitted eight specific comments, most of which fall within two general areas of concern: issues with the criteria themselves and the use of subjective judgment in making bundling decisions. Further, NEI stated that the NRC's proposed criteria do not adequately incorporate the relevant Commission guidance on this issue and that industry comments made at an earlier public meeting were not taken into account by the NRC staff.

The second commenter, NRSG, called the proposed criteria "a positive step in providing detailed guidance in this area for the first time" and suggested some refinements to the criteria so that "all proposed new regulatory requirements receive a proper analysis of their costs and benefits." NRSG had three comments. The first was that separate analysis of individual requirements should be required to the extent practicable. The second was that the criteria must be consistent with the standards of the backfitting rule. The last comment concerned the criteria guidance on backfitting issues related to the American Society of Mechanical Engineers (ASME) Code.

The staff has concluded that no changes to the proposed criteria are necessary in response to NEI and NRSG comments. The staff notes that the proposed criteria are consistent with OMB's latest regulatory guidance (Circular A-4), and the specified criteria applicable to ASME code changes are consistent with previously documented Commission guidance. The staff's response also notes the positive comments received from the Committee to Review Generic Requirements (CRGR) and the ACRS. As a result, the final criteria contained in Section III of the attached FRN will be incorporated into Revision 4 of the Guidelines after they are approved by the Commission.

With respect to conforming changes to OMB Circular A-4, the NRC staff identified six areas where changes to the Guidelines are appropriate. These changes appear in Section 4 of the Guidelines. Five of the changes should not affect NRC value-impact calculations. The staff has made these changes because they clarify and amplify current NRC guidance and will improve the overall quality of the Guidelines. These changes involve openness and transparency, minimum quality standards, market failure and externalities, the baseline case, and threshold analysis.

The sixth change has subtle implications for the NRC's value impact calculations. Consistent with previous OMB guidance, the Guidelines currently prescribe the use of a 7-percent real discount rate for base case calculations and a 3-percent real rate for sensitivity analyses. OMB now recommends that the base case be expressed as a range of values using both a 3-percent and a 7-percent real discount rate. Further, for analyses with 'intergenerational' effects (i.e., long time-horizons), OMB supports continued use of the 3-percent – 7-percent range, but acknowledges that lower rates and supplemental information may be provided to account for ethical and technical considerations. In contrast, current NRC policy is that for intergenerational issues with long time-horizons, value-impact results should be displayed first, based on a 3-percent discount rate, and second, by depicting the consequences at the time they are incurred with no present worth conversion. With respect to the latter, the staff considers it a practical application of supplemental information.

The staff has reviewed OMB's basis for this change. Because there are sound technical arguments for both the 3-percent and the 7-percent rates, the staff finds this change reasonable. Further, the staff sees merit in maintaining consistency with OMB on this matter because consistency promotes risk harmonization, which in turn helps to ensure that decisions throughout the Federal Government result in an efficient and proper allocation of society's resources. It is for these reasons that current NRC policy, as discussed in the Guidelines, Revision 3, calls for NRC's conformance with OMB's latest recommended discount rate.[1]

[1] Page 26 of the NRC Guidelines currently states: "Based on OMB guidance, present-worth calculations are to use the recommended discount rate specified in the latest version of OMB Circular A-94." (Circular A-4 has replaced Circular A-94 as OMB's regulatory analysis guidance document.)

The implications of this change are mostly minimal. In a typical regulatory analysis, value-impact results will continue to be displayed for both discount rates, with somewhat greater weight given to the 3-percent result because it is now deemed part of the base case. For most NRC scenarios, where the benefits tend to be more future-oriented than the costs, this will increase net benefits. It is difficult to quantify the difference because the temporal distribution of consequences is different for each regulatory action. However, because of inherent uncertainties in a value-impact assessment, the difference is not perceived as significant. For intergenerational analyses, the effects of including a 7-percent discount rate for a typical initiative would have the opposite effect, decreasing the present-worth benefits by a similar amount. However, because analysts can also consider a lower discount rate and supplemental analyses under the new policy, it seems reasonable to expect the decision maker to place more weight on the low end of the discount rate range, which will minimize the impact of this policy change on the NRC.

Circular A-4 contains additional issues that conflict with NRC's guidance. The staff reviewed these issues and determined that they should not be formally incorporated in the NRC's Guidelines. OMB's guidance is meant for ?significant" regulatory initiatives that have a very high threshold for economic and policy import. Also, OMB meant for many of these additional issues to apply only to the most controversial and costly rules from among these initiatives. In fact, NRC initiatives rarely meet OMB's basic threshold standard of $100 million. The staff has not included these additional issues in NRC's Guidelines because their inclusion would greatly expand the scope and complexity of a regulatory analysis when, in most cases, these issues would not be required by OMB because they would not be necessary nor justified due to the increased level of effort involved. For these reasons, rather than explicitly adding this material to the Guidelines, the staff proposes that the Guidelines simply acknowledge a possible benefit from more extensive and complex analyses and discussions, and refer the analyst to Circular A-4 when a specific rulemaking is deemed a highly controversial, significant initiative.

Attachment 2 contains the proposed changes to the Guidelines based on Circular A-4. The staff recommends that these changes be made without further public comment because the changes are relatively minor and fully conform to OMB's guidance. This guidance is based on sound scientific principles, is widely used throughout the Federal Government, and has already been subjected to public, interagency, and peer review. Further, the one change having the potential to alter NRC's value-impact results is not a policy change because, as noted above, the Guidelines currently specify that NRC analysts are to use OMB's latest recommended discount rate. For the reasons discussed above, neither the ACRS nor the CRGR have been asked to review the conforming changes.

Approval of these OMB-conforming changes, without further public review, will permit their inclusion in Revision 4 without significantly delaying its issuance. Under this approach, Revision 4 will address all outstanding regulatory analysis concerns in a timely and efficient manner.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections.

The CRGR reviewed these criteria and concurred with them.

RECOMMENDATIONS:

That the Commission:

1. Approve, the recommended final criteria for publication in the *Federal Register* and the issuance of Revision 4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," to incorporate the recommended final criteria for the treatment of individual requirements in a regulatory analysis, and the conforming changes based on OMB's recent Circular A-4.

2. Note that, the staff's general approach for the treatment of uncertainties in a regulatory analysis, as approved by the Commission on July 31, 2002, will be incorporated into this revision of the Guidelines.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. *Federal Register* Notice
2. Conforming changes to NUREG/BR-0058

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

Regulatory Analysis Guidelines: Final Criteria for the Treatment of Individual Requirements in a Regulatory Analysis

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing its final criteria for the treatment of individual requirements in a regulatory analysis, because aggregating or "bundling" different requirements in a single regulatory analysis could potentially mask the inclusion of an individual requirement that is not cost-justified. As a result of these new criteria, the NRC will issue Revision 4 of its Regulatory Analysis Guidelines, NUREG/BR-0058 in the near future.

FOR FURTHER INFORMATION CONTACT: Brian J. Richter, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-1978; e-mail bjr@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC usually performs a regulatory analysis for an entire rule in evaluating a proposed regulatory initiative to determine if the rule is cost-justified. External stakeholders from the nuclear power industry raised concerns that bundling different requirements in a single regulatory analysis can potentially mask the inclusion of an individual requirement when the net benefit from one of the requirements supports a second requirement that is not cost-justified.

In order to address this concern, the NRC published proposed criteria for the treatment of individual requirements in a regulatory analysis for comment on April 18, 2003 (68 FR 19162).

II. Comments on the Proposed Criteria

After publishing its proposed criteria for the treatment of individual requirements in a regulatory analysis, the NRC received two sets of comments: one set from the Nuclear Energy Institute (NEI), an organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry and the second from the Nuclear Regulatory Services Group (NRSG), a consortium of power reactor licensees.

In general, NEI states that the NRC's proposed criteria do not adequately incorporate the relevant Commission guidance on this issue and that the public comments made at a public meeting on March 21, 2002, were not taken into account by the NRC staff. The two areas of concern to NEI were the NRC's criteria necessary to evaluate the bundling of individual requirements and the NRC's guidance on using subjective judgment in making bundling decisions.

The law firm of Ballard Spahr Andrews & Ingersoll, LLP, also submitted a set of comments on behalf of the Nuclear Regulatory Services Group (NRSG). NRSG calls the proposed criteria "a positive step in providing detailed guidance in this area for the first time" and suggested some refinements of the criteria so that "all proposed new regulatory requirements receive a proper analysis of their costs and benefits."

Comment: NEI's initial comment was that on " . . . rules that provide risk-informed voluntary alternatives to current regulations, an individual requirement should have to be cost-justified and integral to the purpose of the rule rather than [NRC's position that it be] cost-justified or integral to the purpose of the rule." NEI claims that the NRC's criteria " . . . would be a significant disincentive to implementation of voluntary alternative requirements developed by

industry groups because of the lack of scrutable guidance regarding the addition of individual requirements by the NRC staff."

Response: The NRC believes that its position is correct with respect to the need for each criterion to be considered as a basis for bundling. NRC's position may be clearer if one considers requirements that are not necessary to a rule as enhancements. Then, if one uses NEI's criteria of requiring both conditions, i.e., being both cost beneficial **and** necessary, no enhancements to a rule would be tolerated or should even be considered because an enhancement is not necessary to the purpose of the rule. But a fundamental principle of cost benefit methodology is to select the alternative that achieves the largest net benefit, which could conceivably be an alternative with enhancements. Thus, NEI's position is tantamount to ignoring the cost benefit implications of any requirement that is not necessary to meet the objective of the rule. Under NEI's approach, cost-beneficial relaxations could not be included in a rulemaking if they were not necessary to the purpose of the rule.

Alternatively, the NRC's position allows for the selection of the alternative with the largest net benefit. Also, the NRC does not believe that NEI has demonstrated how the proposed criteria would be a "significant disincentive" to the implementation of voluntary alternative requirements developed by industry groups. As long as the voluntary alternatives are shown to be cost-beneficial and result in no decrease in safety from the NRC's proposed requirement, there should not be a problem.

Comment: NEI notes that the phrase "integral to the purpose of the rule," used both in a Staff Requirements Memorandum (SRM), dated January 19, 2001, and in the February 2002 preliminary criteria, was subsequently dropped from the proposed criteria. The phrase relates to whether a proposed requirement can be "integral to the purpose of the rule" if the individual

requirement is not cost-beneficial, not required for compliance, and not required for adequate protection. NEI's position is that the phrase should be included in the NRC's final criteria.

Response: The NRC replaced the phrase "integral to the purpose of the rule" as stated in the 2002 criteria, with "necessary to the purpose of the rule" because NRC believes that "necessary" conveys a clearer meaning. As discussed in both the proposed and final criteria papers, a requirement is necessary to the purpose of the rule if it is needed for the regulatory initiative to resolve the problems and concerns, and meet the stated objectives that are the focus of the regulatory initiative.

Comment: NEI believes that NRC analysts need more guidance on making bundling judgments. They claim that because NRC's guidance is confusing and provides no meaningful standard, it is easier for the NRC staff to aggregate requirements without explanation.

Response: The NRC's guidance is consistent with that provided in the Office of Management and Budget's (OMB) Circular A-4, "Regulatory Analysis" issued September 17, 2003, in which OMB recognizes the need to examine individual provisions separately and goes on to state:

> Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

The OMB circular recognizes that judgment must be used for such analyses. The level of analysis needs to be tempered by many factors such as controversiality, complexity, magnitude of consequences, and the like. Also, each regulatory analysis could possibly have unique features that would likely affect the type of analysis that should be done. Further, NRC

final guidance will include reference to the OMB circular and the NRC does not believe additional guidance is needed.

Comment: NEI claims that the use of an analyst's judgment as proposed by the NRC relies too much on NRC management review and public comment. They state: "The burden should be on the NRC to provide sufficient information to evaluate regulatory analysis decisions."

Response: Regulatory analyses are well founded and rely on sound judgments. This is done through peer review, management oversight, review of public comments, etc., and reliance on the analyst's judgment which is central to the regulatory analysis process. The NRC believes that its guidance ensures that its regulatory analyses will provide sufficient information for the public to evaluate regulatory decisions and makes the process both "meaningful and scrutable."

Comment: NEI quotes the SRM calling for regulatory analyses to be "meaningful and scrutable" and claims that the analysis cannot meet this requirement unless there is some documented basis for disaggregation.

Response: The NRC believes that regulatory analyses prepared under the revised guidelines are "meaningful and scrutable," especially given that the guidance is consistent with that provided by OMB on this issue. The reason for disaggregation would be discussed in each regulatory analysis on a case-by-case basis.

Comment: NEI states that the proposed criteria are inconsistent with the other detailed guidance on the treatment of values and impacts contained in NUREG/BR/0058, as currently written.

Response: The NRC disagrees with this comment and believes this final guidance clarifies and supports existing guidance in NUREG/BR-0058. Further, the NRC believes this new guidance is directly relevant to the current discussion on the identification of alternatives.

This guidance considers the scope of requirements and the variability in physical and technical requirements as bases for defining alternatives. This bundling issue should be viewed as an extension or clarification of that discussion.

Comment: NEI states with respect to bundling that the "proposed criteria do not establish a common understanding of new requirements, do not establish a scrutable process for making regulatory decisions about voluntary initiatives, and do not provide sufficient documentation to inform future decisions."

Response: The NRC reiterates its position that "bundling" guidance sets forth in detail how an analyst should handle the "bundling" issue and is also consistent with the cited OMB guidance. The NRC also believes that regulatory analyses and supporting documentation prepared under the revised guidance will be sufficient to provide documentation which may be reviewed to inform future decisions. The NRC notes that regulatory analyses are prepared as tools to support reasoned decision making and public understanding of the NRC's decisions; in this regard, the NRC believes that the revised guidelines achieve these objectives.

Comment: NEI requests that the NRC defer its final decision on these criteria until previous comments are "properly addressed."

Response: Sufficient information was not provided to defer a final decision. The NRC maintains that it has properly addressed all public comments. Also, the Advisory Committee on Reactor Safeguards has stated in a July 17, 2003, letter from its Chairman, Mario V. Bonaca, to the Chairman of the Commission, that the NRC staff's criteria "are appropriate and responsive to the Commission's direction."

Comment: NRSG stated that the NRC should require separate analysis of individual requirements to the extent practicable. They went on to state "that disaggregation of requirements should be the preferred approach, with the burden on the NRC to justify why separate analysis of individual requirements is not appropriate in a given case."

Response: The NRC does not agree with the commenter that disaggregation of all requirements is by default either practicable or desirable. The underlying purpose of a regulatory analysis is to provide decision makers with a tool for choosing between options or alternatives. When a regulatory initiative has a number of discreet, yet *necessary* requirements, the decision maker's choice is not whether to include or exclude *necessary* individual requirements but, rather, whether or not to enact the initiative as a whole. Determining the costs of each necessary requirement provides no additional value to the regulatory analysis because those costs are not discretionary with respect to the proposed action under review. Thus, analyses of necessary individual requirements present information which is irrelevant to the decision making.

Further, as stated in the proposed criteria, published for public comment in the *Federal Register* on April 18, 2003 (68 FR 19162): "Specifically, this guidance states that a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality, and that a more detailed disaggregation would only be appropriate if it produces substantially different alternatives with potentially meaningful results." This implies that the analyst must be able to demonstrate that any aggregation in the analysis would not result in different conclusions of the analysis. Therefore, the NRC still does not believe that disaggregation in all cases should be the preferred approach and stands by the position stated in the proposed criteria. As stated in the guidance, "the NRC does not believe that there should be a general requirement for a separate analysis of each individual requirement of a rule. This could lead to unnecessary complexities." Also, NRC believes that its guidance is consistent with OMB Circular A-4, cited above.

Comment: NRSG states that if, according to the criteria, an individual requirement must be both "related" to the stated objective of the regulatory initiative and be "cost-beneficial," then the NRC should clarify what it means by "cost-beneficial." The commenter also states that the

criteria for the treatment of any individual requirement must be consistent with the standards of the backfitting rule. Under the backfit rule, any new requirement that is a backfit must be shown to be cost-justified and produce a "substantial increase" in overall safety. Lastly, their final two points in this section are in agreement with the NRC criteria. First, the commenter agrees with the NRC that in "cases where a new backfit requirement is being considered for inclusion in a voluntary alternative, to current regulations . . . NRC should consider imposing such a new requirement, if justified under the standards of Section 50.109, through the normal disciplined backfitting process, . . . rather than merely including it in a voluntary-alternative rule." Second, NRSG "agree(s) with the NRC position that if an individual backfit requirement is *not* related to the objective of the regulatory initiative . . . , the 'requirement must be addressed and justified as a backfit separately.'"

Response: For the most part, the NRC agrees with these comments. With respect to the NRC's meaning of "cost-beneficial" in the situation discussed by the commenter, the NRC means that the regulatory initiative results in a larger net benefit than would accrue to an action without that requirement. An individual requirement is related to the stated regulatory objective of the regulatory initiative and, overall, is cost justified and constitutes a substantial increase in safety.

Comment: NRSG stated that there should be further guidance on backfitting issues related to the American Society of Mechanical Engineers (ASME) Code. Specifically, they state:

> NRC's guidance should allow the NRC discretion to perform a cost-benefit analysis of individual new requirements contained in later editions of Section XI before they are incorporated wholesale into Section 50.55a. If the NRC finds that individual new requirements of later Code editions are not cost-beneficial for some or all plants, the

> NRC should screen out those new individual requirements in accordance with the standards of the backfitting rule.

Response: The Commission's policy regarding Inservice Inspection (ISI) requirements is to assure the integrity of the reactor coolant system (RCS) boundary and containment as they relate to defense-in-depth considerations, that do not lend themselves to cost/benefit analyses. Further, in this specific instance, cost/benefit analyses are not well suited to determine if new requirements that address aging on components are appropriate because of the many uncertainties associated with the effects of aging.

When the Commission formulated its policy, the then Chairman stated that: "Both the ASME and the ACRS have strongly urged that the Commission maintain the current updating requirement" and that –

> ASME asserts that the failure of the NRC to incorporate later editions of the Code in the requirements, absent justification under a backfit analysis, would serve to undermine ASME because of the disincentive of volunteers to engage themselves in an ASME process that will not necessarily affect operating plants. Moreover, because some states routinely establish requirements based on current ASME codes, the acceptance of the staff's approach would create the anomaly that non-nuclear facilities might be required to conform to more modern codes than nuclear facilities.

The Chairman also indicated he was aware "that industry participates in the development of the ASME codes and that costs are considered in the amendment process. Thus, although the revisions may not be analyzed with the rigor required by our backfit analysis, the costs and benefits are implicitly weighed."

Another Commissioner commented:

> 10 CFR 50.109 has served the NRC, our licensees, and our stakeholders well, and thus, my decision to not subject ASME Code updates to its backfit provisions was made only after I carefully considered how the staff's recommended option should exacerbate the complexity, inconsistency, and program divergence associated with our current update process. My decision also came after considering the diverse makeup of the ASME members that produce Code changes and the consensus process they use. . . . I believe that considerations of increased safety versus cost are implicit in the ASME consensus process.

In sum, NRSG's suggested approach is inconsistent with the Commission's previous guidance to the staff.

III. Final Criteria

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is cost-justified. However, aggregating or "bundling" different requirements in a single analysis could potentially mask the inclusion of an unnecessary individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second unnecessary requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis,[1] the net benefit from one requirement could potentially support another requirement that is not cost-justified.[2]

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[1] "The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (NUREG/BR-0058) have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the Backfit Rule and the provisions of the CRGR Charter.

[2] This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine if it is appropriate to include each individual requirement. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives[3] that are the focus of the regulatory initiative.

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should follow the following guideline:

> If the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and benefits of the regulatory initiative with and without the individual requirement included, and a direct comparison of those results.[4]

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documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

[3]The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

[4]There may be circumstances in which the analyst considers including an individual requirement that is unrelated to the overall regulatory initiative. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory initiative more cost-beneficial. In those instances in which the individual requirement is a backfit, the requirement must be addressed and justified as a backfit separately. These backfits are not to be included in the overall regulatory analysis of the remainder of the regulatory initiative.

In applying this guideline, the NRC will need to separate out the discrete requirements in order to evaluate their effect on the cost-benefit results. In theory, each regulatory initiative could include several discretionary individual requirements and each of those discretionary requirements could be comprised of many discrete steps, in which each discrete step could be viewed as a distinct individual requirement. This raises the potential for a large number of iterative cost-benefit comparisons, with attendant analytical complexities. Thus, considerable care needs to be given to the level of disaggregation that one attaches to a discretionary requirement.

In general, a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality. For example, more detailed disaggregation is only appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public comment stage.[5] For further guidance, the analyst is referred to principles regarding the appropriate level of detail to be included in a regulatory analysis, as discussed in Chapter 4 of the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

In some cases, an individual requirement that is being considered for inclusion in a voluntary alternative to current regulations may be justifiable under the backfit criteria. In these cases the individual requirement is both cost-justified and provides a substantial increase in the overall protection of the public health and safety or the common defense and security. If so, the

[5]See NUREG/BR-0053, Revision 5, March 2001, "U.S. Nuclear Regulatory Commission Regulations Handbook," Section 7.9, for discussion of how to treat comments.

NRC should consider imposing the individual requirement as a backfit affecting all plants to which it applies, rather than merely including it in a voluntary-alternative rule affecting only those plants where the voluntary alternative is adopted.

A special case involves the NRC's periodic review and endorsement of voluntary consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. These NRC endorsements can typically involve hundreds, if not thousands, of individual provisions. Thus, evaluating the benefits and costs of each individual provision in a regulatory analysis can be a monumental task. Further, the value gained by performing such an exercise appears limited. These voluntary consensus standards tend to be noncontroversial and have already undergone extensive external review and been endorsed by industry. Although regulatory actions endorsing these voluntary consensus standards must be addressed in a regulatory analysis, it is usually not necessary for the regulatory analysis to address the individual provisions of the voluntary consensus standards.

The NRC believes this is appropriate for several reasons:

(1) It has been longstanding NRC policy to incorporate later versions of the ASME Code into its regulations; and thus, licensees know when receiving their operating licenses that updating the ASME Code is part of the regulatory process;

(2) Endorsement of the ASME Code is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking; and

(3) These voluntary consensus standards undergo significant external review and discussion before being endorsed by the NRC.

Some aspects of these regulatory actions endorsing voluntary consensus standards are backfits which must be addressed and justified individually. For example, NRC endorsement

(incorporation by reference) of the ASME Boiler and Pressure Vessel Code (BPV) provisions on inservice inspection and inservice testing, and the ASME Operations and Maintenance (OM) Code, are not ordinarily considered backfits, because it has been the NRC's longstanding policy to incorporate later versions of the ASME codes into its regulations. However, under some circumstances the NRC's endorsement of a later ASME BPV or OM Code is treated as a backfit. The application of the backfit rule to ASME code endorsements is discussed in the Appendix below. Aside from these backfits, these regulatory analyses should include consideration of the major features (e.g., process changes, recordkeeping requirements) of the regulatory action which should then be aggregated to produce qualitative or quantitative estimates of the overall burdens and benefits in order to determine if the remainder of the action is justified.

Dated in Rockville, Maryland, this _____ day of _____, 2004.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission.

APPENDIX

Guidance on backfitting related to ASME codes

Section 50.55a requires nuclear power plant licensees to construct ASME *Boiler and Pressure Vessel Code* (BPV Code) Class 1, 2, and 3 components under the rules provided in Section III, Division 1, of the ASME BPV Code; inspect Class 1, 2, 3, Class MC, and Class CC components under the rules provided in Section XI, Division 1, of the ASME BPV Code; and test Class 1, 2, and 3 pumps and valves under the rules provided in the ASME *Code for Operation and Maintenance of Nuclear Power Plants* (OM Code). From time to time, the NRC amends 10 CFR 50.55a to incorporate by reference later editions and addenda of: Section III, Division 1, of the ASME BPV Code; Section XI, Division 1, of the ASME BPV Code; and the ASME OM Code.

Section A. Incorporation by reference of later editions and addenda of Section III, Division 1 of ASME BPV Code

Incorporation by reference of later editions and addenda of Section III, Division 1, of the ASME BPV Code is prospective in nature. The later editions and addenda do not affect a plant that has received a construction permit or an operating license, or a design that has been approved because the edition and addenda to be used in constructing a plant are, by rule, determined on the basis of the date of the construction permit and are not changed, except voluntarily by the licensee. Thus, incorporation by reference of a later edition and addenda of Section III, Division 1, does not constitute a “backfitting” as defined in § 50.109(a)(1).

Section B. Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV and OM Codes

Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV Code and the ASME OM Code affect the ISI and IST programs of operating reactors. However, the backfit rule generally does not apply to incorporation by reference of later editions and addenda of the ASME BPV (Section XI) and OM codes for the following reasons--

(1) The NRC's longstanding policy has been to incorporate later versions of the ASME codes into its regulations; thus, licensees know when receiving their operating licenses that such updating is part of the regulatory process. This is reflected in § 50.55a which requires licensees to revise their in-service inspection (ISI) and in-service-testing (IST) programs every 120 months to the latest edition and addenda of Section XI of the ASME BPV Code and the ASME OM Code incorporated by reference into § 50.55a that is in effect 12 months before the start of a new 120-month ISI and IST interval. Thus, when the NRC endorses a later version of a code, it is implementing this longstanding policy.

(2) ASME BPV and OM codes are national consensus standards developed by participants with broad and varied interests, in which all interested parties (including the NRC and utilities) participate. This consideration is consistent with both the intent and spirit of the backfit rule (*i.e.,* the NRC provides for the protection of the public health and safety, and does not unilaterally imposed undue burden on applicants or licensees).

(3) Endorsement of these ASME codes is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking.

Section C. Other circumstances where the NRC does not apply the backfit rule to the endorsement of a later code

Other circumstances where the NRC does not apply the backfit rule to the endorsement of a later code are as follows--

(1) When the NRC takes exception to a later ASME BPV or OM code provision, but merely retains the current existing requirement, prohibits the use of the later code provision, or limits the use of the later code provision, the Backfit Rule does not apply because the NRC is not imposing new requirements. However, the NRC provides the technical and/or policy bases for taking exceptions to the code in the Statement of Considerations for the rule.

(2) When an NRC exception relaxes an existing ASME BPV or OM code provision but does not prohibit a licensee from using the existing code provision.

Section D. Endorsement of later ASME BPV or OM codes that are considered backfits

There are some circumstances when the NRC considers it appropriate to treat as a backfit the endorsement of a later ASME BPV or OM code–

(1) *When the NRC endorses a later provision of the ASME BPV or OM code that takes a substantially different direction from the currently existing requirements, the action is treated as a backfit.* An example was the NRC's initial endorsement of Subsections IWE and IWL of Section XI, which imposed containment inspection requirements on operating reactors for the first time. The final rule dated August 8, 1996 (61 FR 41303), incorporated by reference in § 50.55a the 1992 Edition with the 1992 Addenda of IWE and IWL of Section XI to require that containments be routinely inspected to detect defects that could compromise a containment's structural integrity. This action expanded the scope of § 50.55a to include components that were not considered by the existing regulations to be within the scope of ISI. Because those

requirements involved a substantially different direction, they were treated as backfits, and justified under the standards of 10 CFR 50.109.

(2) *When the NRC requires implementation of later ASME BPV or OM code provision on an expedited basis, the action is treated as a backfit.* This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expedited language. An example was the final rule dated September 22, 1999 (64 FR 51370), which incorporated by reference the 1989 Addenda through the 1996 Addenda of Section III and Section XI of the ASME BPV Code, and the 1995 Edition with the 1996 Addenda of the ASME OM Code. The final rule expedited the implementation of the 1995 Edition with the 1996 Addenda of Appendix VIII of Section XI of the ASME BPV Code for qualification of personnel and procedures for performing ultrasonic (UT) examinations. The expedited implementation of Appendix VIII was considered a backfit because licensees were required to implement the new requirements in Appendix VIII before the next 120-month ISI program inspection interval update. Another example was the final rule dated August 6, 1992 (57 FR 34666), which incorporated by reference in § 50.55a the 1986 Addenda through the 1989 Edition of Section III and Section XI of the ASME BPV Code. The final rule added a requirement to expedite the implementation of the revised reactor vessel shell weld examinations in the 1989 Edition of Section XI. Imposing these examinations was considered a backfit because licensees were required to implement the examinations before the next 120-month ISI program inspection interval update.

(3) *When the NRC takes an exception to an ASME BPV or OM code provision and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code.* An example of this is presented in the portion of the final rule dated September 19, 2002, in which the NRC adopted dissimilar metal piping weld UT examination coverage requirements from those in the ASME code.

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

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[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.