NRC Response to Public Comments

NUREG/BR-0058, Revision 5
"REGULATORY ANALYSIS GUIDELINES OF THE U.S. Nuclear Regulatory Commission"

ADAMS Accession No. ML17221A011

I. INTRODUCTION

This document presents the responses from the U.S. Nuclear Regulatory Commission (NRC) to written public comments received in response to publication in the *Federal Register* (FR) (82 FR 18163, April 17, 2017) of draft NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission." The NRC considered all comments submitted in finalizing NUREG/BR-0058, Revision 5.

II. OVERVIEW OF COMMENTERS AND COMMENTS

The NRC received three comment submissions with a total of 58 individual comments. One of the comment submissions was a request from the Nuclear Energy Institute (NEI) (ADAMS Accession No. ML17142A297) to extend the public comment period for an additional 60 days. The NRC did not extend the public comment period and provided a letter to NEI (ADAMS Accession No. ML17145A322) to communicate this decision. Table 1 presents information on the commenters who submitted comments on draft NUREG/BR-0058, Revision 5.

Table 1. Information on Commenters

Name	Affiliation	ADAMS Accession No. for Comment Submission	Identifier
James Slider	NEI	ML17179A247	NEI
Mike Zoccola	private citizen	ML17143A225	MZ

Similar comments were binned, as appropriate, to facilitate providing NRC responses:

a. Comments Related to the Main Body of NUREG/BR-0058, Revision 5
b. Comments Related to Appendix A, "Qualitative Factors Assessment Tools"
c. Comments Related to Appendix D, "Guidance on Regulatory Analysis Related to ASME Code Changes"
d. Comments Related to Appendix E, "Special Circumstances and Relationship to Other Procedural Requirements"

No public comments were received on Appendix B, "Cost Estimating and Best Practices," or Appendix C, "Treatment of Uncertainty."

a. Comments Related to the Main Body of NUREG/BR-0058, Revision 5

Comment a1 (NEI): Are statements made in the introduction meant to be descriptive or directive? Some read as if they could be directives to staff. Others read as if they merely summarize and allude to binding directives and procedures found elsewhere. In some areas, Revision 5 reads like a procedure or checklist to be followed verbatim. In other areas, it reads like Wikipedia or a compendium of someone's notes on how to work in the area of regulatory analysis. The variations make it difficult to gauge how well Revision 5 will serve its intended use.

NRC Response: The NRC agrees with this comment and has revised the text in the Introduction section to clarify that the statements made in the Introduction section are meant to be descriptive (i.e., not binding directives).

Comment a2 (NEI): Page 1-1, lines 12-13; 42-48. This paragraph explains that the NRC is not required to conduct cost-benefit analyses, but has done so voluntarily since 1976. Although this statement is generally correct, the NRC should update this section to reflect more recent Executive Orders and case law that are relevant in this area, and clarify that cost-benefit analyses are required by rule when backfitting is involved.

Suggested Wording Change:

"Although the NRC is not required to conduct cost-benefit analyses (except as required by the Commission's backfitting rules), it voluntarily began performing them in 1976.

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

In 2011, President Obama issued E.O. 13563, which supplements and reaffirms Executive Order 12866. This updated order explains that an agency "must…propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs." As with these past Executive Orders on regulatory reform, the Commission likewise recognizes the spirit of recent Executive Orders. For example, E.O. 13783 renews the federal government's long-standing position that "necessary and appropriate environmental regulations comply with the law [and] are of greater benefit than cost, when permissible." The Commission also agrees that "it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." E.O. 13771.

The Commission also recognizes recent Supreme Court precedent on the importance of cost-benefit analysis in rulemaking. In *Michigan v. EPA*, 135 S. Ct. 2699 (2015), the Supreme Court explained that agency action must rest "on a consideration of the relevant factors," which includes costs." "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate." In making this evaluation, the Court instructed that agencies should be mindful that "costs includes more than the expense of complying with regulations; and

disadvantages could be termed a cost." "No regulation is 'appropriate,'" the Court explained, "if it does significantly more harm than good."

In November 1995, the NRC issued Revision 2 to NUREG/BR-0058 to reflect….[sic]"

NRC Response: The NRC agrees, in part, with this comment, and has revised the text in the Introduction section to reflect more recent executive orders that are relevant to this area. However, the preparation of a cost-benefit analysis is not necessary when one of the backfit analysis exceptions applies. A cost-benefit analysis supports a backfit analysis but is not required for a backfit analysis nor is a cost-benefit analysis required by the backfitting regulations. Therefore, the NRC did not incorporate the commenter's clarifying language that cost-benefit analyses are required by rule when backfitting is involved.

Comment a3 (NEI): "This revision of NUREG/BR-0058 has been prepared to accomplish three objectives…"

This paragraph appears late in the Introduction section. It appears to be fundamental to understanding the purpose of Revision 5. This paragraph should be made more prominent by, for example, moving it to appear as the second paragraph in the Introduction (page 1-1, line 12).

NRC Response: The NRC agrees with this comment, and has moved the three objectives of the document to the second paragraph in the Introduction.

Comment a4 (NEI): The last two sentences of footnote "a" promote the idea that the Commission has determined that the "substantial increase" requirement does not apply when evaluating backfits pursuant to 10 CFR 70.76. This is incorrect.

This assertion is based on SRM-SECY-98-185. In that SRM, the Commission disapproved a proposed rule that would have modified 10 CFR Part 70. Instead, the Commission directed the staff to provide a revised rule package within 6 months of issuance of the SRM. SRM-SECY-98-185 does include the following statement:

> The Commission supports a requirement that any new backfit pass a cost-benefit test, without the "substantial" increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis.

But, in approving the final rule revising 10 CFR Part 70 just a few years later, the Commission directed the staff to include the "substantial increase" standard in § 70.76, stating:

> The Commission has approved inclusion of the word "substantial" into the backfit requirement in § 70.76(a)(3). Staff should develop guidance to make clear that an adequate demonstration can be based on quantitative or qualitative evaluations of the nature of the increase in the overall health and safety procedures of the public.

SRM-SECY-00-0111. Indeed, 10 CFR 70.76(a)(3) states:

> [T]he Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, 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.

Thus, it is clear that both the "substantial increase" and "cost-justified" findings are required to support backfitting under § 70.76. The last two sentences of footnote "a" present an incomplete picture of the Commission's decision-making process, misstate the standard required pursuant to 10 CFR 70.76, and should be deleted.
Suggested Wording Change:

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

NRC Response: The NRC agrees with this comment, and has deleted the suggested text from the footnote in Table 1-1.

Comment a5 (NEI): Page 2-1, lines 1-6. This paragraph describes the NRC's "statutory mission." The NRC's "statutory mission" is primarily defined by the substantive requirements of the Atomic Energy Act, as amended, which is the agency's organic statute. See "Limited Work Authorizations for Nuclear Power Plants: Final Rule," 72 Fed.Reg. 57,416,57,57,425 [sic] (Oct. 9, 2007). The general description of the agency's "statutory mission" provided in Rev. 5 should more closely reflect the general authority granted to the agency in Section 161 of the Atomic Energy Act.

Suggested Wording Change:

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

NRC Response: The NRC agrees with this comment, and has made the suggested changes to the text in Section 2.0.

Comment a6 (NEI): Page 2-1, lines 8-16. This bullet describes the standard that must be met under the Commission's backfitting rules, but the references are limited to §§ 50.109 and 76.76. The references should be expanded to include all of the relevant backfitting provisions.

Suggested Wording Change:

"Proposed actions subject to the Commission's backfitting rules ~~(10 CFR 50.109),~~ and not within the exceptions at 10 CFR 50.109(a)(4), 70.76(a)(4), 72.62(b), and 10 CFR 76.76(a)(4), provide a substantial increase in the overall protection of public health and safety or the common defense and security and that the direct and indirect costs of implementation are justified in view of this substantial increase in protection."

NRC Response: The NRC agrees with this comment, and has made the suggested changes to the text in Section 2.0. The NRC has also added issue finality to the text.

Comment a7 (NEI): "This approach of 'substantial increase' is consistent with the Agency's policy of encouraging voluntary initiatives."

Why is this statement important here? How does "this approach of substantial increase" encourage voluntary initiatives?

NRC Response: To the extent that this comment indicates that the quoted phrasing is unclear, the NRC agrees with this comment and the text has been removed from Section 2.0.

Comment a8 (NEI): "The requirement applies to actions initiated internally by the NRC, from a petition to the NRC, or industry initiatives."

How does the requirement to perform a regulatory analysis apply to industry initiatives? We suggest this text mention Section 5.3.1, "Treatment of Industry Initiatives."

NRC Response: The NRC agrees with this comment, and has revised the text in Section 2.0 to clarify that this requirement applies to regulatory actions that may be initiated by the NRC, from a petition to the NRC, or as a result of industry initiatives. The NRC has determined that a cross reference to Section 5.3.1 is not necessary based on this change.

Comment a9 (NEI): "For several types of regulatory actions, a detailed cost-benefit analysis could introduce additional costs that are disproportionate relative to the action being undertaken. These include the issuance of generic communications, regulatory guides, standard review plans, branch technical positions, enforcement guidance memoranda, interim staff guidance documents, some NUREG publications, standard technical specifications, and other documents that provide guidance for applicants or licensees. In general regulatory analysis should be limited only in terms of depth of discussion and analysis, not in the reduction of the scope of the regulatory analysis and not in the need to justify the proposed action."

What are the "additional costs"? Are they costs borne by NRC for performing the analysis or the cost of impacts on the affected licensees? How is the regulatory analyst to decide when and in what ways to curtail the depth of analysis?

Please clarify what this paragraph means to the regulatory analyst.

NRC Response: To the extent that this comment suggests that this language should be clarified, the NRC agrees with this comment that the language could be clearer. The NRC has

revised the text in Section 2.0 to clarify that, “for certain regulatory actions, a less detailed cost-benefit analysis is sufficient because the proposed changes are of smaller magnitude.”

Comment a10 (NEI): Page 2-2 states, “Regulatory analyses are not necessary for requirements arising out of litigation.”

We understand this statement to mean that regulatory analyses are not necessary prior to imposition of requirements that the NRC is compelled to impose as a result of litigation. But this statement seems overly broad. Specifically, a regulatory analysis could be appropriate in situations where litigation results in the agency being compelled to impose a requirement, but where the agency retains the discretion to choose between alternative approaches to meeting the mandate flowing from the litigation. In such a scenario, the regulatory analysis could be an extremely useful tool in guiding the NRC’s decision on how to comply with the mandate.

Please clarify the specific situations in which litigation would forgo the need for a regulatory analysis.

NRC Response: The NRC agrees with this comment, and has added the following clarifying language as a footnote in Section 2.0:

“In litigation, an adverse ruling may require a specific outcome with only one possible method for compliance. In such a case, cost would not be a factor because there is only a single means to achieve the specific outcome imposed by the adverse ruling, so a regulatory analysis would not be necessary. In contrast, if there are multiple ways of achieving a specific outcome imposed by an adverse ruling, a regulatory analysis would be performed to determine the costs and benefits of each alternative.”

Comment a11 (NEI): Page 2-4 states, “The safety goal evaluation is intended to determine whether the residual risk is already acceptably low such that a regulatory requirement should not be imposed generically on nuclear power plants. The intent is to eliminate some proposed requirements from further consideration independently of whether they could be justified by a regulatory analysis on their net-value basis. The safety goal evaluation <u>can also be used</u> for determining whether the substantial additional protection standard of 10 CFR 50.109(a)(3) is met.”

This passage indicates that the safety goal evaluation may be useful in both regulatory analyses that involve backfitting and those that do not. But, page 2-5 states, “The safety goal evaluation, as discussed in this section, <u>is applicable only to</u> regulatory initiatives considered to be generic safety enhancement backfits, subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). A safety goal evaluation is not needed for new requirements within the exceptions at 10 CFR 50.109(a)(4)(i)-(iii). If the proposed safety goal screening criteria are satisfied, the NRC considers that the substantial additional protection is met for the proposed new requirement.”

This passage seems to limit the applicability of the safety goal evaluation to the analysis of backfits under 10 CFR 50.109. The NRC should clarify that the safety goal evaluation may be used by the staff, outside of the backfitting context, to determine whether to eliminate certain requirements or guidance from further consideration.

NRC Response: The NRC agrees with this comment, and has revised the text in Section 2.2.1 to clarify that the safety goal evaluation is required for, but not only applicable to, generic safety enhancement backfits. The safety goal evaluation can be used by the NRC outside of the backfitting context to determine appropriate action such as eliminating or modifying certain initiatives or guidance from further consideration.

Comment a12 (NEI): "The staff should provide documentation that the analysis is based on the best reasonably attainable scientific, technical, and economic information available, quantified when possible."

Please provide some examples of what the NRC considers to be "reasonably attainable scientific, technical, and economic information."

NRC Response: The NRC agrees with the commenters that examples should be provided. The NRC has revised the text in Section 2.3 to clarify that the NRC has established minimum quality standards, and a reference to these standards has also been added to the text.

Comment a13 (NEI): "This element allows the analyst to carefully establish the details of the problem and its background, boundaries, significance, and objective."

The burden should be on the originator of the regulatory initiative to establish the details of the problem statement and its "boundaries, significance, and objective," not on the regulatory analyst. Please clarify that the regulatory analyst is not inventing a new problem statement or substantially revising an existing problem statement. The regulatory analyst must depend on the originator of the regulatory initiative to define the problem. The regulatory analyst must take the problem statement from the documentation of the regulatory initiative being analyzed.

NRC Response: The NRC agrees with this comment and changed "carefully establish" to "document" in Section 2.3.1 to clarify that the analyst is not inventing a new problem statement or substantially revising an existing problem statement.

Comment a14 (NEI): "This determination will usually result in a conclusion regarding whether a major effort (e.g. Fukushima-related) or standard effort (e.g., American Society of Mechanical Engineers Code case rule or a reporting change requirement) is needed to resolve the problem."

Please provide some examples of what would constitute a "major effort," as opposed to a "standard effort."

NRC Response: The NRC agrees with this comment. However, the NRC determined that a discussion of major and standard efforts in this section was unnecessary and deleted the sentence quoted above to prevent unnecessary confusion.

Comment a15 (NEI): "Hypothetical best- and worst-case consequences <u>may</u> be estimated for sensitivity…"

This paragraph illustrates the varying uses of permissive language (i.e., may, should or can). If these differences are important, please choose one permissive term and use it consistently.

NRC Response: The NRC agrees with this comment and the differences in terminology have been defined in Section 1.1.

Comment a16 (NEI): "Complete the above steps for each alternative evaluated."

The six elements of a regulatory analysis were identified earlier in Section 2. Please clarify what "steps" this sentence refers to.

NRC Response: The NRC agrees with this comment and has revised the text in Section 2.3.3 to clarify that the steps refer to those described under the "estimation and evaluation of costs and benefits" element of the regulatory analysis.

Comment a17 (NEI): "The presentation provides a uniform format for recording the results of the evaluation of all quantitative attributes, plus a comments section to discuss other attributes and special circumstances."

Please clarify where the analyst finds this uniform format.

NRC Response: The NRC agrees with this comment and added a table in Section 2.3.4 to provide a uniform format for presenting the results of the regulatory analysis. This will ensure consistency across the NRC cost analyses in providing a uniform format of the regulatory analysis results, focusing on the key aspects of the analysis.

Comment a18 (NEI): "In cases where uncertainties are substantial or where important benefits cannot be quantified, alternatives that yield equivalent benefits may be evaluated, based on their cost effectiveness."

Substantial uncertainties are not in and of themselves a reason to use cost effectiveness. This would be true only when those uncertainties indicate that an alternative might be beneficial.

Please correct or clarify the text per our comment.

NRC Response: The NRC agrees with this comment that substantial uncertainties are not in and of themselves a reason to use cost effectiveness. The NRC has revised the text in Section 2.3.4 for clarification.

Comment a19 (NEI): "Nonquantifiable attributes can only be factored into the decision in a subjective way; the experience of the decisionmaker will strongly influence the weight that they are given. These attributes may be significant factors in regulatory decisions and should be considered."

(a) What does "strongly influence" mean here?
(b) Lines 24-26 provide stakeholders with no clarity on how qualitative factors will actually be treated. Additional guidance is needed on this. This guidance should consider the robustness of the quantitative analysis, how well uncertainties are addressed in the quantitative analysis, and what the quantitative results say about the cost-benefit of the change. Also, it is not clear why these are referred to as "nonquantifiable attributes" here, when the rest of the document and appendices seem to refer to them as qualitative factors.

NRC Response: The NRC agrees with this comment, and has revised the text in Section 2.3.5 for clarity on how qualitative factors will be treated. Specifically, Appendix A and Appendix C of NUREG/BR-0058 contain further guidance on the treatment of qualitative factors.

Comment a20 (NEI): It is important to recognize the additional margin provided by FLEX equipment.

Suggested Wording Change:

"For example, an analyst addressing proposed improvement to diesel generator performance at power reactors should be aware of any diesel generator improvements or alternate power supplied by other means (e.g. FLEX Mitigating Strategies) already addressed in station blackout considerations.

NRC Response: The NRC agrees with this comment that the additional margin provided by FLEX equipment is important to recognize. The NRC has made the suggested changes to Section 2.4.

Comment a21 (NEI): "To the extent possible, the analyst should modify the risk equations of the representative plant to reflect the upgraded status quo from these other safety improvements."

Please clarify what "risk equations" are being referenced in this sentence.

NRC Response: The NRC agrees with this comment that the reference to the term "risk equations" is unclear in this context. This terminology had been inadvertently carried over from NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," which had previously illustrated how an analyst can calculate the change in risk associated with a proposed regulatory action using a set of risk equations. Since this approach is no longer anticipated with the use of existing technology, the NRC has replaced the term "risk equations" in Section 2.4 with "PRA model."

Comment a22 (NEI): "These references provide CDF [core damage frequency] and conditional containment failure probability information for the fleet of operating nuclear power plants in the 1990s."

CDF values have fallen as a result of safety improvements across the industry. In our view, it would be appropriate to recognize this and point to a source for current CDF data.

Suggested Wording Change:

"These references provide CDF and conditional containment failure probability information for the fleet of operating nuclear power plants in the 1990s.

However, newer internal event CDF information may be obtained from ICES, which is used as the data source for the MSPI indicator."

NRC Response: The NRC agrees with this comment that more recent PRA information is available for the existing fleet of operating nuclear power plants and that results from more recent PRAs indicate that significant reductions in mean internal events CDF have been realized since the 1990s. However, the trend over time for the contribution to CDF from external events is more difficult to discern due to a variety of factors, including: (1) changes in the external hazard profile for regions of the U.S. and nuclear power plant sites located within them; and (2) changes in the maturity of external hazards PRA technology (i.e., methods, models, data, and analytical tools used to assess the external hazards risk contribution).

In addition to changes made in response to the next comment (a23), the NRC added the following text to Section 2.4.1.1:

"The analyst can obtain more recent CDF information for the existing fleet of operating nuclear power plants from various data sources, dependent upon the scope of the regulatory analysis and data source access restrictions. Examples of more recent sources of CDF information include: (1) internal NRC Standardized Plant Analysis Risk (SPAR) model databases; (2) reports that document the results of severe accident mitigation alternatives (SAMA) analyses; and (3) the Institute of Nuclear Power Operations Consolidated Events System database (proprietary), which is used as a data source for estimating the plant-specific Mitigating Systems Performance Index for risk-informed decisionmaking in the Reactor Oversight Process."

Comment a23 (NEI): "This will result in identifying and assessing the range of reduction in CDF, as well as estimating the representative change for the class."

It is important to recognize the improvement in CDF across the industry.

Suggested Wording Change:

"This will result in identifying and assessing the range of reduction in CDF, as well as estimating the representative change for the class. Since the 1990's, a significant reduction in plant, as well as industry, mean CDF has been realized. Use of dated CDF information may not represent the as-built, as-operated plant today. Inaccurate conclusions may be reached if the dated information is used without consideration of newer information."

NRC Response: The NRC agrees with this comment that the use of dated CDF information may not represent the current as-built, as-operated plant and that inaccurate conclusions could potentially be reached if dated information is used without consideration of newer information.

However, while results from more recent PRAs indicate that significant reductions in mean internal events CDF have been realized since the 1990s, the trend over time for the contribution to CDF from external events is more difficult to discern due to a variety of factors, including those identified in the response to the previous comment (a22).

The following text has been added to Section 2.4.1.1:

"More recent PRAs indicate that a significant reduction in mean internal events CDF has been realized at both the level of individual nuclear power plants and as an average across all operating plants in the U.S. nuclear industry since the completion of the IPE and IPEEE studies. However, the trend over time for the contribution to CDF from external events is more difficult to

discern due to a variety of factors, including changes in the external hazards profile for regions of the United States and nuclear power plant sites located within them and changes in the maturity of external hazards PRA technology (i.e., methods, models, data, and analytical tools used to assess the external hazards risk contribution)."

The following additions were also made to the text regarding the analyst's use of Table 2-1:

"Analysts should use Table 2-1 or more recent data, as appropriate, to perform a preliminary screening of the merit of the proposed new requirements for the appropriate class of nuclear power plants."

Comment a24 (NEI): "More than one significant figure in the mantissa is not appropriate in most cases."

Cases involving a small change in delta CDF could be an exception to this statement.

Suggested Wording Change:

"More than one significant figure in the mantissa is not appropriate in most cases unless needed to characterize a small delta-CDF change."

NRC Response: The NRC agrees with this comment and determined that the statement is unnecessary. The NRC has deleted the sentence in Section 2.4.1.1.

Comment a25 (NEI): "This goal has been determined by the staff to be a useful benchmark but is not a Commission approved safety goal."

The "benchmark" of subsidiary CDF and LERF [large early release frequency] goals to the Safety Goals is based on a 25-year old understanding of severe accident phenomena and even older modeling tools. More recent work, such as SOARCA and CPRR [containment protection and release reduction], has shown that there is significant margin between the Subsidiary Objectives for CDF/LERF and the Safety Goal QHOs [quantitative health objectives]. This means that a decision being made on substantial improvement in safety that relies on these values is potentially overstating the significance and unduly triggering cost-benefit evaluations. For backfits, it will tend to cause more changes to screen into cost-benefit analysis.

Suggested Wording Change:

Append the following text:
"However, more recent severe accident investigations, performed by the NRC and industry, have shown that there is significant margin between the Subsidiary Objectives for CDF/LERF and the Safety Goal Quantitative Health Objectives (QHOs). This increased margin could impact a decision being made in that there is potential in overestimating the risk benefit when performing cost-benefit evaluations."

NRC Response: The NRC agrees with this comment that the NUREG-1150 PRA studies used to demonstrate that the subsidiary numerical objectives for CDF and LERF are useful surrogate measures for the average individual latent cancer fatality risk QHO and that average individual early fatality risk QHO, respectively, are becoming increasingly dated.

However, while the NRC acknowledges that more recent severe accident consequence analyses indicate there is a significant margin between the subsidiary numerical objective for mean CDF of 10^{-4} per year and the average individual latent cancer fatality risk QHO, it is important to consider the scope limitations of these more recent studies. The safety goals and QHOs are designed to be compared against results from full-scope Level 3 PRAs that address a broader spectrum of potential accident scenarios than were included in the more recent severe accident consequence analyses. Therefore, contemporary full-scope Level 3 PRA studies will be needed to quantify the relevant margins and to reevaluate the relationship between the subsidiary numerical objectives for CDF and LERF and the corresponding safety goal QHOs. For this reason, the NRC did not incorporate the suggested language.

The NRC disagrees that continued use of the subsidiary numerical objective for mean CDF of 10^{-4} per year will necessarily result in overestimating the safety significance of proposed regulatory actions and trigger unnecessary cost-benefit analyses. The safety goal screening criteria are based on the estimated *change in* CDF associated with a proposed regulatory action, not the baseline value of the CDF relative to the 10^{-4} subsidiary numerical objective. The NRC also disagrees with the following statement in the proposed additional text: "This increased margin could impact a decision being made in that there is potential in overestimating the risk benefit when performing cost-benefit evaluations." The risk benefit—as measured by the public health (accident) attribute in cost-benefit analyses—is calculated by estimating expected changes in radiation exposures to the public due to changes in accident frequencies or accident consequences associated with a proposed regulatory action.

The NRC made no changes to the document in response to this comment.

Comment a26 (NEI): Figure 2-3 is confusing. The relationship between the three "Staff Actions" at the top and the table below is not at all clear. The text does not appear to explain the roles of these two parts. The top three lines refer to "Estimated Reduction in CDF." This seems to be equivalent to ΔCDF. The table uses ΔCDF on the ordinate axis. If the terms are equivalent, then the criteria do not align since a "priority" is shown only for high ΔCDF and high CCFP. It is not clear what value the three lines at the top are intended to provide. Recommend deleting them.

Each cell spans two orders of magnitude of frequency and overlap. For example, the "No Action Taken" box overlaps by a full order of magnitude with the Management Decision boxes and the Management Decision boxes overlap an order of magnitude with the "Proceed to Cost-Benefit" boxes. Also, the lowest value in the "Proceed to Cost-Benefit" box is equivalent to the "No Action Taken" upper value. Such wide spans seem to provide little in the way of guidance.

NRC Response: The NRC agrees with this comment that the format and structure of Figure 2-3 is confusing. The NRC has revised the figure based on the suggestions in this comment.

Comment a27 (NEI): The term conditional containment failure probability (CCFP) is used in Figure 2-3 on page 2-19. The term conditional probability of containment failure or bypass (CPCFB) is introduced in Section 2.4.1.2. Page 2-20, lines 39 and 40 imply they are synonymous. If so, a single term is recommended (or at least a clear statement of

equivalence). If not, then it is not clear how CPCFB is to be used and the definition of CCFP should be provided.

NRC Response: The NRC agrees with this comment and revised the document to ensure only CPCFB is used.

Comment a28 (NEI): "The definition recognizes the impacts of early failure and uses that as a baseline from which to assess containment performance (e.g., CPCFB changes)."

It is important to recognize post-Fukushima requirements that could impact this.

Suggested Wording Change:

"The definition recognizes the impacts of early failure and uses that as a baseline from which to assess containment performance (e.g., CPCFB changes). Recognize that the Fukushima-related Orders associated with mitigation strategies and severe accident containments venting for BWR Mark I and II containments may have an impact on CPCFB and should be considered accordingly."

NRC Response: The NRC agrees with this comment that it is important to recognize post-Fukushima requirements. The NRC has made the suggested changes to Section 2.4.1.2.

Comment a29 (NEI): This paragraph describes the purpose of the Commission's backfitting rules, focusing on regulatory discipline and stability. Although these are important purposes of the backfitting rules, we believe that maintaining a safety and security focus is also a primary purpose of the rules. Revision 5 should clearly communicate that an important purpose of the backfitting rules is to focus industry and NRC resources on the most safety- and security-significant regulatory activities.

Suggested Wording Change:

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

NRC Response: The NRC agrees, in part, with this comment. As a consequence of the backfitting process, a licensee may use its resources on the most safety- and security-significant regulatory activities. However, focusing resources on the most safety- and security-significant regulatory activities may be an outcome of backfitting rules, but is not a primary purpose of them.

The NRC has not made the suggested changes to Section 3.1.

Comment a30 (NEI): "Expected changes in radiation exposure from a nuclear power reactor accident should be measured over a 50-mile appropriate distance from the licensed facility."

Please delete the word "appropriate" or clarify what it means.

NRC Response: The NRC agrees with this comment. The NRC has deleted the word "appropriate" from this sentence in Section 5.2.1.

Comment a31 (NEI): Page 5-8, lines 10-17. This section of Revision 5 states that, "The NRC is currently developing guidelines designed to increase the NRC's assurance that industry initiatives will be effective long-term alternatives to regulatory actions." This statement was also made in Revision 4, which was published in September 2004. See Rev. 4, at page 25. The NRC should clarify whether they are currently developing such guidelines and, if so, provide information regarding expected completion dates and plans for stakeholder engagement.

NRC Response: The NRC agrees with this comment. This sentence was carried over from NUREG/BR-0058, Revision 4, and the staff recommendation in SECY-13-0132, "U.S. NRC Staff Recommendation for the Disposition of Recommendation 1 of the Near-Term Task Force Report" (ADAMS Accession No. ML13277A413), to revise NRC policies and procedures to ensure that licensee voluntary initiatives are well documented and transparent to the public. In the May 19, 2014, SRM to SECY-13-0132 (ADAMS Accession No. ML14139A104), the Commission did not approve this recommendation. Therefore, the NRC has deleted the sentence referenced in the comment from Section 5.3.1.

Comment a32 (NEI): Section 5.3.1 discusses how the staff will address the costs and benefits of potential regulatory actions that overlap with, or are related to, voluntary industry initiatives. Specifically, this section states that the staff should examine the sensitivity associated with giving voluntary industry initiatives "full credit" versus "no credit, which would affect the baseline from which the incremental costs and benefits of a proposed regulatory action are measured. But the example given in Section 5.3.1 only addresses how the "full credit" / "no credit" assumption would affect the "incremental values" (i.e., the benefits) associated with a proposed regulatory action. The "no credit" assumption would increase such incremental benefits and the "full credit" assumption would decrease such incremental benefits. There is no discussion of how the crediting of the voluntary initiative would impact incremental cost. Industry believes that the NRC should clarify that either:

1) The "no credit" / "full credit" assumption would also be applied to costs (i.e., the "no credit" scenario would result in a corresponding increase in the incremental costs along with the incremental benefits of a proposed regulatory action and vice versa); or
2) The costs of voluntary industry initiatives are considered sunk costs and this will not be credited by the NRC in its cost-benefit analysis (this would be equivalent to a "no credit" assumption from a cost standpoint).

Section 5.3.1 goes on to state:

> Ordinarily, voluntary actions are not included in the cost estimate for backfit analyses. The backfit rule applies to actions that impose positions or requirements on licensees; it does not apply to requested actions that are optional or voluntary. The term "voluntary" as it applies to "voluntary actions" or from "mandatory actions" or "mandatory

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

This passage is confusing and seems to conflate two distinct issues: (1) whether to consider the costs associated with "voluntary actions" in backfitting analyses and (2) whether the backfitting rule applies to "voluntary actions" or "voluntary relaxations."

On issue (1), the first sentence makes a statement that the costs of "voluntary actions" should not be considered in backfitting analyses. Presumably, neither the costs nor the benefits of purely voluntary actions that are not related to the imposition of a proposed backfit would be considered in a backfitting analysis. Further, Section E2.2 of Appendix E states that sunk costs, which include costs associated with voluntary actions undertaken at an earlier date, are not to be included in NRC cost-benefit analyses. Accordingly, the costs of voluntary actions that have occurred in the past would not be considered in any NRC cost-benefit analysis – regardless of whether a backfit is involved. Thus, we recommend that the first sentence be deleted because it is confusing, incomplete, and is already addressed by the section of Appendix E that discusses sunk costs.

Issue (2) is discussed in NUREG-1409 and the CRGR Charter, as it addresses the applicability of the backfitting rule (rather than the conduct if NRC's cost-benefit analyses). Guidance on the applicability of the backfitting rule should be maintained in NUREG-1409, the CRGR Charter and Management Directive 8.4. Thus, we recommend that the rest of this passage also be deleted.

Suggested Wording Change:

Add the following bullet to the relevant characteristics list.

- <u>whether the industry has formally adopted the initiative as mandatory through NEI's Nuclear Strategic Issues Advisory Committee</u>

Delete the following text.

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

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

NRC Response: The NRC agrees with this comment that the text is confusing. The NRC has deleted the text in Section 5.3.1, as recommended by this comment, and added the suggested bullet to the relevant characteristics list.

Comment a33 (NEI): Table 5-1, Expected Population Doses for Power Reactor Release Categories, is taken from NUREG-1150 (published in 1990). The note on this page says, "This table will be updated and moved to Appendix H in the future."

Our knowledge of severe accident consequences has greatly expanded since NUREG-1150 was published. What are the staff's plans to update this table? If this table is moved, how will this part of Chapter 5 change?

NRC Response: In consideration of this comment, the NRC removed the outdated Tables 5-1 and 5-2 from the NUREG. The NRC is currently evaluating options for updating the tables and placing them in a future appendix (Appendix H) for use as screening information that could be applied when performing standard analyses. The NRC is evaluating sources of information that are more recent than NUREG-1150, such as SAMA analyses supporting license renewal applications. The public will have an opportunity to comment on the proposed updated approach when the draft Appendix H, "Severe Accident Risk Analysis," is published for comment as part of the Phase 2 update.

Comment a34 (NEI): Page 5-15, lines 8-9. This table is unnumbered, untitled, and not specifically mentioned in the text. What is the analyst to do with this table? The note below the table, like the note below Table 5-1, says that this table will be updated and moved to Appendix H in the future. What will the basis for the update and what is the plan for updating this table?

Please clarify the intended use of this table.

NRC Response: The NRC agrees with this comment that the omission of the table heading caused confusion. This table heading was inadvertently removed during the publication process. This is Table 5-2, "Weighted Population Dose Factors for the Five NUREG-1150 Power Reactors," referenced on p. 5-12 of the draft report for comment. The NRC has removed the outdated Tables 5-1 and 5-2 from the NUREG. The NRC is currently evaluating options for updating the tables and placing them in a future appendix (Appendix H) for use as screening information that could be used for performing standard analyses. The NRC is evaluating sources of information that are more recent than NUREG-1150, such as SAMA analyses supporting license renewal applications. The public will have an opportunity to comment on the

proposed updated approach when draft Appendix H is published for comment, as mentioned above.

Comment a35 (MZ): The NRC should consider inclusion of a market analysis of the ongoing economic viability of large nuclear reactor suppliers and constructors because of the detrimental impacts associated with market withdrawal of these suppliers. Case in point: Westinghouse US subsidiary of parent company Toshiba.

With the bankruptcy filing of Westinghouse, it is not clear that this major equipment supplier and constructor will be able to fulfill contract obligation to complete many of the new nuclear power plants. Indeed, by some estimate, Westinghouse AP 1000 is the largest supplier of these new reactors, yet we don't know the impact to the industry. In my estimation, the NRC would be remiss by not considering the impact during development of regulatory analysis guideline.

NRC Response: The NRC considers this comment to be outside the scope of NUREG-BR/0058, Revision 5. The purpose of the NUREG is to provide guidelines to NRC staff who are conducting regulatory analyses. The market analysis proposed by the commentor, while providing information of interest to NRC stakeholders, would not be used in a regulatory analysis. Therefore, no changes were made in response to this comment.

Comment a36 (NEI): Sections 2.3.2 and 2.3.5 are not listed in the Table of Contents. Should section number 2.3.3 be 2.3.2? (There is no section 2.3.2 shown in draft Revision 5.) Should section 2.3.4 be section 2.3.3? Should section 2.3.6 be 2.3.4? Should section 2.3.7 be section 2.3.5?

NRC Response: The NRC agrees with the observations made in this comment and that the document should be revised for consistency. The NRC revised the document to ensure that the section numbers and table of contents are consistent.

Comment a37 (NEI): The reference to Figure 2-1 should be changed to Figure 2-2. Should the reference to Figure 2-2 be corrected to Figure 2-3?

NRC Response: The NRC agrees with this comment and revised the document to ensure that all figures are labeled correctly.

Comment a38 (NEI): Should Block C, "Safety Goal Analysis," refer to Section 2.4 (instead of 2.2)? If not, then it would be more straightforward to re-order Figure 2-2 to align with the section numbers or reorder the sections to follow the flowchart. Most of the section numbers in Figure 2-2 (see Blocks D, E, F, &G) don't align with the body of the document to which they refer.

NRC Response: The NRC agrees with this comment, and has revised the blocks in Figure 2-2 to accurately refer to the appropriate sections in the body of the document.

Comment a39 (NEI): Some of the values in Table 2-1 are likely to be out of date. Please review and update contents of Table 2-1 as necessary.

NRC Response: The NRC disagrees with this comment. The values in Table 2-2 (previously Table 2-1) represent a snapshot in time. As the response to Comment a23 indicates, the NRC has revised the text in Section 2.4.1.1 to clarify this:

"Analysts should use Table 2-2 [sic] or more recent data, as appropriate, to perform a preliminary screening of the merit of the proposed new requirements for the appropriate class of nuclear power plants."

Comment a40 (NEI): Some places in the text use the term "core melt." Others use "core damage." Recommend using "core damage" everywhere.

NRC Response: The NRC agrees with this comment and has changed the term "core melt" to "core damage" throughout the NUREG.

Comment a41 (NEI): Page 5-1, lines 22-30. This section describes six steps of the regulatory analysis differently than they are described on page 2-8, lines 612. Is there a compelling reason why the description is different here in Chapter 5?

Consider aligning the wording on pages 2-8 and 5-1 or simply point back to the wording on page 2-8. Also decide whether a regulatory analysis consists of six "steps" or six "elements" and use the chosen label consistently throughout BR-0058.

NRC Response: The NRC agrees with this comment and has revised the text in Sections 2.3 and 5.1.1 for consistency and is using the term "elements" throughout.

Comment a42 (NEI): On page 5-2, line 36, "See Appendix H for additional guidance."

Appendix H is presently an empty placeholder. Where is the analyst to turn for the additional guidance until Appendix H is published?

Consider revising the reference to Appendix H or clarifying what the analyst is to do until Appendix H is complete.

NRC Response: The NRC agrees with the comment, especially considering that Appendix H currently is not planned to address nonreactor facilities. The NRC has removed references to future appendices. The analyst should apply the information contained in the current version of NUREG/BR-0184 until further guidance is issued as part of the Phase 2 update.

b. Comments Related to Appendix A

Comment b1 (NEI): "The purpose of this appendix on the qualitative factors assessment methodology is to provide guidance and best practices for use in estimating intrinsic costs and benefits (i.e., qualitative factors) to improve the clarity, transparency, and consistency of the U.S. Nuclear Regulatory Commission's (NRC) regulatory, backfit, and environmental analyses."

The term "intrinsic" seems inappropriate in defining qualitative factors. Quantified benefits and costs are also "intrinsic." It seems like a term "intangible" or "less

quantifiable' would be more appropriate.

NRC Response: The NRC agrees with this comment and has replaced "intrinsic" with "intangible" in Appendix A.

Comment b2 (NEI): Page A-1, Lines 6-34. First two paragraphs stress importance of qualitative factors, describing the use of qualitative information has [sic] "essential for the evaluation and selection of the preferred alternative." Similar statements are contained in Section 2.0 of Revision 5. See e.g., pg. 2-4 ("qualitative factors can be significant elements of a regulatory analysis"), 2-13 ("These [nonquantifiable] attributes may be significant factors in regulatory decisions and should be considered."), 2-21 ("If the net value calculation required by Section 2.4.1 is not positive, further activities an analyses should be terminated unless there is a qualitative justification for proceeding further."). After stressing the importance of qualitative information, midway through the third paragraph on page A-1, Revision 5 states:

> However, as directed by the Commission in SRM-SECY-14-0087…analysts are encouraged 'to quantify costs to the extent possible and use of qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data).' These methods should only be used when quantification may not be practical; they are not a substitute for collecting accurate information to develop realistic cost estimates and do not constitute an expansion of the consideration of qualitative factors in regulatory, backfit, or environmental analyses.

Although the information presented in Appendix A and Section 2.0 regarding qualitative factors is generally accurate, we believe that it may be inappropriately interpreted as setting the Commission's direction in SRM-SECY-14-0087 at odds with the idea that qualitative information can be useful in cost benefit analyses.

To the contrary, our understanding of the direction provided in SRM-SECY-14-0087 is that the Commission has appropriately placed a premium on the use of quantitative information in regulatory analyses because such information improves the usefulness of these documents as decision-making tools. While recognizing the qualitative information should be considered in situations where meaningful quantification is not possible, the primacy of quantitative information in the conduct of regulatory impact analyses is recognized in OMB's Circular A-4, which states:

> Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions. Circular A-4 (September 17, 2013), at pg. 26.

NEI has not advocated that the NRC abandon the use of qualitative factors in its cost-benefit analyses, however we have objected to over-reliance on qualitative information to justify imposition of proposed backfits in situations where robust quantitative risk analyses were available and failed (by over an order of magnitude) to demonstrate that the proposed backfits would result in a substantial increase in safety or security. Consistent with the Commission's direction in SRM-SECY-14-0087, we believe that the agency's guidance on the conduct of cost-benefit and backfitting analyses "should continue to encourage quantifying costs to the

extent possible and use qualitative factors to inform decision making in limited cases, when quantitative analyses are not possible or practical."

In order to avoid the impression that the Commission's direction in SRM-SECY-14-0087 is tension [sic] with the idea the qualitative information can be important but in limited circumstances, we suggest revisions to Appendix A.

Suggested Wording Change:

In SRM-SECY-14-0087, "Staff Requirements – SECY-14-0087 – Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses," dated March 4, 2015 (ADAMS Accession No. ML15063A568), the Commission directed the NRC staff "to quantify costs to the extent possible and use qualitative factors to inform decision making, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data.)"

Consistent with this direction, and as explained in Section 2.3.4, the analyst should make every effort to use quantitative attributes relevant to the cost-benefit analysis. The quantification should employ monetary terms whenever possible. Dollar benefits should be defined in real or constant dollars (i.e., dollars of constant purchasing power). If monetary terms are inappropriate, the analyst should strive to use other quantifiable benefits.

There may, however, be some attributes that cannot be readily quantified, despite the analyst's best efforts to do so. These attributes are termed "qualitative" and this Appendix captures best practices for the consideration of such qualitative factors by providing a number of methods that can be used to support the NRC's evidence-based, quantitative, and analytical approach to decisionmaking. This guidance provides a toolkit to enable analysts to clearly present analyses of qualitative results in a transparent way that decisionmakers, stakeholder, and the general public can understand.

The methods described in this Appendix should be used when quantification is not practical or possible; they are not a substitute for collecting accurate information to develop realistic estimates of costs and benefits, and do not constitute an expansion of the consideration of qualitative factors in regulatory, backfit, or environmental analyses.

~~The identification, characterization, and analysis of both monetized costs and benefits (i.e., those measured in dollars) and qualitative (e.g., functional or nonmonetized) costs and benefits are essential for the evaluation and selection of the preferred alternative.~~

~~The NRC uses cost-benefit analyses to determine whether a regulatory action is justified on the basis of a comparison of predicted costs and benefits. Consideration of the relative importance of qualitative attributes in the decision rationale is an extremely useful and powerful tool for desicionmakers and stakeholders. It is important to realize that monetary units are not the only way to assign value to outcomes of concern to the general public. A known limitation of cost-benefit analysis is that some outcomes are rarely ever priced or traded in the economy, making it difficult to assign monetary value to some types of costs and benefits.~~

~~This appendix captures best practices for the consideration of qualitative factors by providing a number of methods that can be used to support the NRC's evidence based, quantitative, and~~

~~analytical approach to decisionmaking. This guidance provides a toolkit to enable analysts to clearly present analyses of qualitative results in a transparent way the decisionmakers, stakeholders, and the general public can understand. However, as directed by the Commission in SRM-SECY-14-0087, "Staff Requirements – SECY-14-0087 – Qualitative Consideration of Factors in the Development of Regulatory Analyses and Backfit Analyses,' dated March 4, 2015 (ADAMS Accession No. ML15063A568), analysts are encouraged "to quantify costs to the extent possible and use qualitative factors to inform decisionmaking, in limited cases, when quantitative analyses are not possible or practical (i.e., due to lack of methodologies or data). These methods should only be used when quantification may not be practical; they are not a substitute for collecting accurate information to develop realistic cost estimates and do not constitute an expansion of the consideration of qualitative factors in regulatory, backfit, and environmental analyses.~~

NRC Response: The NRC agrees with this comment and has incorporated the suggested language into Appendix A.

Comment b3 (NEI): "Intangible costs and benefits do not easily lend themselves to direct, quantitative measures. In other words, these types of attributes: (1) do not have readily available standard measurement scales, and (2) tend to be subject to great interindividual measurement variability."

What does "great interindividual measurement variability" mean? How does this phrase apply? Cost-benefit analyses don't measure anything; they model things.

NRC Response: The NRC agrees with this comment, and has modified this language in Appendix A to state that "Intangible costs and benefits do not easily lend themselves to direct, quantitative modeling or measurement. In other words, these types of attributes: (1) do not have readily available standard measurement scales, and (2) tend to be subject to greater variability in modeling and results."

Comment b4 (NEI): The title of Section A.3 is "The Need for Consistent Methods," yet the text of Section A.3 says nothing about consistency or consistent methods. Ironically, the next section, Section A.4 provides different methods without any guidance on how to consistently choose the appropriate method.

Please clarify what is meant by "Need for Consistent Methods."

NRC Response: The NRC agrees with the comment that the body of the text needs to clarify what is meant by the title of Section A.3, "Need for Consistent Methods," and that Section A.4 needs to provide guidance on how to consistently choose the appropriate method. As a result of this comment, the NRC deleted Section A.3 and added the following paragraph to the beginning of Section A.4 (now renumbered to A.3):

"To facilitate the selection of consistent methods this section provides analysts with several methods for modeling qualitative attributes, and explains under what circumstances each method would be useful. The use of consistent methods enables analysts to present qualitative results in a transparent way that decisionmakers, stakeholders, and the general public can understand."

Additionally, the NRC has added the following text to the renumbered Section A.3:

"By carefully considering the descriptions and applicability of the qualitative tools in this appendix when selecting the appropriate tool, the analyst can ensure consistency with prior regulatory analyses performed by the staff. The sophistication of the method selected should be commensurate with the complexity of the issue, and the particular method selected by the analyst should be determined based on the nature and importance of the qualitative factor, as described below for each method."

c. Comments Related to Appendix D

Comment c1 (NEI): Section D.5 "Endorsement of Later ASME BPV or OM Codes that are Considered Backfits" describes three circumstances under which the NRC considers incorporation of later code revisions to constitute backfits:

(1) When NRC endorses a later provision of the ASME BPV or OM code that takes a substantially different direction from the current requirements;

(2) When NRC requires implementation of later ASME BPV or OM code provisions on an expedited basis (i.e., faster than required by 50.55a);

(3) When the NRC takes an exception to ASME BPV or OM code provisions and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code.

The NRC should clarify that – consistent with the agency's long-standing backfitting guidance on regulatory changes that provide licensees with additional alternatives, or that provide for the voluntary relaxation of requirements – eliminating or relaxing code requirements would not generally be considered backfitting. [NRC emphasis]

NRC Response: The NRC agrees with this comment. However, Section D.5 has been deleted from Appendix D in order to refocus the appendix solely on regulatory analysis for ASME Code cases.

d. Comments Related to Appendix E

Comment d1 (NEI): Section E.2.3 Treatment of Industry Initiatives, covers the same topic as Section 5.3.1, but the two sections are not entirely consistent. Covering the same material in both sections is unnecessary and creates the potential for inconsistencies and confusion. Thus, we recommend that Section E.2.3 of Appendix E be deleted.

NRC Response: The NRC agrees with this comment. The NRC has revised Section 5.3.1 of NUREG/BR-0058, Revision 5 to ensure it contains the necessary information, and has deleted the former Section E.2.3 Treatment of Industry Initiatives of Appendix E. The appendix has been renumbered and Section E.2.3 has been redesignated as Criteria for the Treatment of Individual Requirements.

Comment d2 (NEI): Section E.2.4 discusses the bundling or aggregation of requirements and includes the following statement:

> This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfitting analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (although costs may be considered in determining how to achieve a certain level of protection).

Section 50.109(a)(4) includes both the adequate protection and compliance exceptions to the backfitting rule. Contrary to the above-quoted paragraph, in a December 2016 memorandum the NRC Solicitor provided guidance stating the costs must be considered when the NRC staff is invoking the compliance exception provided in § 50.109(a)(3) and the extent to which costs must be considered is unclear, the statement in the above-quoted paragraph that costs are not considered in determining whether use of the compliance exception is justified is no longer correct. Thus, we recommend that the NRC narrow the applicability of this statement to the adequate protections exceptions to the backfitting rule.

Suggested Wording Change;

"This discussion does not apply to backfits that the Commission determines to qualify under one of the exceptions in 10 CFR 50.109(a)(4)(ii) and (iii).

NRC Response: The NRC agrees with this comment and has added the suggested wording to redesignated Section E.2.3 (formerly E.2.4, but E.2.3 from the draft document was deleted as noted above).

Comment d3 (NEI): Section E.3.1 describes the Committee to Review Generic Requirements. However, footnotes b, c, and d on page E-9 address policy issues related to the applicability of the NRC's backfitting rules (e.g., the legal and policy implications of the rule, the applicability of the rule to voluntary activities, the applicability of the rule to reporting requirements). NEI strongly believes that guidance of this type should reside primarily in NUREG-1409, which we understand is currently under revision. This type of information is not essential to the information being provided in Table E-1 and including it in NUREG/BR-0058 could cause confusion by creating inconsistencies with NUREG-1409. Thus, NEI recommends that footnotes b, c, and d be deleted.

Likewise, the discussion beginning on line 8 of page E-9 and running through line 28 on page E-10 deals primarily with the applicability of the backfitting rule. Thus, we recommend that it be deleted for the reasons discussed above.

NRC Response: The NRC agrees with the comment that the table notes b, c, and d can be deleted. The NRC has removed the table and table notes to avoid confusion. The NRC agrees in part that some of the discussion dealing with the applicability of the backfit rule should be deleted and should reside in NUREG-1409. However, portions of the backfitting text should remain in Appendix E for context and clarity.