

POLICY ISSUE
(NOTATION VOTE)

August 14, 2014

SECY-14-0087

FOR: The Commissioners

FROM: Mark A. Satorius
Executive Director for Operations

SUBJECT: QUALITATIVE CONSIDERATION OF FACTORS IN THE DEVELOPMENT OF
REGULATORY ANALYSES AND BACKFIT ANALYSES

PURPOSE:

The purpose of this paper is to provide the Commission with the U.S. Nuclear Regulatory Commission (NRC) staff's recommendation for qualitatively considering factors in regulatory analyses and backfit analyses as directed by Staff Requirements Memorandum (SRM)-SECY-12-0157, "Consideration of Additional Requirements for Containment Venting Systems for Boiling Water Reactors with Mark I and Mark II Containments," dated March 13, 2013.

SUMMARY:

In regulatory analyses and backfit analyses, the NRC staff considers many factors both quantitatively and qualitatively, which is consistent with NRC guidance and past Commission direction. Specifically, qualitative consideration of factors is used through NRC risk-informed decisions, adequate protection determinations and cost-justified substantial safety enhancements. Such qualitative evaluations arise when the analysis does not lend itself to a quantitative evaluation due to, for instance, lack of methodologies or data. The use of qualitative considerations is also consistent with other federal and international agencies' practices. In particular, the Office of Management and Budget has published regulatory guidance highlighting that a "good regulatory analysis" includes both qualitative and quantitative considerations. Given the significant precedent for qualitatively considering factors, both within the NRC and externally, the staff has concluded that the current regulatory framework is sound. Nonetheless, the staff recognizes that the lack of specific guidance for how to qualitatively consider factors has led to a perception that such qualitative evaluations can be used arbitrarily. Thus, the staff proposes to update cost-benefit guidance to include a set of

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methods that could be used for qualitative consideration of factors within a cost-benefit analysis for regulatory analyses and backfit analyses. This approach would lead to greater transparency and consistency of NRC decisions. If approved by the Commission, this guidance development would be incorporated into the staff's planned cost-benefit updates that were described in SECY 14 0002, "Plan for Updating the U.S. Nuclear Regulatory Commission's Cost Benefit Guidance," dated January 2, 2014.

BACKGROUND:

On November 26, 2012, the NRC staff recommended modifying boiling-water reactors (BWRs) with Mark I and Mark II reactor containment venting systems by adding engineered filters described in SECY-12-0157. The addition of engineered filters to reactor containment venting systems would limit the release of radioactive materials and would improve the reliability of these systems during severe accident conditions. The staff based its recommendation on a quantitative analysis supplemented by a qualitative analysis. The qualitative analysis for SECY-12-0157 provided the necessary supplemental factors for a sufficient cost justification for installing the engineered filters (i.e., cost-benefit).

In response, the Commission directed the NRC staff, in SRM-SECY-12-0157, to require BWR licensees with Mark I and Mark II containments to upgrade or replace the reliable hardened vents with a containment venting system that is designed and installed to remain functional during severe accident conditions (by preparing and submitting to the Commission a draft modification of Order EA-12-050) and to develop a rulemaking for filtering strategies with drywell filtration and associated severe accident management of BWRs with Mark I and Mark II containments. In addition, the Commission directed the staff, independent of the issue involving BWRs with Mark I and Mark II containments, to "seek detailed Commission guidance regarding the use of qualitative factors in a future notation voting paper." The focus of this paper is on the qualitative consideration of factors in regulatory analyses and backfit analyses for all NRC-licensed activities.¹

It is important to note the broader context for this paper on qualitative analyses. First, it is part of the NRC staff's plan for updating the cost-benefit guidance found in SECY-14-0002. In addition, SECY-14-0002 notes that this paper is linked to SECY-13-0132, "U.S. Nuclear Regulatory Commission Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report," dated December 6, 2013, specifically through Improvement Activity 2, "Establish Commission Expectations for Defense-in-Depth," as defense-in-depth has historically been a factor subject to qualitative consideration by the Commission and the staff in a variety of policy and licensing issues. Furthermore, SECY-13-0132 states that the Risk Management Regulatory Framework (RMRF) Working Group "is exploring an RMRF policy statement, which would be an overall agency policy statement broadly covering a risk management decisionmaking process where defense-in-depth would be a key element." In SRM-SECY-13-0132, the Commission disapproved the staff's proposed Improvement Activity 2²

¹ Although analyses under the National Environmental Policy Act are not in the scope of this paper, the staff notes that Title 10 of the *Code of Federal Regulations* (10 CFR) Section 51.71(d) states that draft environmental impact statements will "to the fullest extent practicable, quantify the various factors considered." In addition, the regulation at 10 CFR 51.71(d) states that "to the extent that there are important qualitative considerations or factors that cannot be quantified, these considerations or factors will be discussed in qualitative terms."

² Specifically, under Improvement Activity 2, the staff proposed the development of a defense-in-depth policy statement that would have included the definition, objectives, and principles of defense-in-depth; associated implementation guidance

regarding defense-in-depth and directed that the objectives of the activity instead be reevaluated in the context of the Commission direction on the RMRF policy statement. The staff held a Category 3 public meeting on May 28, 2014, to seek public feedback on SECY-14-0002 and the staff's qualitative consideration of factors. The results of that meeting informed this SECY paper.

Because of the nature of these prior NRC staff actions and Commission directions, the staff will present to the Commission in this notation vote paper the current practices and guidance for the consideration of qualitative factors and a recommendation for future consideration of such factors.

Qualitative Consideration of Factors within the NRC

In regulatory analyses and backfit analyses for nuclear materials and nuclear power plants, the NRC staff considers many factors both quantitatively and qualitatively, although as discussed later, backfit analyses are limited in the kinds of factors which may be considered. Some reasons which may lead the staff to qualitatively consider a factor rather than quantify it include the following:

- no commonly accepted quantitative measure;
- lack of methodologies to accurately quantify the factor; and
- lack of data to apply to a given quantification methodology.

NRC guidance allows for the qualitative consideration of factors. Revision 4 to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," issued September 2004, (hereinafter referred to as the Guidelines), identifies NRC cost-benefit guidance as follows:

Estimated [costs] and [benefits]³ 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.... 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.... [Costs] and [benefits] that are determined to be unquantifiable should be identified and discussed qualitatively.

containing decision criteria for ensuring adequacy of defense-in-depth; and conforming guidance to ensure integration of defense-in-depth with risk.

³ NUREG/BR-0058 uses the terms "impacts" and "values" instead of "costs" and benefits." The term "impacts" is defined as "[t]he costs anticipated from a proposed regulatory action such as, but not limited to, the (1) direct costs to the 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 term "values" is defined as "[t]he 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." NUREG/BR-0058, Rev. 4, p. 22.

An attribute should not be omitted from a regulatory analysis document simply because it is determined to be unquantifiable.⁴

Simply stated, the NRC guidance directs the NRC staff to quantify benefits and costs of a proposed regulatory action to the extent possible. When it is not feasible to quantify benefits and costs, the staff must discuss nonquantifiable elements in qualitative terms. It is also important to consider the inherent uncertainties associated with qualitatively considering factors. This current guidance is consistent with NRC precedent.

Prior to 1983, regulatory analyses were called “value-impact” analyses. These analyses followed the value-impact guidelines in SECY-77-388A, “Value-Impact Guidelines,” dated December 19, 1977. Beginning with this guidance, the NRC staff was instructed to consider, both qualitatively and quantitatively, factors in assessing the incremental value of proposed alternatives in providing “the decisionmaker (e.g., the Commission) with an estimate of what would happen if a certain decision rather than another is made.”⁵ The NRC issued the initial version of the Guidelines in 1983 and the initial version and all subsequent revisions directed the staff to qualitatively consider factors in preparing regulatory analyses.

The Commission adopted the NRC staff’s backfitting requirements as self-imposed restrictions on the agency’s actions (i.e., a statutory requirement for backfitting limitations does not exist). In 1970, the NRC established the Backfit Rule for nuclear power reactors in 10 CFR 50.109, “Backfitting.”⁶ In regard to backfitting under 10 CFR 50.109, the Commission stated in SRM-SECY-93-086, “Backfit Considerations,” dated June 30, 1993, that the “substantial increase” criterion “allow[s] for qualitative [consideration of factors to determine] that a given proposed rule would substantially increase safety.” In backfitting, the benefits (both quantitative and qualitative) are limited to health and safety or common defense and security factors.

The current practice at the NRC, with respect to the qualitative consideration of factors in regulatory analyses and backfitting analyses, is informed by the guidance documents NUREG/BR-0058, NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook,” January 1997, and NUREG-1409, “Backfitting Guidelines,” June 1990. Generally, these guidance documents describe how to estimate values for use in a cost-benefit analysis. These guidance documents also provide that the NRC staff should use a qualitative analysis for those attributes when there is not enough data, or when there are no accepted models to support a

⁴ NUREG/BR-0058, Rev. 4, p. 24.

⁵ SECY-77-388A (ADAMS Accession No. ML12234B122), p. 17. Commission direction is based upon Commission comment in an August 5, 1977, memo from SECY to the EDO provided as Enclosure A to SECY-77-388 and discussion during the briefing for Commissioner Kennedy.

⁶ The regulations at 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” establish the analogous backfitting provisions that apply to early site permits and standard design certifications, which the staff refers to as “issue finality” provisions. These issue finality provisions, which differ from those in 10 CFR 50.109, are 10 CFR 52.39, “Finality of Early Site Permit Determinations,” 10 CFR 52.63, “Finality of Standard Design Certifications,” 10 CFR 52.59, “Criteria for Renewal” (addressing finality during renewal of standard design certifications), 10 CFR 52.83, “Finality of Referenced NRC Approvals; Partial Initial Decision on Site Suitability,” and 10 CFR 52.98, “Finality of Combined Licenses; Information Requests.”

The backfit requirements for materials facilities, each entitled “Backfitting,” are 10 CFR 70.76, 10 CFR 72.62, and 10 CFR 76.76. These provisions are similar to the reactor backfit requirements; however, some differences do exist. For example, the backfit provision in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” has limited applicability (i.e., backfit provisions apply only to Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material,” of 10 CFR Part 70).

quantitative analysis. These NUREGs, however, provide no specific guidance on which tools to use for the qualitative evaluation of factors, or the relative importance of factors for cost-benefit analysis outcomes. The analyst has a degree of flexibility and ability to choose evaluation techniques that are meaningful to the decision. The staff has qualitatively considered factors in the majority of NRC regulatory analyses and backfitting analyses.

Enclosure 1 provides a list of past NRC regulatory actions since 1998 for which qualitative considerations were elements in the NRC staff's recommendation and a list of the factors which were qualitatively considered in these past actions.

NRC Risk-Informed Decisions

The technical and policy bases for the qualitative consideration of factors are well established within the NRC's regulatory processes. The Commission's Safety Goals and Probabilistic Risk Assessment Policy Statements include the importance of qualitatively considering factors, such as the NRC's defense-in-depth philosophy and analysis uncertainties. Similarly, the NRC staff's integrated risk-informed approach includes the qualitative consideration of factors, following the guidance in Revision 2 to Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," (May 2011). Regulatory Guide 1.174 states that decisions "are expected to be reached in an integrated fashion, considering traditional engineering and risk information, and may be based on qualitative factors, as well as quantitative analyses and information."⁷ In addition, fuel cycle facility applicants and licensees are allowed to use qualitative methods in their integrated safety analyses to demonstrate compliance with the consequence and likelihood performance requirements of 10 CFR 70.61.⁸

Adequate Protection Determinations

The Commission has used qualitatively considered factors or other policy considerations in determining whether a regulatory action rises to the level of adequate protection. The concept of adequate protection is limited to considerations of public health and safety and common defense and security as discussed in SECY-12-0110, "Consideration of Economic Consequences within the U.S. Nuclear Regulatory Commission's Regulatory Framework," and, as mentioned in the January 10, 2014, Commission meeting on Near-Term Task Force Recommendation 1, is a level that is determined at the discretion of the Commission.⁹ The only quantitative measures that are somewhat related to the consideration of adequate protection for power reactors is the safety goal surrogates (i.e., core damage frequency and containment failure probability) to the quantitative health objectives. Specifically, the NRC's Regulatory Analysis Guidelines provide guidance that the NRC should make a determination regarding adequate protection or compliance for a change in core damage frequency (CDF) greater than 1×10^{-4} per reactor year accompanied with a conditional containment failure probability greater than 0.1. However, a change in CDF cannot be applied in evaluating all potential regulatory

⁷ NRC Regulatory Guide 1.174, Rev. 2, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," p.6 (ADAMS Accession No. ML100910006).

⁸ See 10 CFR 70.61 and NUREG-1520 Rev. 1 "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," May 2010.

⁹ This and other NRC webcasts are available on the NRC public website at <http://video.nrc.gov/>.

actions (e.g., spent fuel pools and materials), and in some cases, determining the change in CDF would be difficult (e.g., safeguards).

Cost-Justified Substantial Safety Enhancement (Backfitting)

If the goal of a proposed backfitting action is to provide an additional level of safety or security, above and beyond adequate protection, then the NRC must conduct a backfit analysis which includes the consideration of costs. The NRC's backfit rule for power reactors (10 CFR 50.109) states, in part, the following:

[T]he Commission shall require the backfitting of a facility only when it determines ... that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.¹⁰

NUREG-1409, "Backfitting Guidelines," (July 1990), provides for the qualitative consideration of factors in the development of a backfit analysis. NUREG-1409 states that "the backfit rule does not require a strict quantitative showing that benefits exceed costs."¹¹ It further states the following:

Qualitative factors can be considered. Many of the factors to be addressed in the analysis may not be easily quantified, and the backfit rule permits consideration of other relevant and material factors.¹²

The qualitative consideration of factors in NRC regulatory analyses and backfit analyses is consistent with the Guidelines and the practices of other Federal agencies.

Qualitative Consideration of Factors in Other Federal and International Agencies

President Clinton issued Executive Order (E.O.) 12866, "Regulatory Planning and Review," in September 1993.¹³ E.O. 12866 directed Federal executive agencies to assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.¹⁴ Section 1(a) of E.O. 12866 states the following:

Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures

¹⁰ 10 CFR 50.109(a)(3)

¹¹ NUREG-1409, Section 2.1.3(1)(b), p.5

¹² Id.

¹³ E.O. 12866 is available on the White House's Web site at http://www.whitehouse.gov/omb/inforeg_riaguide/.

¹⁴ In February 2002, President George W. Bush issued E.O. 13258, which reaffirms and supports E.O. 12866. In January 2007, he issued E.O. 13422, which reaffirms and supports E.O. 12866. In January 2011, President Obama issued E.O. 13563, which reaffirms and supports E.O. 12866. E.O. 13563 states the following:

Our regulatory system...must take into account benefits and costs, both quantitative and qualitative.... [E]ach agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. Where appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify.

of costs and benefits that are difficult to quantify but nevertheless essential to consider.¹⁵

The Office of Management and Budget (OMB) published regulatory analysis guidance in Circular A-4, "Regulatory Guidance," which it published on September 17, 2003. Circular A-4 states that a "good regulatory analysis include(s)...an evaluation of the benefits and costs—quantitative and qualitative." Circular A-4 further states the following:

With this information, [the staff] should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified, as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, [the staff] should also identify them in [the staff's] analysis so policymakers can compare them with the monetary benefits and costs. When [the staff's] analysis is complete, [the staff] should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.¹⁶

The OMB Office of Information and Regulatory Affairs (OIRA) has noted that many agency "major rules have important nonquantified benefits and costs that may have been a key factor in an agency's decision to select a particular approach."¹⁷ Enclosure 2 lists those rules reviewed by OMB from October 1, 2011, through September 30, 2012.

The OMB OIRA has published a primer¹⁸ to assist agencies in developing regulatory analyses. The primer explains how Federal executive agencies should address benefits and costs that are difficult to quantify. It states, in part, the following:

Benefits and costs that are difficult to quantify. If the agency cannot quantify a benefit or cost, the agency should explain why and present any available quantitative information. For example, the agency may not be able to quantify the number of individuals exposed to a risk but may be able to quantify the magnitude of the risk to those who are exposed. The agency should also provide a detailed qualitative description of any unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. The agency should provide a discussion of the strengths and limitations of the qualitative information.¹⁹

¹⁵ 58 FR 51735; October 4, 1993.

¹⁶ OMB Circular A-4 (ADAMS Accession No. ML11231A834), p. 3.

¹⁷ See the OIRA report entitled, "2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act," issued April 2013, p. 17. This report is available at <http://www.whitehouse.gov/omb/inforeg/regpol/reports/congress/>.

¹⁸ See the OMB OIRA primer entitled, "Regulatory Impact Analysis: A Primer," which is available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/regpol/circular-a-4_regulatory-impact-analysis-a-primer.pdf.

¹⁹ OMB OIRA primer, p. 13.

In summarizing the regulatory analysis, the primer instructs NRC staff to rank qualitative impacts, which should be categorized or ranked “in terms of their importance (e.g., certainty, likely magnitude, and reversibility).”²⁰ The regulatory analysis should also “distinguish the effects that are likely to be significant enough to warrant serious consideration by decisionmakers from those that are likely to be minor.”²¹

The NRC’s established regulatory review procedures, provided in the Guidelines and other related guidance documents, support qualitative evaluations consistent with the provisions of E.O. 12866. Furthermore, the NRC staff has voluntarily complied with Circular A-4 since its issuance. Therefore, the NRC’s regulatory analysis process, particularly the qualitative consideration of factors, is consistent with those agencies subject to E.O. 12866.²²

The International Atomic Energy Agency and the Organization for Economic Cooperation and Development (OECD) Nuclear Energy Agency (NEA) provide little direct guidance on qualitative consideration of factors in cost-benefit analyses. The OECD/NEA report entitled “Methodologies for Assessing the Economic Consequences of Nuclear Reactor Accidents,” dated April 25, 2000,²³ provided methodologies and techniques to quantify the economic effects of nuclear reactor accidents and suggested uses of the methodologies. This report, however, also discusses the instances when one cannot quantify a factor and emphasizes the importance of qualitative considerations.

Enclosure 2 further discusses techniques used by other Federal agencies and international organizations to qualitatively consider factors in cost-benefit analysis.

DISCUSSION:

Based on the availability of quantitative information, four scenarios emerge that involve the qualitative consideration of factors within a cost-benefit analysis for a regulatory analysis and backfit analysis. The four scenarios are outlined as follows:

- Scenario A: Benefits cannot be quantified and are presented only qualitatively. The costs are quantified. This scenario has applied to security-related regulatory actions and nonpower reactor regulatory actions.
- Scenario B: Some benefits can be quantified. Costs are quantified. The net benefit of the quantitative analysis is positive, and the NRC staff’s qualitative consideration of those factors that cannot be quantitatively evaluated, strengthen the staff’s cost-benefit justification.
- Scenario C: Some benefits can be quantified. Costs are quantified. The net benefit of the quantitative analysis is negative; however, the NRC staff relies upon its qualitative consideration of those factors that cannot be quantitatively evaluated to otherwise

²⁰ Id., p. 16.

²¹ Id.

²² Section 3(b) of E.O. 18266 excludes “independent regulatory agencies” from its definition of the term “agency” (58 FR 51737; October 4, 1993).

²³ The OECD/NEA report is available at [10.1787/9789264181472-en](https://www.oecd.org/energy/10.1787/9789264181472-en).

support the action. In this scenario, the staff qualitatively considers those factors in relation to the quantitative measures and makes a recommendation based on that analysis. This was the scenario for the regulatory analysis and backfit analysis in SECY-12-0157.

- Scenario D: Some benefits can be quantified. Costs are quantified. The NRC staff identifies those factors that it qualitatively considers; however, the staff does not consider them in the quantitative analysis and does not make a recommendation in regard to those factors. The staff relies on the Commission to qualitatively consider those factors that cannot be quantitatively evaluated. In this scenario, those factors that cannot be quantitatively evaluated are normally minor considerations and thus, not significant enough to make a change in the recommendation.

The qualitative consideration of factors in regulatory decisionmaking is important to the overall understanding and discussion of the impacts of a regulatory action. This consideration should be consistent with the Commission's 1995 Probabilistic Risk Assessment (PRA) Policy Statement and Regulatory Guide 1.174. Such considerations are also aligned with the practices of other Federal agencies and international bodies. Thus, the current framework for the qualitative consideration of factors is satisfactory and forms the basis for the staff's recommendation, recognizing that the staff would be improving the presentation of qualitative consideration of factors in regulatory analyses and backfit analyses and making the qualitative consideration of factors more reflective of Commission Policy. Enclosure 3 describes some of these methods and includes a discussion of threshold analyses, bounding analysis, cost-effectiveness analysis, internal rate of return, and qualitative assessment supplemented by decision analysis tools.

The current framework for the qualitative consideration of factors within regulatory analyses and backfitting analyses has been working to inform NRC decisionmakers about the whole range of information that is pertinent to the decision. However, because of lack of specific guidance on the qualitative consideration of factors, the perception is that such qualitative evaluation can be arbitrarily weighted against the cost-benefit quantitative assessment to arrive at a recommendation that is not predictable or consistent. In other words, would different NRC staff at a different time, given the same information and conditions, come to a different assessment or qualitative weighting of those factors to arrive at a different recommendation? Although the current guidance on the qualitative consideration of factors provides flexibility to the analyst, such that the right factors and the right assessment tools can be chosen for the specific information available and the specific decision to be made, this flexibility may not foster consistency in analysis outcomes and result in a perceived negative effect on regulatory stability. The staff finds that developing guidance clarifying the potential tools available to analysts for the qualitative evaluation of factors would enhance the clarity and consistency of the regulatory process. Similarly, the staff finds that developing guidance on how staff should document the qualitative consideration of factors for a given regulatory action, particularly when such factors are compared with the quantitative costs of such action, would improve transparency of the NRC's decisions.

Staff's Proposal

The staff proposes updating cost-benefit guidance, including the Guidelines, to include a set of methods that could be used for the qualitative consideration of factors within a cost-benefit analysis for regulatory analyses and backfit analyses. The revised Guidelines would provide methods to assist the staff in developing the rationale of how the staff's recommendation

considered quantitative analysis with the qualitative consideration of those factors that cannot be quantitatively evaluated, where practical. These methods will be consistent with the PRA Policy Statement through Regulatory Guide 1.174. Part of the rationale would include describing the qualitative evaluation of such factors and the significance of each factor, and how they contribute to the integrated decisionmaking process. The staff would develop and formalize these methods consistent with its plans to update the agency's cost-benefit guidance (i.e., SECY-14-0002). Additionally, the guidance revision would preserve emphasis that quantifying estimates of benefits and costs are preferable to qualitative descriptions of benefits and costs. The revised guidance would also include information regarding how and when to apply the methodologies (see Enclosure 3) and how the results of the analyses would be used to inform decisions, so that the tools would be applied consistently. Upon completion, the staff will submit the updated guidance document to the Commission.

The advantages for this approach include:

- establishes a systematic process for the qualitative consideration of factors that cannot be quantitatively evaluated;
- increases transparency of how the NRC staff's recommendation qualitatively considered such factors in relation to the quantitative analysis; and
- increases consistency across business lines in regard to the qualitative consideration of factors for regulatory analyses and backfit analyses.

The disadvantages for this approach include:

- increases NRC staff resources for each regulatory analysis and backfit analysis given the more robust description of qualitative considerations;
- increases staff resources to update the cost-benefit analysis guidance to include a set of methods that could be used for the qualitative consideration of factors; and
- the qualitative consideration of factors remains subjective and may imply objectivity by formalizing the process.

RECOMMENDATION:

The NRC staff recommends that the Commission approve the staff's plans for updating guidance regarding qualitatively considering factors in regulatory analyses and backfit analyses. These updates would be implemented in accordance with the staff's plans for holistically updating cost-benefit guidance found in SECY-14-0002.

RESOURCE IMPLICATIONS:

Resources are currently included in the fiscal year (FY) 2014 Current Estimate and the FY 2015 Congressional Budget Justification, to update cost-benefit guidance to include a set of methods that could be used for the qualitative consideration of factors within a cost-benefit analysis for regulatory analyses and backfit analyses. A detailed breakdown of resources by business line

and preliminary estimates of resources for future years are provided in Enclosure 4. Resources beyond FY 2016 will be addressed during the Planning, Budgeting, and Performance Management process.

COORDINATION:

The Office of the General Counsel has reviewed this Commission paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection.

Interactions with the Advisory Committee on Reactor Safeguards

The NRC staff has plans to discuss the qualitative consideration of factors in the development of regulatory analyses and backfit analyses with the Advisory Committee on Reactor Safeguards in the Fall of 2014.

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Enclosures:

1. [List of Regulatory Actions That Rely Upon the Qualitative Consideration of Factors](#)
2. [The Qualitative Consideration of Factors by External Organizations](#)
3. [Evaluation Techniques for Benefits and Costs That Are Difficult To Quantify](#)
4. Resources Estimates

LIST OF REGULATORY ACTIONS THAT RELY UPON THE QUALITATIVE CONSIDERATION OF FACTORS

The U.S. Nuclear Regulatory Commission (NRC) staff performed a review of backfit analyses and regulatory analyses for orders, rulemaking, and other regulatory actions to identify when the NRC staff qualitatively considered factors that cannot be quantitatively evaluated or do not otherwise lend themselves to a quantitative evaluation. The list below includes the types of factors that were qualitatively evaluated by the NRC staff in the list of backfit analyses and regulatory analyses presented in the subsequent tables. The subsequent tables provide a high-level summary of this review for the following factors:

- defense in depth (DID)
- uncertainty
- decreased risk of a security-related event
- decreased risk of exposure to the public
- decreased risk of exposure to workers
- improved state of knowledge
- increased public confidence
- decreased risk of onsite property damage
- decreased risk of offsite property damage
- increased regulatory efficiency
- increased regulatory effectiveness
- tribes given the option of being informed of commercial nuclear waste shipments passing through their reservations
- improvements in knowledge and increased potential for public perception of unauthorized disclosure of safeguards information due to wider dissemination of information
- core damage frequency (CDF) unaffected
- substantial increase to public health and safety
- added assurance that risk of offsite releases is acceptably low
- insufficient information and modeling to quantify
- subversion of detection process
- ineffective fitness-for-duty (FFD) requirements
- ambiguous regulatory language
- technical developments
- FFD program integrity
- reduction of unnecessary burden

- appropriate balance between the prevention and mitigation of severe accidents, including fission product removal, long-term containment pressure, and severe accident management
- hydrogen control
- external events
- severe accident management
- regulatory efficiency
- improvements in knowledge
- general public
- increased and consistent environmental protection (EP) measures that would decrease the risk of exposure to the public
- increased accident mitigation if it is beyond operator actions
- safety and security-related benefits that would offset the cost
- increased defense capabilities
- safeguards and security considerations
- workplace productivity and efficiency
- public perception
- an improved understanding of the emergency core cooling system (ECCS) and containment spray system (CSS) recirculation at pressurized-water reactor (PWR) facilities

Table 1 Orders with Qualitative Discussions in Backfit Determinations¹

ORDER	CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS
Reliable Hardened Severe Accident Capable Vents <i>Order EA-13-109</i>	ML13143A321	Cost-Justified Substantial Safety Enhancement	Quantitative and Qualitative (DID)	ML12312A456 <i>(includes regulatory analysis)</i>
Spent Fuel Pool Instrumentation <i>Order EA-12-051</i>	ML12054A679	Administrative Exemption <i>(significant safety enhancement)</i>	Qualitative	-
Reliable Hardened Containment Vents <i>Order EA-12-050</i>	ML12056A043	Adequate Protection	-	-
Mitigation Strategies for Beyond-Design-Basis External Events <i>Order EA-12-049</i>	ML12056A045	Adequate Protection	-	-

¹ A regulatory analysis was not prepared with Order EA-12-049, Order EA-12-050, and Order EA-12-051. Regulatory analysis requirements for a given action may be eliminated or modified at the discretion of the Commission, the Executive Director of Operations, or a Deputy Executive Director or at the discretion of the responsible U.S. Nuclear Regulatory Commission (NRC) Office Director. A factor that could influence this decision is the degree of urgency associated with the regulatory action. For example, the NRC may need to issue urgent bulletins and orders without regulatory analyses. (See page 5 of Revision 4 to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," issued September 2004.)

Table 2 Rulemaking with Qualitative Discussions in Backfit Analysis or Regulatory Analysis or Both

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions <i>(Title 10 of the Code of Federal Regulations (10 CFR) Parts 30, 40, 70, 170, and 171)</i>	78 FR 32310 (May 29, 2013)	Not a Backfit	Qualitative <i>(the decreased risk of a security-related event will decrease the risk of exposure to the public, will improve the state of knowledge, and will increase public confidence)</i>	-	ML12171A222
Physical Protection of Irradiated Reactor Fuel in Transit <i>(10 CFR 73.37)</i>	78 FR 29550 (May 20, 2013)	Not a Backfit	Qualitative <i>(the decreased risk of a security-related event will decrease the risk of exposure to workers and the public, will decrease the risk of onsite and offsite property damage, and will improve regulatory efficiency)</i>	-	ML120050180
Physical Protection of Byproduct Material <i>(10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, 51, 71, and 73)</i>	78 FR 17007 (March 19, 2013)	Not a Backfit	Qualitative <i>(the decreased risk of a security-related event will decrease the risk of exposure to workers and the public and will decrease the risk of onsite and offsite property damage)</i>	-	ML112920114

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria <i>(10 CFR 52.99)</i>	77 FR 51880 (August 28, 2012)	Not a Backfit	-	-	77 FR 51890–51891 <i>(summarizing regulatory analysis)</i> ML120100062 <i>(qualitative factors listed as decision elements)</i>
Requirements for Distribution of Byproduct Material <i>(10 CFR Parts 30, 31, 32, 40, and 70)</i>	77 FR 43666 (July 25, 2012)	Not a Backfit	Qualitative <i>(increased regulatory efficiency and effectiveness)</i>	-	ML12104A260
Advance Notification to Native American Tribes of the Transportation of Certain Types of Nuclear Waste <i>(10 CFR Parts 71 and 73)</i>	77 FR 34194 (June 11, 2012)	Not a Backfit	Qualitative <i>(tribes given the option of being informed of commercial nuclear waste shipments passing through their reservations and improvements in knowledge and increased potential for public perception of unauthorized disclosure of safeguards information due to wider dissemination of information)</i>	-	ML112220344
Enhancements to Emergency Preparedness <i>(10 CFR 50.47)</i>	76 FR 72560 (November 23, 2011)	Not a Backfit (portion); Cost-justified Substantial Safety Enhancement (portion)	Qualitative <i>(an unaffected CDF decreases the risk of exposure to the public)</i>	ML112971541	ML112971541

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Enhanced Weapons, Firearms, Background Checks, and Security Event Notifications <i>(10 CFR Part 73)</i>	76 FR 6200 (February 3, 2011)	Not a Backfit (portion); Adequate Protection (portion)	Voluntary	76 FR 6231	76 FR at 6226 – 6231 <i>(summarizing regulatory analysis)</i> ML061380803 and ML061440013 <i>(appendices from the October 2006 proposed rule)</i>
Alternate Fracture Toughness Requirements for Protection against Pressurized Thermal Shock <i>(10 CFR 50.61)</i>	75 FR 13 (January 4, 2010)	Not a Backfit	-	-	ML092710544 <i>(regulatory flexibility is discussed as a decision element)</i>
Revisions to Environmental Review for Renewal of Nuclear Power Plant Operating Licenses <i>(10 CFR Part 51) (proposed rule)</i>	74 FR 38117 (July 31, 2009)	Not a Backfit	-	-	ML083460087 <i>(qualitative factors listed as decision elements)</i> <i>Note that the regulatory analysis for the final affirmed rule is ML110760321.</i>
Aircraft Impact Assessment Rule <i>(10 CFR 50.150)</i>	74 FR 28112 (June 12, 2009)	Not a Backfit (portion); Administrative Exemption (portion)	Qualitative <i>(uncertainty; found a substantial increase to public health and safety)</i>	<i>c.f.</i> 74 FR 28144–28145	74 FR 28142
Power Reactor Security Requirements <i>(10 CFR Part 73 and 10 CFR 50.54)</i>	74 FR 13926 (March 27, 2009)	Not a Backfit (portion); Cost-Justified Substantial Safety Enhancement (portion)	Qualitative <i>(provides added assurance that the risk of offsite releases is acceptably low; the reduction in the risk to the public has not been fully quantified because of insufficient information and modeling to support such a justification)</i>	ML083390372 and ML081680090 (appendices)	ML083390372

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Fitness for Duty Programs <i>(10 CFR Part 26)</i>	73 FR 16966 (March 31, 2008)	Cost-Justified Substantial Safety Enhancement	Qualitative <i>(insufficient information and modeling to quantify; subversion of detection process, regulatory efficiency, ineffective FFD requirements, ambiguous regulatory language, technical developments, and FFD program integrity)</i>	73 FR 17172 (portion) ML080580135	ML080580135
Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements <i>(10 CFR Parts 30, 31, 32, and 150)</i>	72 FR 58473 (October 16, 2007)	Not a Backfit	Qualitative <i>(increased regulatory efficiency and effectiveness and the reduction of unnecessary burden)</i>	-	ML071760296
Limited Work Authorizations for Nuclear Power Plants <i>(10 CFR 50.10)</i>	72 FR 57416 (October 9, 2007)	Not a Backfit	-	-	ML071870012 <i>(qualitative factors listed as decision elements)</i>
Requirements for Expanded Definition of Byproduct Material <i>(10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171)</i>	72 FR 55864 (October 1, 2007)	Not a Backfit	Qualitative <i>(the decreased risk of a security-related event will decrease the risk of exposure to workers and the public and will decrease the risk of onsite and offsite property damage)</i>	-	ML070750118

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Licenses, Certifications, and Approvals for Nuclear Power Plants <i>(10 CFR Part 52)</i>	72 FR 49352 (August 28, 2007)	Not a Backfit	-	-	ML071490350 <i>(qualitative factors listed as decision elements)</i>
Design-Basis Threat <i>(10 CFR 73.1)</i>	72 FR 12705 (March 19, 2007)	Adequate Protection	-	-	ML070530193 <i>(qualitative factors discussed as decision elements)</i>
Safeguards Information Protection Requirements <i>(10 CFR Part 73)</i>	73 FR 63546 (October 24, 2008)	Not a Backfit (portion); Adequate Protection (portion)	-	-	ML072190656 <i>(qualitative factors discussed as decision elements)</i>
Emergency Planning and Preparedness for Production and Utilization Facilities <i>(10 CFR Part 50, Appendix E)</i>	70 FR 3591 (January 26, 2005)	Not a Backfit	-	-	70 FR 3595 <i>(qualitative factors discussed as decision elements)</i>
Post-Fire Manual Actions <i>(10 CFR 50.48)</i> <i>(not approved by the Commission)</i>	ML041940511 <i>(SECY-04-0233)</i> ML050180267 <i>(SRM)</i>	Not a Backfit	-	-	ML041950046 <i>(regulatory efficiency and public confidence)</i>
Risk-Informed Categorization and Treatment of SSCs for Nuclear Power Plants <i>(10 CFR 50.69)</i>	69 FR 68008 (November 22, 2004)	Not a Backfit	-	-	ML041000474

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Voluntary Fire Protection Requirements for Light-Water Reactors; Adoption of NFPA-805 as a Risk-Informed, Performance-Based Alternative <i>(10 CFR 50.48)</i>	69 FR 33536 (June 16, 2004)	Not a Backfit	-	-	ML040540542 <i>(regulatory flexibility discussed as a decision element)</i>
Financial Information Requirements for Applications To Renew or Extend the Term of an Operating License for a Power Reactor <i>(10 CFR 50.76)</i>	69 FR 4439 (January 30, 2004)	Not a Backfit	-	-	ML032460795 <i>(qualitative factors discussed as decision elements)</i>
Changes to the Adjudicatory Process <i>(10 CFR Part 2)</i>	69 FR 2182 (January 14, 2004)	Not a Backfit	-	-	69 FR 2231-2232 <i>(qualitative factors discussed as decision elements)</i>

Table 3 Regulatory Actions² with Qualitative Discussions in Backfit Analysis or Regulatory Analysis or Both

REGULATORY ACTION	CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Policy and Key Technical Issues Pertaining to the Westinghouse AP600 Standardized Passive Reactor Design <i>SECY-97-044</i>	ML003708316 (SECY) ML003756168 (SRM)	-	Qualitative (appropriate balance between prevention and mitigation of severe accidents, including fission product removal, long-term containment pressure, and severe accident management)	-	ML003708316
Post-Fire Safe-Shutdown Circuit Analysis Spurious Actuations <i>Generic Letter 2006-XX</i> (issuance of generic letter denied by the Commission)	ML061950031 (SECY) ML063490261 (Commission denial)	Not a Backfit	Qualitative (the quantitative net benefit was negative)	-	ML061950031
Potential Impact of Debris Blockage on Emergency Recirculation during Design-Basis Accidents at PWRs <i>Generic Letter 2004-02</i>	ML042360586	Compliance	Qualitative (the quantitative net benefit was negative)	-	ML042260449
Accept the Guidance in NEI 99-01 as an Alternative Methodology for the Development of Emergency Action Levels <i>Revision 4 of Regulatory Guide 1.101</i>	ML032020276	-	-	-	ML030440632 (qualitative factors discussed as decision elements)
Emergency Response Planning and Preparedness for Nuclear Power Reactors <i>Revision 5 of Regulatory Guide 1.101</i>	ML050730286	Not a Backfit	Voluntary	-	ML050730286 , Page 6

² The staff reviewed bulletins, but it did not find any that had qualitative discussions in the backfit analysis or the regulatory analysis or both.

REGULATORY ACTION	CITATION	BACKFIT DETERMINATION	JUSTIFICATION	LOCATION OF BACKFIT ANALYSIS	LOCATION OF REGULATORY ANALYSIS
Training and Qualification of Security Personnel at Nuclear Power Reactor Facilities <i>Regulatory Guide 5.75</i>	ML091690037	Not a Backfit (portion); Cost-Justified Substantial Safety Enhancement (portion)	Qualitative <i>(relied on the backfit analysis of the power reactor security rule)</i>	76 FR 13968 (March 27, 2009)	-
Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts <i>Regulatory Guide 1.217</i>	ML092900004	Not a Backfit	Voluntary	-	ML112101610 <i>(references 10 CFR 50.150)</i> 74 FR 28112 and 28136 (June 12, 2009)

Table 4 List of Regulatory Actions for which Qualitative Factors Justified a Decision That May Not Have Been Quantitatively Cost Justified

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	QUANTITATIVE JUSTIFICATION^{3,4,5} (millions)	QUALITATIVE JUSTIFICATION	LOCATION OF BACKFIT/REGULATORY ANALYSIS
Reliable Hardened Severe Accident Capable Vents <i>Order EA-13-109</i>		Cost-Justified Substantial Safety Enhancement	Contains costs and benefits (\$50 to \$77) <i>BWR Mark I</i> (\$45 to \$100) <i>BWR Mark II</i>	DID, hydrogen control, external events, and severe accident management	ML12312A456
Requirements for Maintenance of Inspections, Tests, Analyses, and Acceptance Criteria <i>(10 CFR 52.99)</i>	77 FR 51880 (August 28, 2012)	Not a Backfit	(\$2.16 to \$1.98)	Regulatory efficiency, improvements in knowledge, and general public	77 FR 51890-91 <i>(summarizes regulatory analysis)</i> ML120100062 <i>(full regulatory analysis)</i>
Enhancements to Emergency Preparedness <i>(10 CFR 50.47)</i>	76 FR 72560 (November 23, 2011)	Not a Backfit (portion); Cost-Justified Substantial Safety Enhancement (portion)	(\$75.9 to \$59.8)	Increased and consistent EP measures that would decrease the risk of exposure to the public and increased accident mitigation if it is beyond operator actions	ML112971541 <i>(backfit analysis and regulatory analysis)</i>

³ The range of net benefits results from using 3-percent and 7-percent net present values for consistency with NUREG/BR-0058.

⁴ Unless stated otherwise, benefits were not quantified within the quantitative justification.

⁵ The sign convention is “favorable consequences are positive” and “adverse consequences are negative.”

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	QUANTITATIVE JUSTIFICATION^{3,4,5} (millions)	QUALITATIVE JUSTIFICATION	LOCATION OF BACKFIT/REGULATORY ANALYSIS
Enhanced Weapons, Firearms, Background Checks, and Security Event Notifications <i>(10 CFR Part 73)</i>	76 FR 6200 (February 3, 2011)	Not a Backfit (portion); Adequate Protection (portion)	(\$70.2 to \$47.4)	Safety and security-related benefits that would offset the cost, enhanced regulatory efficiency, and increased defense capabilities	76 FR 6231 <i>(backfit analysis)</i> 76 FR 6226–6231 <i>(summarizes regulatory analysis)</i> ML061380803 and ML061440013 <i>(appendices from the October 2006 proposed rule)</i>
Alternate Fracture Toughness Requirements for Protection against Pressurized Thermal Shock <i>(10 CFR 50.61)</i>	75 FR 13 (January 4, 2010)	Not a Backfit	(\$57.3 to \$49.7)	Regulatory efficiency and improvements in knowledge	ML092710544 <i>(regulatory analysis)</i>
Revisions to the Environmental Review for Renewal of Nuclear Power Plant Operating Licenses <i>(10 CFR Part 51)</i> <i>(proposed rule)</i>	74 FR 38117 (July 31, 2009)	Not a Backfit	(\$2.64 to \$2.29)	Improvements in knowledge and regulatory efficiency	ML083460087 <i>(regulatory analysis)</i> <i>Note that the regulatory analysis for the final affirmed rule is ML110760321.</i>
Aircraft Impact Assessment Rule <i>(10 CFR 50.150)</i>	74 FR 28112 (June 12, 2009)	Not a Backfit (portion); Administrative Exemption (portion)	(\$6.0 to \$4.9)	Reduced risk to the public and occupational health and offsite and onsite property, improvements in knowledge, and safeguards and security considerations	<i>c.f.</i> 74 FR 28144–28145 <i>(backfit analysis)</i> 74 FR 28142 <i>(regulatory analysis)</i>

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	QUANTITATIVE JUSTIFICATION^{3,4,5} (millions)	QUALITATIVE JUSTIFICATION	LOCATION OF BACKFIT/REGULATORY ANALYSIS
Power Reactor Security Requirements <i>(10 CFR Part 73 and 10 CFR 50.54)</i>	74 FR 13926 (March 27, 2009)	Not a Backfit (portion); Cost-Justified Substantial Safety Enhancement (portion)	(\$857.3 to \$590.2)	Safeguards and security, regulatory efficiency, and reduced risk to the public and occupational health and offsite and onsite property	ML083390372 <i>(backfit analysis and regulatory analysis)</i> ML081680090 <i>(appendices)</i>
FFD Programs <i>(10 CFR Part 26)</i>	73 FR 16966 (March 31, 2008)	Cost-Justified Substantial Safety Enhancement	(\$694 to \$445) <i>(insufficient modeling)</i>	Reduced risk to the public and occupational health and offsite and onsite property, regulatory efficiency, public perception, and workplace productivity and efficiency	73 FR 17172 <i>(portion of backfit analysis)</i> ML080580135 <i>(backfit analysis and regulatory analysis)</i>
Licenses, Certifications, and Approvals for Nuclear Power Plants <i>(10 CFR Part 52)</i>	72 FR 49352 (August 28, 2007)	Not a Backfit	(\$19.3 to \$10.2) <i>(benefits quantified)</i>	Regulatory efficiency	ML071490350 <i>(regulatory analysis)</i>
Safeguards Information Protection Requirements <i>(10 CFR Part 73)</i>	73 FR 63546 (October 24, 2008)	Not a Backfit (portion); Adequate Protection (portion)	(\$18.8 to \$15.8)	Positive effect on public and occupational health, increased protection of onsite and offsite property, and increased protection of common defense and security of the Nation	ML072190656 <i>(regulatory analysis)</i>
Post-Fire Safe-Shutdown Circuit Analysis Spurious Actuations <i>Generic Letter 2006-XX (issuance of generic letter denied by the Commission)</i>	ML061950031 (SECY) ML063490261 <i>(Commission denial)</i>	Not a Backfit	(\$52.8 to \$67.4) <i>(benefits quantified)</i>	Improvements in knowledge and regulatory efficiency	ML061950031

RULE	FEDERAL REGISTER (FR) CITATION	BACKFIT DETERMINATION	QUANTITATIVE JUSTIFICATION ^{3,4,5} (millions)	QUALITATIVE JUSTIFICATION	LOCATION OF BACKFIT/REGULATORY ANALYSIS
Potential Impact of Debris Blockage on Emergency Recirculation during Design-Basis Accidents at PWRs <i>Generic Letter 2004-02</i>	ML042360586	Compliance	Of the four scenarios provided, some had negative benefits, and the others had positive benefits. <i>(benefits quantified)</i>	Regulatory efficiency, improved understanding of ECCS and CSS recirculation at PWR facilities, improved public health and safety, and increased public confidence	ML042260449
Training and Qualification of Security Personnel at Nuclear Power Reactor Facilities <i>Regulatory Guide 5.75</i>	ML091690037	Not a Backfit (portion); Cost-Justified Substantial Safety Enhancement (portion)	(\$857.3 to \$590.2)	Safeguards and security, regulatory efficiency, and reduced risk to the public and occupational health and offsite and onsite property	76 FR 13968 (March 27, 2009) <i>(relied on the regulatory analysis of the power reactor security rule)</i>
Guidance for the Assessment of Beyond-Design-Basis Aircraft Impacts <i>Regulatory Guide 1.217</i>	ML092900004	Not a Backfit	(\$6.0 to \$4.9)	Reduced risk to the public and occupational health and offsite and onsite property, improvements in knowledge, and safeguards and security considerations	ML112101610 <i>(references 10 CFR 50.150)</i> 74 FR 28112 and 28136 (June 12, 2009) <i>(relied on regulatory analysis of the aircraft impact assessment rule)</i>

THE QUALITATIVE CONSIDERATION OF FACTORS BY EXTERNAL ORGANIZATIONS

The U.S. Nuclear Regulatory Commission staff performed a limited review of how select federal agencies and international organizations qualitatively consider factors in cost-benefit analyses. The information below provides a high-level summary of that review.

Federal Agencies

The Office of Management and Budget (OMB) submits to Congress each year a report entitled “Report to Congress on the Benefits and Costs of Federal Regulations” (OMB Report).¹ The staff reviewed the draft 2013 OMB Report, which summarized estimates made by Federal regulatory agencies of the quantified and monetized benefits and costs of major Federal regulations reviewed by OMB over the last 10 years.²

During fiscal year (FY) 2012, executive agencies issued the 47 major rules listed in Table 1. Of these 47 major rules, 22 rules are transfer rules (i.e., rules that primarily caused income transfers generally from the taxpayer to program beneficiaries); these rules appear in the shaded portions of Table 1. Agencies issue these kinds of rules in response to statutes that authorize and often require them. Although rules that affect Federal budget programs are subject to Executive Orders 12866 and 13563 and OMB Circular A-4, “Regulatory Guidance,” dated September 17, 2003, and are reviewed by OMB, past reports have focused primarily on regulations that have effects largely through private sector mandates.

The remaining unshaded 25 non-transfer rules listed in Table 1 provide information on their monetized benefits, costs, and transfers. Eleven of the 25 nontransfer rules partially monetized either benefits or costs. Two of these rules, the U.S. Department of the Interior’s Migratory Bird Hunting regulations,³ assessed only benefits. Nine rules reported only monetized costs or cost savings and relevant transfers without monetizing benefits. The “Other Information” column in Table 1 describes the potential transfer and non-quantitative effects of these rules.

The 2013 OMB Report also documents major rules issued by independent Federal agencies from October 1, 2011, to September 30, 2012. In this report, the U.S. Government Accountability Office (GAO) reported that 5 agencies issued a total of 21 major rules during this period. Table 2 lists each of these major rules and the extent to which GAO reported the benefits and estimates for the rule. Sixteen of the 21 rules provide some information on the

¹ See Section 624 of the Treasury and General Government Appropriations Act of 2001, Public Law No. 106-554.

² The subject report and all previous reports are available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/2013_cb/2013_cost_benefit_report_updated.pdf. The OMB explains the reason for their 10-year period for aggregation as follows (see page 11 of final report). As discussed in previous reports, OMB chose a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than 10 years ago are of questionable relevance today. The estimates of the benefits and costs of Federal regulations over the period October 1, 2002, to September 30, 2012, are based on agency analyses conducted prior to issuance of the regulation and subjected to public notice, comments, and OMB review under Executive Orders 12866 and 13563.

³ The Department of the Interior issued two sets of Migratory Bird Hunting Regulations, one for the early season and one for the late season.

benefits and costs of the regulation. Six rules included analyses that monetized portions of the costs, although none of the rules analyzed include monetized estimates of benefits.

**Table 1 Summary of the Executive Agency Final Rules Issued between
October 1, 2011, and September 30, 2012
(As of the Date of the Completion of the OMB Review)**

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
U.S. Department of Agriculture				
0584-AD59	Nutrition Standards in the National School Lunch Program (NSLP) and School Breakfast Program (SBP)	Not Estimated	\$479 million Range: \$479–\$500 million	Source: Regulatory Information Services Center/OIRA Consolidated Information System (ROCIS) ⁴ The primary benefit of this rule is to align the regulations with the requirements placed on schools under the National School Lunch Act (NSLA) to ensure that meals are consistent with the goals of the most recent Dietary Guidelines and the Dietary Reference Intakes. It has additional benefits, including an alignment between Federal program benefits and National nutrition policy, improved confidence by parents and families in the nutritional quality of school meals, and the contribution that improved school meals can make to the overall school nutrition environment. Local school food authorities will incur food, labor, and administrative costs to comply with new National School Lunch Program (NSLP) and School Breakfast Program (SBP) meal requirements. State education agencies will incur additional training, technical assistance, and School Food Authorities (SFA) monitoring and compliance costs. The direct regulation of small business does not exist.

⁴ The Regulatory Information Service Center (RISC) of the U.S. General Services Administration operates two information systems for the Office of Information and Regulatory Affairs (OIRA) – the Regulations Review and AGENDA modules of the RISC and OIRA Consolidated Information System (ROCIS) and the Reports Management System (RMS).

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0584-AE15	Certification of Compliance with Meal Requirements for the NSLP under the Healthy Hunger-Free Kids Act of 2010	Not Estimated	\$2 million	Transfers: \$227–\$230 million Source: ROCIS This rule encourages compliance with NSLP and SBP meal standards by providing an additional reimbursement of \$0.06 for lunches that meet the requirements. Costs are a combination of State, School Food Authorities (SFA), and Federal costs, including the administrative costs for submitting and processing compliance claims. Transfers are the sum of transfers from the Federal Government to State agencies plus transfers from the Federal Government to SFA for meal reimbursements.
U.S. Department of Education				
1810-AB12	Teacher Incentive Fund	Not Estimated	Not Estimated	Transfers: \$224 million Source: ROCIS Transfers are from the Federal Government to States, local education agencies, and nonprofits.
1810-AB15	Race to the Top Program—Early Learning Challenge Phase 2	Not Estimated	Not Estimated	Transfers: \$105 million Source: ROCIS Transfers are from the Federal Government to States.
1840-AD11	Federal Pell Grant Program	Not Estimated	Not Estimated	Transfers: \$3,787–\$3,807 million Source: Preamble Transfers are from recipients of a second Pell grant to the Federal Government.
1894-AA01	Race to the Top Program Fund Phase 3	Not Estimated	Not Estimated	Transfers: \$160 million Source: ROCIS Transfers are from the Federal government to States that were runners up in Phase 3 of the Race to the Top Program.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
U.S. Department of Energy				
1904-AB50	Energy Efficiency Standards for Fluorescent Lamp Ballasts	\$1,049 million Range: \$759– \$1,553 million	\$297 million Range: \$178– \$452 million	Source: ROCIS
1904-AB90	Energy Conservation Standards for Residential Clothes Washers	\$1,129 million Range: \$1,010– \$1,802 million	\$151 million Range: \$151– \$253 million	Source: ROCIS
U.S. Department of Health and Human Services				
0938-AO53	Home and Community-Based State Plan Services Program and Provider Payment Reassignments (CMS-2249-P2)	Not Estimated	Not Estimated	Transfers: \$118–\$120 million Source: ROCIS Transfers are from the Federal Government to providers with an additional transfer of \$113–\$115 million (in 2012 dollars) annually from State Governments to providers.
0938-AQ01	Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements Changes in Provider Agreements (CMS-6010-F)	Not Estimated	Not Estimated	Transfers: \$108–\$109 million Source: ROCIS Transfers are from providers and suppliers to the Federal Government. This antifraud measure results in savings due to the reduction in fraud.
0938-AQ11	Administrative Simplification: Adoption of Standards for Electronic Funds Transfer (CMS-0024-IFC)	\$222– \$331 million	\$2–\$3 million	Source: ROCIS

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0938-AQ13	Administrative Simplification: Standard Unique Identifier for Health Plans and ICD-10 Compliance Date Delay (CMS-0040-F)	\$721 million Range: \$425– \$1,017 million	\$469 million Range: \$150– \$758 million	Source: ROCIS
0938-AQ22	Medicare Shared Savings Program: Accountable Care Organizations (ACOs) (CMS-1345-F)	Not Estimated	\$90 million	Transfers: -\$88 million Range: -\$191–\$9 million Source: ROCIS Transfers are from the Federal Government to ACO providers. The low estimate reflects a Federal cost, whereas primary and high estimates reflect Federal savings. Costs represent average startup investments and ongoing annual operating costs borne by ACO participants.
0938-AQ25	Revisions to Payment Policies under the Physician Fee Schedule and Part B for Calendar Year (CY) 2012 (CMS-1524-FC)	Not Estimated	Not Estimated	Transfers: \$15,353 million Source: ROCIS This annual rule revises payment policies under Part B. Transfers are from physicians, other practitioners, and providers and suppliers who receive payments under Medicare to the Federal Government.
0938-AQ26	Changes to the Hospital Outpatient Prospective Payment System (PPS) and Ambulatory Surgical Center Payment System for CY 2012 (CMS-1525-F)	Not Estimated	Not Estimated	Transfers: \$516 million Source: ROCIS Transfers from the Federal Government to Medicare outpatient hospitals added to transfers from the Federal Government to Medicare American Cancer Society providers to derive a total transfers figure.
0938-AQ27	End-Stage Renal Disease (ESRD) PPS for CY 2012, Quality Incentive Program for CY 2013 and CY 2014; Ambulance Fee Schedule; and Durable Medical Equipment (CMS-1577-F)	Not Estimated	\$10 million	Transfers: \$150 million Transfers are the sum of transfers from the Federal Government to Medicare ESRD providers plus transfers from the Federal Government to Medicare ambulance providers less transfers from ESRD providers to the Federal Government. In addition, there is a transfer of \$50 million (in 2011 dollars) from patients to ESRD providers because of the increased beneficiary co-insurance for the ESRD PPS that is not included in the total.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0938-AQ30	Home Health (HH) PPS Refinements and Rate Update for CY 2012 (CMS-1353-F)	Not Estimated	Not Estimated	<p>Transfers: \$344 million</p> <p>Source: ROCIS</p> <p>Transfers are from home healthcare providers to the Federal Government that reflect reduced Government payments to providers. The aggregate impact to the proposed CY 2012 HH PPS reflects the distributional effects of an updated wage index, the 1.4% home health market basket update (\$280 million increase in 2011 dollars), and the 3.79% case-mix adjustment applicable to the National standardized 60-day episode rates.</p> <p>(-\$720 million in 2011 dollars)</p>
0938-AQ35	Community First Choice Option (CMS-2337-F)	Not Estimated	Not Estimated	<p>Transfers: \$1,469–\$1,510 million</p> <p>Source: ROCIS</p> <p>Transfers are from the Federal Government to Medicaid qualified providers with additional transfers of \$1.09–\$1.12 million annually (in 2012 dollars) from State Governments to Medicaid qualified providers.</p>
0938-AQ62	Medicaid Eligibility Expansion Under the Affordable Care Act of 2010 (CMS-2349-F)	Not Estimated	Not Estimated	<p>Transfers: \$23,772–\$24,948 million</p> <p>Source: ROCIS</p> <p>Transfers are from the Federal Government to Medicaid recipients with additional transfers of \$2.6 million (in 2012 dollars) annualized using a 7% discount rate and of \$2.7 million using a 3% discount rate from State Governments to Medicaid recipients.</p>

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0938-AQ67	Establishment of Exchanges and Qualified Health Plans Part I (CMS-9989-F)	Not Estimated	\$552 million Range: \$539–\$552 million	Transfers: \$539–\$552 million Source: ROCIS Benefits include improved access to health insurance with numerous positive effects, including earlier treatment and improved morbidity, fewer bankruptcies, and decreased use of uncompensated care. Exchanges will also serve as a distribution channel for insurance, thus reducing administrative costs as a part of the premiums and providing comparable information on health plans to offer a more efficient shopping experience. Costs are offset by grant outlays from the Federal Government to States to establish exchanges.
0938-AQ84	Medicare and Medicaid Electronic Health Record (EHR) Incentive Program— Stage 2 (CMS-0044-F)	Not Estimated	Range: \$147–\$151 million	Transfers: \$1,941–\$2,033 million Source: ROCIS Transfers are from the Federal Government to Medicare-eligible professionals. Monetized costs include private industry costs associated with the reporting requirements of the rule. Qualitative costs include the impact of EHR activities, such as reduced staff productivity due to the time needed to learn how to use the EHR technology, the need for additional staff to work with health information technology issues, and administrative costs related to reporting.
0938-AQ86	Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 (CMS-4157-F)	Not Estimated	Not Estimated	Transfers: \$3,907–\$3,957 million Source: Calculations based on numbers in the preamble Transfers are from drug manufacturers to Medicare recipients who were in a coverage gap (also called the “donut hole”). The agency lists these transfers as a cost; however, they do not represent a cost to society as a whole. In addition, there is a transfer of \$215 to \$221 million annually (in 2011 dollars) from the Federal Government to Medicare organizations and a transfer of \$0.4 million (in 2011 dollars) annually from Part D sponsors and from Medicare organizations to States.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0938-AQ89	Medicare and Medicaid Programs: Reform of Hospital and Critical Access Hospital Conditions of Participation (CMS-3244-P)	Not Estimated	-\$740 million	Source: ROCIS
0938-AQ96	Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-9070-P)	Not Estimated	-\$102 million	Source: ROCIS
0938-AQ98	Establishment of the Consumer-Operated and -Oriented Plan Program (CMS-9983-F)	Not Estimated	Not Estimated	Transfers: Not Estimated The preamble contains cost and transfer estimates for a single hypothetical buyer.
0938-AR01	Administrative Simplification: Adoption of Operating Rules for Electronic Funds Transfer and Remittance Advice (CMS-0028-IFC)	Range: \$208–\$318 million	\$101–\$262 million	Source: ROCIS
0938-AR07	State Requirements for Exchange— Reinsurance and Risk Adjustments (CMS-9975-F)	Not Estimated	Not Estimated	Transfers: \$7,703–\$7,937 million Source: ROCIS Risk adjustment transfers funds among individual and small group market health plan issuers. Reinsurance collects funds from all issuers and distributes them to individual market issuers. Qualitative benefits include improved access to health insurance, earlier treatment, improved morbidity, fewer bankruptcies, and decreased use of uncompensated care. The exchange will also serve as a distribution channel for insurance, thus reducing administrative costs and providing comparable information on health plans to allow for a more efficient shopping experience.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
0938-AR12	Changes to the Hospital Inpatient and Long-Term Care PPS for FY 2013 (CMS-1588-F)	Not Estimated	Not Estimated	Transfers: \$1,665 million Source: ROCIS Transfers are the sum of transfers from the Federal Government to International Pelvic Pain Society providers plus transfers from the Federal Government to Long Term Care Hospital PPS providers.
0938-AR20	PPS and Consolidated Billing for Skilled Nursing Facilities (SNFs)—Update for FY 2013 (CMS-1432-N)	Not Estimated	Not Estimated	Transfers: \$527 million Source: ROCIS Transfers are from the Federal Government to SNF Medicare providers.
U.S. Department of Homeland Security				
1625-AA32	Standards for Living Organisms in Ships' Ballast Water Discharged in U.S. Waters	\$163 million Range: \$4–\$442 million	\$79 million Range: \$77–\$152 million	Source: Regulatory Impact Analysis (RIA) The primary estimate for benefits in the midpoint of the range is provided as a primary estimate in the RIA. The RIA also includes a wider range of benefits; this range is included as the high and low estimates here.
U.S. Department of the Interior				
1014-AA02	Increased Safety Measures for Oil and Gas Operations on the Outer Continental Shelf	Not Estimated	\$107 million	Source: ROCIS
1018-AX97	Migratory Bird Hunting; 2012–2013 Migratory Game Bird Hunting Regulations—Early Season	\$175–\$231 million	Not Estimated	Source: ROCIS
1018-AX97	Migratory Bird Hunting; 2012–2013 Migratory Game Bird Hunting Regulations—Late Season	\$175–\$231 million	Not Estimated	Source: ROCIS

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
U.S. Department of Justice				
1105-AB34	National Standards To Prevent, Detect, and Respond to Prison Rape	Not Estimated	\$375 million Range: \$367–\$375 million	Source: ROCIS The agency did not estimate benefits; however, it conducted a break-even analysis and concluded that costs would break even with the benefits if the standards are successful in avoiding between 1,667 and 2,329 victims.
U.S. Department of Labor (DOL)				
1205-AB58	Labor Certification Process and Enforcement for Temporary Employment in Occupations Other Than Agriculture or Registered Nursing in the United States (H-2B Workers)	Not Estimated	\$1 million	Transfers: \$70–\$100 million Source: ROCIS Transfers are from employers to domestic and foreign workers and include payments for transportation and wage increases for corresponding employment.
1210-AB08	Improved Fee Disclosure for Pension Plans	Not Estimated	\$51 million Range: \$47–\$51 million	Source: ROCIS The final regulation will increase the amount of information that service providers disclose to plan fiduciaries. Nonquantified benefits include information cost savings, discouragement of harmful conflicts of interest, service value improvements through improved decisions and value, better enforcement tools to redress abuse, and harmonization with other Employees Benefits Security Association rules and programs. The impact analysis of the July 16, 2010, interim final regulation includes a detailed analysis of the nonquantified benefits compared to the quantified costs. Quantified costs include costs for service providers to perform compliance reviews and implementation and for disclosure of general, investment-related, and additional requested information for responsible plan fiduciaries to request additional information from service providers to comply with the exemption and to prepare notices to Department Of Labor if the service provider fails to comply with the request.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
1218-AC20	Hazard Communication	\$619 million Range: \$517–\$1,585 million	\$164 million Range: \$132–\$164 million	Source: ROCIS Benefits reflect 43 fatalities and 585 injuries/illnesses prevented annually.
U.S. Department of Transportation				
2126-AA97	National Registry of Certified Medical Examiners	\$121 million Range: \$58–\$180 million	\$28 million Range: \$25–\$28 million	Source: ROCIS
2126-AB26	Hours of Service	\$526 million Range: \$184–\$1,036 million	\$393 million	Source: ROCIS
2127-AK79	Passenger Car and Light Truck Corporate Average Fuel Economy Standards Model Year (MY) 2017 and Beyond	\$9,207 million Range: \$125 – \$17,924 million	\$2,930 million Range: \$3 – \$6,276 million	Source: ROCIS Primary estimates for costs and benefits are derived from best estimates used in the main analysis and are based on the analysis using the 2010 baseline fleet. Low and high estimates are derived from the uncertainty analysis, which also corresponds to the 2010 baseline fleet. Standards cover MY 2017 through MY 2021 vehicles with annualization performed to base year 2017. Transfer payment impacts will occur due to reduced Federal, State, and local fuel tax revenue from reduced fuel consumption. In addition, petroleum market externality payments are offset by reduced receipts from domestic petroleum suppliers. The analysis by the National Highway Traffic Safety Administration excludes these transfer payment impacts.
2130-AC27	Positive Train Control Systems Amendments	\$48 million Range: \$34–\$65 million	\$2 million Range: \$1–\$3 million	Source: ROCIS

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
U.S. Department of the Treasury				
1505-AC42	Assessment of Fees for Large Bank Holding Companies and Nonbank Financial Companies Supervised by the Federal Reserve To Cover the Expenses of the Financial Research Fund	Not Estimated	Not Estimated	Transfers: Not Estimated
U.S. Department of Veterans Affairs				
2900-AO10	Vocational Rehabilitation and Employment Program—Changes to Subsistence Allowance	Not Estimated	Not Estimated	Transfers: \$123–\$129 million Source: ROCIS Transfers are from the Federal Government to eligible veterans.
U.S. Environmental Protection Agency (EPA)				
2060-AN72	Petroleum Refineries—New Source Performance Standards, Subparts J and Ja	\$369–\$668 million	\$84 million	Source: Calculations based on numbers in the preamble Costs are compliance costs. EPA reports the value of natural gas recovered as a negative cost; however, this cost is reported as a benefit here. The total monetized benefits reflect the sum of the value of recovered natural gas plus EPA’s estimate of human health benefits associated with reducing exposure to particulate matter 2.5 micrometers or less in size (PM2.5) through reductions of PM2.5 precursors, such as NO _x and SO ₂ , as well as CO ₂ benefits. Monetized benefits do not include the reduced health effects from direct exposure to SO ₂ and NO _x , ozone exposure, ecosystem effects, or visibility impairment. The analysis year is the year of full rule implementation (2017). Qualitative benefits include a decrease in headaches, eye irritation, and pneumonia due to reduced hazardous air pollutant (HAP) exposure.

RIN	TITLE	BENEFITS (in 2001 dollars)	COSTS (in 2001 dollars)	OTHER INFORMATION
2060-AP52	National Emission Standards for HAPs from Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Electric Utility Steam Generating Units	\$28,185 – \$76,868 million	\$8,199 million	Source: ROCIS
2060-AP76	Oil and Natural Gas Sector—New Source Performance Standards and National Emission Standards for HAPs	\$155 million	\$142 million	Source: Calculations based on numbers in the preamble Costs include engineering, monitoring, reporting, and recordkeeping costs. EPA reports revenue from additional national gas product recovery as a negative cost; however, this revenue is reported as a benefit here. EPA expects that avoided emissions will result in improvements in health effects associated with HAP, ozone, and particulate matter and in climate effects associated with methane; however, the agency could not quantify these benefits because of modeling difficulties.
2060-AQ54	Joint Rulemaking to Establish 2017 and Later MY Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards	\$28,822 million Range: \$21,220 – \$28,822 million	\$8,828 million Range: \$5,305 – \$8,828 million	Source: Regulatory Impact Analysis (RIA) Annualized benefits represent total benefits (including fuel savings, the social cost of carbon, energy security, and other economic impacts) from the EPA's MY analysis. The MY benefits presented here are also based on an average social cost of carbon value derived using a 3% discount rate.
2060-AR55	Regulation of Fuels and Fuel Additives: 2013 Biomass-Based Diesel Renewable Fuel Volume	Not Estimated	\$207–\$311 million	Source: ROCIS

Table 2 Major Rules Issued by Independent Federal Regulatory Agencies between October 1, 2011, and September 30, 2012

RULE	INFORMATION ON BENEFITS OR COSTS	MONETIZED BENEFITS	MONETIZED COSTS
Bureau of Consumer Financial Protection			
Electronic fund transfers (Regulation E) Volume 77 of the <i>Federal Register</i> , page 6194 (77 FR 6194)	Yes	No	No
Fair credit reporting (Regulation V) (76 FR 79308)	Yes	No	No
Commodity Futures Trading Commission			
Business conduct standards for swap dealers and major swap participants with counterparties (77 FR 9734)	Yes	No	No
Core principles and other requirements for designated contract markets (77 FR 36612)	Yes	No	Yes
Customer clearing documentation, timing of acceptance for clearing, and clearing member risk management (77 FR 21278)	No	No	No
Derivatives clearing organization general provisions and core principles (76 FR 69334)	No	No	No
Investment of customer funds and funds held in an account for foreign futures and foreign options transactions (76 FR 78776)	Yes	No	No
Position limits for futures and swaps (76 FR 71626)	Yes	No	Yes
Protection of cleared swaps customer contracts and collateral; conforming amendments to the commodity broker bankruptcy provisions (77 FR 6336)	Yes	No	No
Real-time public reporting of swap transaction data (77 FR 1182)	Yes	No	No
Swap data recordkeeping and reporting requirements (77 FR 2136)	Yes	No	No

RULE	INFORMATION ON BENEFITS OR COSTS	MONETIZED BENEFITS	MONETIZED COSTS
Swap dealer and major swap participant recordkeeping, reporting, and duties rules; futures commission merchant and introduction of broker conflicts of interest rules; and chief compliance officer rules for swap dealers, major swap participants, and futures commission merchants (77 FR 20128)	No	No	No
Commodity Futures Trading Commission and U.S. Securities and Exchange Commission			
Further definition of “swap dealer,” “security-based swap dealer,” “major swap participant,” “major security-based swap participant,” and “eligible contract participant” (77 FR 30596 (Interim Final Rule), 77 FR 48208 (Final Rule))	Yes	No	Yes
Further definition of “swap,” “security-based swap,” and “security-based swap agreement”; mixed swaps; and security-based swap agreement recordkeeping (77 FR 48208)	No	No	No
Reporting by investment advisers to private funds and certain commodity pool operators and commodity trading advisors on Form PF (76 FR 71128)	Yes	No	Yes
U.S. Consumer Product Safety Commission			
Testing and labeling pertaining to product certification (76 FR 69482)	No	No	No
U.S. Nuclear Regulatory Commission			
Revision of fee schedules and fee recovery for FY 2012 (77 FR 35809)	Yes	No	No
U.S. Securities and Exchange Commission			
Consolidated audit trail (77 FR 45722)	Yes	No	Yes
Disclosure of payments by resource extraction issuers (77 FR 56365)	Yes	No	Yes
Investment adviser performance compensation (77 FR 10358)	Yes	No	No
Net worth standard for accredited investors (76 FR 81793)	Yes	No	No

International Community

Within the international community, the Organization for Economic Cooperation and Development (OECD)/Nuclear Energy Agency (NEA) report entitled, "Methodologies for Assessing the Economic Consequences of Nuclear Reactor Accidents,"⁵ issued in 2000, provides methodologies and techniques to quantify economic impacts of nuclear reactor accidents and applications for economic impact assessments. Chapter 2, "Cost Elements for Consequence Assessment Models," of the OECD/NEA report identifies numerous cost elements that, if quantified, represent a measure of the impact of the accident expressed as a cost to society as a whole. The report further states that the global cost includes both the direct monetary impact and the secondary and intangible impacts, as follows:⁶

The indirect (or secondary) economic consequences would cover the effects, which are produced out of the areas directly impacted by the contamination, as for instance the impact on noncontaminated food marketing, on tourism, or on the nation's nuclear programme. These are normally difficult to quantify a priori, but they are amenable to an a posteriori evaluation.

Also, very difficult to predict and to quantify in terms of cost are the economic effects, which can result from ecological damage, i.e., the general and long-term effects of contamination of wildlife and vegetation (other than agricultural or forestry), or from the loss of the recreational use of contaminated environments. These can have an important economic impact and may need to be considered separately. Such effects can arise not only in the contaminated areas but also in noncontaminated areas, although normally in these areas with less effect.

Finally, there are other effects, which, due to their nature, cannot be easily evaluated by accounting methods, such as the loss of image that the company, the region, or even the country affected by an accident would experience, with the accompanying decrease in investments and loss of intrinsic wealth, which could be made apparent by a depreciation of the nation's currency, for instance. These costs can be called "unquantifiable."

In this respect, the qualitative consideration of factors is recognized within the international community.

⁵ This report is available through the OECD "iLibrary" at [10.1787/9789264181472-en](https://doi.org/10.1787/9789264181472-en).

⁶ OECD/NEA, "Methodologies for Assessing the Economic Consequences of Nuclear Reactor Accidents," (2000), p. 16.

EVALUATION TECHNIQUES FOR BENEFITS AND COSTS THAT ARE DIFFICULT TO QUANTIFY

The U.S. Nuclear Regulatory Commission (NRC) staff uses regulatory analyses to help understand the overall benefits and costs of the agency's regulations and requirements and to help determine whether other more efficient and cost-effective alternatives are available for implementing the proposed regulations. In addition, the agency prepares regulatory analyses for proposed NRC regulations and makes them available to the public as part of the public comment process for the proposed rule. Comments on the regulatory analysis may modify the methodology, assumptions, and calculations of the regulatory analysis; these modifications to the regulatory analysis could ultimately affect the NRC's decision concerning the recommended alternative.

One situation in which issues can arise is when the proposed regulatory alternative cannot be quantified with meaningful limits on uncertainty, such as those involving emergency preparedness, safeguards, and personnel requirements. In these situations, the challenge is to qualitatively consider factors adequately, but not to give them undue consideration. For example, if a proposed alternative is recommended despite monetized benefits falling significantly short of monetized costs (i.e., quantified costs are significantly higher than quantified benefits), the staff must explain, in detail, how the nonmonetized benefits would outweigh the quantitative analysis and the uncertainties in any qualitative evaluation and thus, how the regulatory action is justified. Reliance on a qualitative evaluation of factors should only be used after efforts to develop pertinent quantitative data have been unsuccessful.

This enclosure addresses situations in which the NRC staff relies upon a qualitative consideration of factors and describes techniques for evaluating qualitative benefits in comparison to quantitative costs. This enclosure begins with a discussion of various tools and methods for the qualitative consideration of factors and then describes how these tools and methods are used by other federal agencies and international bodies. Any updates to the NRC's cost-benefit guidance under the staff's proposal would include information on how and when to apply such tools so that they will be applied consistently.

Threshold or Break-Even Analysis

A common method for considering the relative significance of a cost or benefit that is difficult to quantify is a threshold or "break-even" analysis. This analysis allows decisionmakers to understand the significance of unquantified costs or benefits to the overall analysis by showing how small the value of the nonquantified benefit would need to be (or how large the nonquantified costs would need to be) before the proposed action would yield zero net benefits. For example, a proposed regulation that protects water quality costs \$105 million annually and provides significant benefits in reducing pollution in rivers and streams. The benefits of the regulation would exceed its costs only if those effects could reasonably be valued at \$105 million or more annually. Break-even analysis is an important tool that can provide insights to the NRC staff when quantification is speculative or impossible.

Bounding Analysis

A bounding analysis could be used when data is lacking or unknown to estimate the benefit of a potential program. In these cases, the NRC staff could use a parameter's limiting values as the lower and upper bounds. For instance, the effectiveness of a certain parameter could range from 0 to 100% for a given scenario. An analyst could evaluate the resulting probability and associated consequences at each of the conservative bounds (i.e., 0 and 100% effectiveness) to determine the range of severity of the accident. If the net benefit estimate is positive across this range, decisionmakers can have some confidence that the program is beneficial. The staff should carefully describe judgments or assumptions made in selecting appropriate bounding values.

Cost-Effectiveness Analysis

Cost-effectiveness analysis is similar to cost-benefit analysis with the exception that it does not attempt to place a value on the major benefits of the proposed regulatory action; instead, cost-effectiveness analysis compares the costs of alternative ways of producing the same or similar outcome (e.g., outputs or benefits). Health organizations¹ often use this type of analysis to find the option that meets a predefined objective at a minimum cost. The unit of measurement is usually nonmonetary, such as the number of events prevented, the number of lives saved, or cases of cancer reduced per unit cost.

Revision 4 to NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," issued September 2004, states the following:²

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 the 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.

Cost-effectiveness analysis can provide a way to identify options that achieve the most effective use of the available resources without requiring monetization of all the relevant benefits and costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands that are protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement). This approach provides useful information about the relative performance of regulatory alternatives.

¹ World Health Organization (WHO) report entitled, "Making Choices in Health: WHO Guide to Cost-Effectiveness Analysis," issued 2003 (Geneva). This report is available at http://www.who.int/choice/publications/p_2003_generalised_cea.pdf.

² Pages 33 and 34

When cost-effectiveness analysis is applied to public health and safety rulemakings, the NRC staff must select a measure of effectiveness that permits a comparison of proposed regulatory alternatives. For example, effectiveness measures could include the number of events prevented, the number of lives saved, or cases of cancer reduced per unit cost. This result then requires a value judgment on whether sufficient value is provided for the estimated costs. In any event, the regulatory analysis should explain and justify why an effectiveness measure was selected and how it was implemented.

Under the Office of Management and Budget (OMB) Circular A-4, "Regulatory Guidance," dated September 17, 2003, the conduct of a cost-effectiveness analysis should generally be done for rules in which the primary effectiveness metric is public health or safety. OMB Circular A-4 (Section D. Analytical Approaches) states the following:

Both benefit-cost analysis [BCA] and cost-effectiveness analysis [CEA] provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, [the staff] should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. [The staff] should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in estimating benefits and costs across regulations and agencies, subject to statutory limitations.... If some of the primary benefit categories cannot be expressed in monetary units, [the staff] should also conduct a CEA. In unusual cases where no quantified information on benefits, costs, and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Cost-utility analysis is a variant of cost-effectiveness analysis that measures the relative effectiveness of alternative interventions in achieving two or more given objectives and typically includes a quality of life component associated with morbidity using common health indices, such as quality-adjusted life years and disability-adjusted life years. Both cost-effectiveness analysis and cost-utility analysis provide measures of the relative effectiveness of analyzed alternatives in achieving a given objective (or two given objectives in the case of a cost-utility analysis).

Internal Rate of Return

Cost-beneficial calculations using the net present value (NPV) method to discount future benefits and costs to present value is the preferred method for the evaluation of alternatives. However, mathematical alternatives to NPV analysis are available and may be useful in combination with NPV. If an NPV has already been calculated, the calculation of alternative measures can likely be done as well.

The internal rate of return (IRR) is a potentially useful alternative measure, particularly in cases that have a lot of uncertainty about which discount rate is appropriate for use in the analysis. The IRR is the discount rate that would give an NPV of zero based on expected cash flows. However, the IRR produces unusual results in certain cases, as follows:

- the IRR cannot possibly be found at all (i.e., a discount rate that gives an NPV of zero does not exist);
- mathematically, more than one IRR may exist, and deciding which one to use is difficult; and
- the IRR does not distinguish between alternatives of different sizes. Using IRR as the sole criterion, a proposed alternative that has an NPV of \$100,000 and an IRR of 25 percent may be preferable to an alternative that has an NPV of \$1 million and an IRR of 20 percent. The alternative with the smaller NPV may be preferable even though it has a higher IRR.

Because of these limitations, the OMB Office of Information and Regulatory Affairs (OIRA) does not recommend that IRR be used as a criterion for choosing among mutually exclusive alternatives.³ NRC guidance in NUREG/BR-0184, "NRC Regulatory Analysis Technical Evaluation Handbook," dated January 1997, is consistent with this position. Section 5.2, "Methods," of NUREG/BR-0184 states the following:

To the extent possible, all attributes, whether values or impacts, are quantified in monetary terms and added together (with the appropriate algebraic signs) to obtain the net value in dollars. The net value calculation is generally favored over other measures, such as a value-impact ratio or internal rate of return.

Qualitative Assessment Supplemented with Decision Analysis Tools

Even with these alternative methods, the NRC staff may find that it is still not possible to quantify some costs and benefits in the regulatory analysis with any accuracy, and their inclusion in the quantitative cost-benefit analysis may in fact be more misleading than helpful. In such circumstances, the staff should include: (1) sensitivity analysis around key variables (recommended), or (2) a qualitative evaluation of those costs and benefits that cannot be quantified. The staff should exercise professional judgment in identifying the importance of the qualitative consideration of factors and should assess to the extent possible how the effect of these factors might change the ranking of alternatives based on estimated net benefits. If the qualitative consideration of factors is likely to be important, the regulatory analysis should include a thorough discussion on which of these factors are of sufficient importance to justify their consideration in the regulatory decision. This discussion should also include a clear explanation that supports designating these factors as important. In this case, the staff should also consider including a threshold analysis to help decisionmakers and other users of the analysis understand the potential significance of these factors in the staff's decision rationale.

³ OMB/OIRA report entitled, "Economic Analysis of Federal Regulations under Executive Order 12866," January 11, 1996. This report is available at http://www.whitehouse.gov/omb/inforeg_riaguide/.

A shortcoming of NUREG/BR-0058 is that a structured approach for presenting a combination of a quantitative evaluation and a qualitative evaluation in a consistent fashion is not provided. To address this limitation and to supplement the discussion of the qualitative consideration of factors, the NRC staff could use decision analysis tools to evaluate and choose among the alternatives analyzed through a systematic approach that may avoid the limitations of an unstructured presentation. This approach is a potential method for implementing the staff's proposal in this SECY paper.

Almost all decision analysis methodologies rely upon the construction of a decision matrix that employs numerical scores to communicate the merit of one alternative in comparison to others on a single scale. Scores are developed from the performance of alternatives in regard to an individual criterion and are aggregated into an overall score. Each alternative's individual scores may be simply summed or averaged, or a weighting mechanism could be used to favor some criteria more heavily than others. The goal of using a decision matrix is to transparently present the NRC staff's rationale based on the expressed scorings of alternatives and the weightings assigned to the evaluated criteria. Through the use of value functions,⁴ this decision analysis method transforms the diverse results (e.g., quantified costs and benefits and qualitative costs and benefits) into a 0 to 100 utility scale that may be combined with weighting functions of the criteria to form a decision score for each alternative and that supplements the qualitative consideration of factors. This method allows individual decisionmakers or users of the regulatory analysis to assign their own scoring and weightings to assess whether they would have reached a different conclusion based on the justification provided.

Regulatory Uses of Decision Theory

Federal Agencies

A review of regulatory and guidance documents reveals several other Federal agency programs that using decision analysis tools and methods. The discussion below describes examples of such tools and methods. The focus of this information is different from Enclosure 2 of this SECY paper, which focuses on other federal agencies' regulatory decisions involving the qualitative consideration of factors (rather than the tools and methods employed to reach such decisions).

Federal Chief Information Officer Council Best Practices Committee

An inter-agency panel, the Federal Chief Information Officer Council Best Practices Committee, recommends the value measuring methodology,⁵ which combines multicriteria assessment techniques with cost-benefit analysis techniques to arrive at an evaluation approach that values

⁴ One method to model preferences if founded on difference measures in which judgments about strength of preference is used to derive a value function.

⁵ Federal Chief Information Officer Council Best Practices Committee report entitled, "Value Measuring Methodology, How-To-Guide," Washington, DC, USA, October 2002. This report is available at http://www.fgdc.gov/policyandplanning/50states/valuemeasuring_methodology_howtoGUIDE_oct_2002.pdf/view. The value measurement methodology is an approach used in the United State for e-commerce projects of national significance sponsored by the Federal Government.

both monetary and nonmonetary aspects of alternatives under investigation. This approach includes the determination of factors and criteria for inclusion, and then it uses a scoring system (with or without weighting) to reflect the relative importance of each one in the overall assessment. In this manner, a single number score for each alternative can be developed. Scoring is usually done using a scale, such as a scoring scale that runs from 0 to 5. Symmetrical scales are also widely used.

Although the scaling approach is subject to debate, it can convert all impacts to a common range of values, and it preserves the relative standing for each factor considered under the different alternatives when scores and scales are combined.

U.S. Army Corps of Engineers

Historically, the U.S. Army Corps of Engineers (USACE) has used essentially a single-measure approach to civil works projects. The USACE has primarily used net national economic development benefits as the single measure to choose among different alternatives. The USACE employs a principles and guidelines method that uses a complex analysis of each alternative to determine the benefits and costs in terms of dollars and other nonmonetized measures (e.g., environmental quality and safety); the alternative with the highest net national economic development benefit (i.e., with no environmental degradation) is usually selected.

U.S. Environmental Protection Agency

The U.S. Environmental Protection Agency (EPA) uses a variety of modeling tools to support its current decisionmaking processes. Several EPA guidance documents introduce decision analytical tools and recommend their use. EPA's "Multi-criteria integrated resource assessment" (MIRA) is a process that directs stakeholders to organize scientific data, establishes links between the results produced by the research community, and organizes applications in the regulatory community. MIRA has been proposed as an alternative framework to existing decision analysis approaches at the EPA. MIRA uses tradeoff analysis based on the analytical hierarchy process (AHP) to determine the relative importance of decision criteria.⁶

U.S. Department of Energy

Several U.S. Department of Energy (DOE) guidance documents introduce decision analysis tools and recommend their use. Guidance also focuses on how to select a decisionmaking tool from among five recommended evaluation methods.⁷ These methods include an analysis of the pros and cons, the Kepner-Tregoe decision analysis, the AHP, the multiattribute utility theory, and a cost-benefit analysis.

⁶ Kiker, G.A., et al., "Application of Multicriteria Decision Analysis in Environmental Decision Making," *Integrated Environmental Assessment and Management*, 1(2):95–108, 2005.

⁷ The DOE guidance document, "Guidebook to Decision-Making Methods," WSRC-IM-2002-00002, December 2001, discusses how to select a decisionmaking tool from among five recommended evaluation methods. This document is accessible at https://www.google.com/url?q=http://www.everyspec.com/DOE/DOE-PUBS/WSRC-IM-2002-00002_36284/&sa=U&ei=c_KzU7fEBfLJsAS264HICg&ved=0CAUQFIAA&client=internal-uds-cse&usq=AFQjCNEIFAxRPK-HjHLwPt3Q2HJBulhObg

International Community

The NRC staff performed a limited review of how selected international organizations qualitatively consider factors in cost-benefit analyses. The following discussion was considered pertinent to this issue. The focus of this information is different from Enclosure 2 of this SECY paper, which focuses on other federal agencies' regulatory decisions involving the qualitative consideration of factors (rather than the tools and methods employed to reach such decisions).

Australian Government Civil Aviation Safety Authority

The Australian Government Civil Aviation Safety Authority uses value management as part of its cost-benefit analysis to identify which nonquantified attributes are the most highly valued and to select the best way to realize these valued benefits.⁸

Norway and the Republic of Botswana

Norway and the Republic of Botswana (based on the Norwegian methodology) use a systematic methodology to assess the relevant advantages (benefits) and disadvantages (costs) of the alternative alignments that road infrastructure projects will generate, regardless of the unit of measurement or whether these alignments are measurable in monetary units.⁹ Analysts use the following three properties assigned on a scale of three (e.g., from small, medium, and large) to evaluate and analyze the nonmonetized impacts:

- value—the perceived value of the item;
- magnitude—the extent of benefit or damage caused; and
- significance—a balanced evaluation of the incremental advantages and disadvantages as compared to the baseline.

The magnitude of the incremental change is presented on a scale of five, ranging from a large negative to a large positive magnitude (e.g., large negative, medium negative, small negative, (none), small positive, medium positive, and large positive). An assessment of the significance of the evaluated impacts is done by combining the value and the magnitude of the impact, as shown in Figure 1. Figure 1 illustrates that the larger the perceived value of the factor, the more serious the adverse impacts. For example, if the value is large and if the magnitude of the negative impact is large, the resulting significance is a “very large negative,” which is shown as

⁸ Australian Government Civil Aviation Safety Authority report entitled, “Cost-Benefit Analysis Methodology Procedures Manual,” Version 1.1, November 2010. This report is available at <http://www.casa.gov.au/wcmswr/assets/main/manuals/regulate/acm/257rfull.pdf>.

⁹ Republic of Botswana, Ministry of Works, Transport and Communications report entitled, “Planning and Environmental Impact Assessment of Road Infrastructure,” Guideline No. 5, September 2001.

four minuses. The guidelines caution that, although value and magnitude can be combined to assess significance, “[they] should not be used too enthusiastically.”¹⁰

Four minuses and four pluses are reserved for extreme impacts in which assets of National importance are affected or will be enhanced in a very significant way. The span from four minuses to four pluses should not be used to differentiate among alternatives whose impact significance does not greatly differ. Analysts should describe small differences in writing.

Similar to other methods described, this method serve as a basis for ranking different alternatives in regard to their total viability and requires that the assessment clearly show how quantitative and qualitative results were considered in the selection of the best alternative.

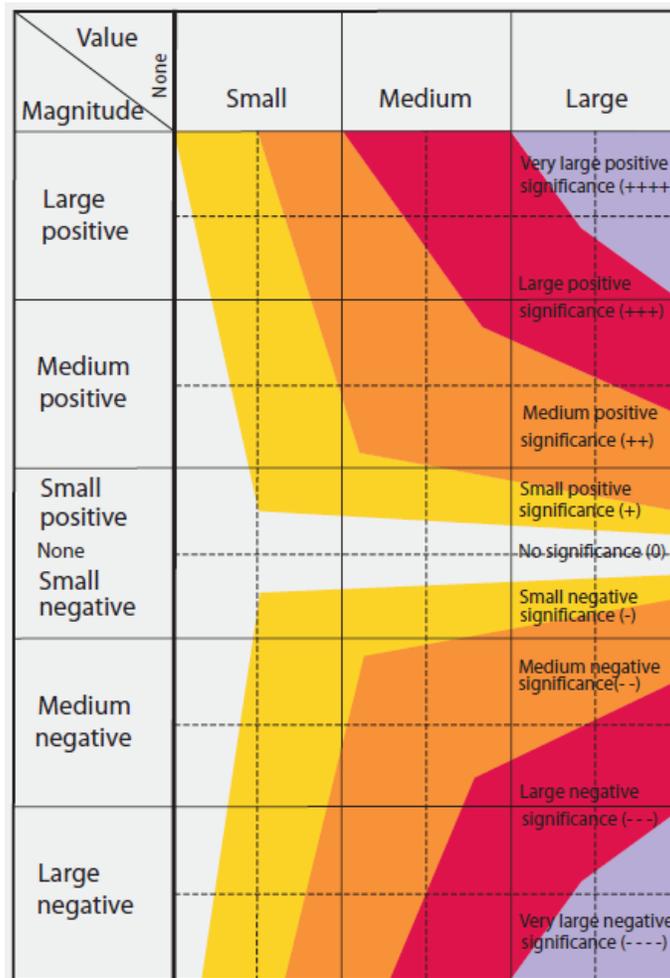


Figure 1 Significance of nonquantified impacts by combining

¹⁰ See page 41 of the Republic of Botswana, Ministry of Works, Transport and Communications report entitled, “Planning and Environmental Impact Assessment of Road Infrastructure.”

their values and magnitudes