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General Comment

Attached PDF file provides comments of the Nuclear Energy Institute on draft Revision 5 of NUREG/BR-0058.

Attachments

06-16-17 Comments on NUREG-BR-0058 Rev 5 Ltr+Att

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NUCLEAR ENERGY INSTITUTE

June 16, 2017

Ms. Cindy K. Bladey
Chief, Rules, Announcements, and Directives Branch
Office of Administration, MS OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Comments on NUREG/BR-0058 Revision 5; 82 FR 18163; Docket ID NRC-2017-0091

Project Number: 689

Dear Ms. Bladey:

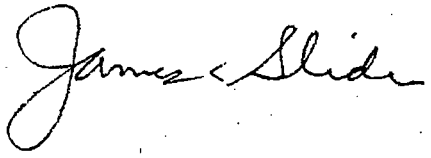
On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)[1] appreciates the opportunity to provide comments on the subject NUREG/BR-0058, Revision 5, "Regulatory Analysis Guidelines of the U.S. NRC." We are sending you this copy of our letter as a courtesy, in parallel with submitting our comments electronically on the regulations.gov website as specified in the subject Federal Register announcement.

We appreciate the aim of the Phase 1 update to NUREG/BR-0058, which is to consolidate and update the NRC's cost-benefit guidance. Our specific comments on Revision 5 are included in the attachment to this letter. Our comments focus primarily on improving the clarity of the proposed revisions to the NUREG; ensuring that the revisions effectively communicate current Commission policy on the relevant issues; and, in the area of backfitting, ensuring that the revisions appropriately focus on providing guidance to the staff regarding the analytical requirements of the Commission's backfitting rules (*e.g.,* how to conduct the cost-justified, substantial-increase analysis), as opposed to backfitting policy (applicability of the backfitting rules, backfitting identification, use of the backfitting exceptions, *etc.*), which are more appropriately addressed in the staff's planned revisions to NUREG-1409.

If you have any questions concerning this letter, please contact me.

[1] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

Sincerely,



James E. Slider

c: Ms. Pamela Noto, NRR, NRC
Mr. R. Frederick Schofer, NRR, NRC
NRC Document Control Desk

Attachment - NEI Comments on NUREG/BR-0058, Revision 5

Page	Lines	Comment	Suggested Wording Change
v	20-26	Sections 2.3.2 and 2.3.5 are not listed in the Table of Contents	
1-1	2	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.	
1-1	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.	"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

Page	Lines	Comment	Suggested Wording Change
			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; any disadvantage 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 . . . . "
1-3	Lines 5-17	"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).	
1-6	Footnote a, lines 6-8	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 (*see* Ref. 26). 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	"[a] Similar provisions detailing what information is to be contained in a backfit analysis are contained in 10 CFR 70.76, 2 10 CFR 72.62, 10 CFR Part 76, and, for issue finality, 10 CFR Part 52. These provisions 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.~~

Page	Lines	Comment	Suggested Wording Change
		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 section 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 protection 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. (emphasis added). Thus, it is clear that both the "substantial increase" and "cost-justified" findings are required to support backfitting under section 70.76. The last two sentences of footnote [a]	~~The Commission believes that modest increases in safety at minimal or inconsequential cost should be justified on a cost-benefit basis." (Ref. 26)"~~

Page	Lines	Comment	Suggested Wording Change
		present an incomplete picture of the Commission's decision-making process, misstate the standard required pursuant to 10 CFR Part 70.76, and should be deleted.	
2-1	1-6	This paragraph describes the NRC's "statutory mission." 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 (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 in Section 161 of the Atomic Energy Act.	"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 applications, 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:"
2-1	8-16	This bullet describes the standard that must be met under the Commission's backfitting rules, but the references are limited to sections 50.109 and 76.76. The references should be expanded to include all of the relevant backfitting provisions.	"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."
2-1	29-30	*"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?	
2-2	13	*"This 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 an industry initiative? We suggest this text mention Section 5.3.1, "Treatment of Industry Initiatives".	
2-2	27-34	*"For several types of regulatory actions, a detailed cost-benefit analysis could*	

Page	Lines	Comment	Suggested Wording Change
		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." [Emphasis added] 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.	

Page	Lines	Comment	Suggested Wording Change
2-2	44-45	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.	
2-4 2-5	38-43 9-14	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. (emphasis added). 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:	NA

Page	Lines	Comment	Suggested Wording Change
		The safety goal evaluation, as discussed in this section, is applicable only to 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 11 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 standard is met for the proposed new requirement. (emphasis added). 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.	
2-5	29	The reference to Figure 2-1 should be changed to Figure 2-2.	
2-7	Figure 2-2	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 re-order the sections to follow the flowchart.	
2-7	Figure 2-2	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.	
2-8	32	*"The staff should provide documentation that the 31 analysis is based on the best reasonably attainable scientific, technical, and economic information 32 available, quantified when possible."* Please provide some examples of what the NRC considers to be "reasonably attainable scientific, technical, and economic information."	
2-8	41-42	*"This element allows the analyst to carefully establish the details of the*	

Page	Lines	Comment	Suggested Wording Change
		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.	
2-10	1	Should this section number be 2.3.2 instead of 2.3.3? (There is no section 2.3.2 shown in draft Revision 5.)	
2-10	31	*"This determination will usually result in a conclusion regarding whether a major or standard effort is needed to resolve the problem."* Please provide some examples of what would constitute a "major effort," as opposed to a "standard effort."	
2-11	14	Should this section number be 2.3.3?	
2-11	35	*"Hypothetical best- and worst-case consequences <u>may</u> be estimated for sensitivity..."* [Emphasis added] 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.	
2-11	44	*"Complete the above steps for each alternative evaluated."* The six <u>elements</u> of a regulatory analysis identified earlier in Section 2. Please clarify what "steps" this sentence refers to.	
2-12	11	Should the section number be 2.3.4, instead of the 2.3.6 shown?	
2-12	31	*"The presentation provides a uniform format for recording the results of the evaluation of all quantitative attributes,*	

Page	Lines	Comment	Suggested Wording Change
		plus a comments section to discuss other attributes and special considerations." Please clarify where the analyst finds this uniform format.	
2-12	43-44	*"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.
2-13	1	Should the section number be 2.3.5 instead of the 2.3.7 shown?	
2-13	24-26	*"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."* [Emphasis added] (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 need 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.	
2-14	17-20	It is important to recognize the additional margin provided by FLEX equipment.	*"For example, an analyst addressing proposed improvements 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*

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			Strategies) already addressed in station blackout considerations."
2-14	20-21	*"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."* [Emphasis added] Please clarify what "risk equations" are being referenced in this sentence.	
2-15	21-23	*"These references provide CDF 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.	*"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."*
2-16	2-4	*"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.	"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."
2-17	Table 2-1	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.	
2-18	22	*"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.	"More than one significant figure in the mantissa is not appropriate in most cases unless needed to characterize a small delta-CDF change."
2-18	39-40	*"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 & LERF goals to the Safety Goals is based on a 25-year- old understanding of	Append to the paragraph that begins at line 32 the underlined text below: "For the purpose of evaluating regulatory initiatives against safety goals, the magnitude of the change in CDF should be considered in concert with the determination of whether the substantial additional protection standard of

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		severe accident phenomena and even older modeling tools. More recent work, such as SOARCA and CPRR, has shown that there is significant margin between the Subsidiary Objectives for CDF/LERF and the Safety Goal QHOs [Ref. EPRI 3002003116, Appendix D]. 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.	the backfit rule is met. Specifically, a single common criterion is to be used for determining whether a regulatory initiative involving a reduction in CDF (1) meets the substantial additional protection standard identified in the backfit rule (Ref. 8) and (2) is appropriate, considering the subsidiary safety goal of 10-4 in mean CDF per reactor year (Ref. 32). This goal has been determined by the staff to be a useful benchmark but is not a Commission approved safety goal. 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."
2-18	48	Should the reference to Figure 2-2 be corrected to Figure 2-3?	
2-19	Figure 2-3	Figure 2-3 is confusing (see our color-coded version pasted at the end of this table of comments). 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.	
2-19	Figure 2-3	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	

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		guidance.	
2-20	24, 26. 33. 34. Etc.	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 & 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.	
2-20	27, 51	Some places in the text use the term "core melt". Others use "core damage". Recommend using "core damage" everywhere.	
2-20	31-33	*"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.	"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."
3-1	3-9	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.	"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."
5-1	22-30	This section describes six steps of the regulatory analysis differently than they are described on page 2-8, lines 6-12. 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	

Page	Lines	Comment	Suggested Wording Change
		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.	
5-2	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.	
5-2	47	*"Expected 45 changes in radiation exposure from a nuclear power reactor accident should be measured over a 50-mile appropriate distance from the licensed facility."* [Emphasis added] Please delete the word "appropriate" or clarify what it means.	
5-8	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 pg. 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.	NA
5-8 5-9	43-50 1-7	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	**5.3.1 Treatment of Industry Initiatives** Industry initiatives are typically actions performed by licensees that either form the bases for continued compliance with the regulations or obviate the need for new regulations. Industry initiatives for NRC regulatory action can provide effective and efficient resolution of issues, without compromising facility safety or reducing the NRC's commitment to safety and sound regulation.

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		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 thus will not be credited by the NRC in its cost-benefit analyses (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 "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	Industry initiatives can generally be put into one of the following categories: (1) those put in place in lieu of, or to complement, a regulatory action to ensure that existing requirements are met, (2) those used in lieu of, or to complement, a regulatory action in which a substantial increase in overall protection could be achieved with costs of implementation justifying the increased protection, and (3) those that were initiated to address an issue of concern to the industry but that may or may not be of regulatory concern. Issues related to adequate protection of public health and safety are deemed the responsibility of the NRC and should not be addressed through industry initiatives. The presence of industry initiatives is potentially very important in the estimation of costs and benefits, and, as such, its treatment in the regulatory analysis should be explicitly considered. All consequences of a proposed regulatory change are measured relative to the baseline, which is how things would be if the proposed regulation were not imposed (status quo). If industry initiatives that complement or substitute for a proposed regulatory action exist, the future role of these industry initiatives should be determined. This determination would affect the baseline, which in turn would affect the calculation of incremental costs and benefits. For example, if "full credit" is given to the industry initiatives (i.e., it is assumed that complementary industry initiatives will continue in the future), the incremental values attributable to the proposed regulation are diminished. Alternatively, if "no credit" is given, the incremental values assigned to the proposed rule are increased. For the purpose of the regulatory analysis, cost-benefit results are to be calculated based, to the extent practicable, on varied assumptions concerning the future role of industry initiatives. Initially, two sets of cost-benefit estimates are to be derived: one based on no credit and the other based on full credit for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes. If the overall value-impact result does not tilt from an overall net cost to

Page	Lines	Comment	Suggested Wording Change
		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 E.2.2 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 potentially confusing, incomplete, and is already addressed by the section of	an overall net benefit (or vice versa), there is no need to proceed further, and the final results would be reported as a range of values that reflect the sensitivity of these results to this assumption. However, if the results are highly sensitive to that level of variation, such that the overall cost-benefit conclusion shifts or the final recommendation changes, the analyst would proceed to develop a "best-estimate" base case. Under this best-estimate base case, the staff will evaluate the specific industry initiatives in question to determine how much credit to give to the industry initiatives. The NRC is currently developing guidelines designed to increase the NRC's assurance that industry initiatives will be effective long-term alternatives to regulatory actions. Clearly, the more an industry initiative satisfies these guidelines, the more credit one should give to the industry initiative. Before these guidelines are formally approved, the staff should rely on relevant features and characteristics of the industry initiatives to assess the weight or amount of credit to attach to any given industry initiative. Relevant characteristics would include the following: • costs associated with the industry initiative (i.e., if the dominant costs are fixed costs that have already been expended or the future recurring costs to maintain the industry initiative are minimal, it is more likely the industry initiative will continue in the future) • the extent to which written commitments exist (i.e., if written commitments exist, it is more likely a licensee will continue that commitment in the future, and the NRC could, if necessary, respond to licensees not adhering to the industry initiative) • whether the industry has formally adopted the initiative as mandatory through NEI's Nuclear Strategic Issues Advisory Committee • the degree to which the industry initiative is noncontroversial and standard industry practice (i.e., if the industry initiative is noncontroversial and standard industry practice, as a function of consistency with provisions of industry codes and standards, the participation rate among relevant licensees, the length of time the program has been operating, or its

Page	Lines	Comment	Suggested Wording Change
		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 of 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.	effectiveness, the more likely it will continue without the rule change) • the scope and schedule for industry initiatives that are still pending (i.e., for industry initiatives that are still works in progress, the more well defined the scope and the sooner the initiative is expected to be in place, the more likely it will be available in the future) Based on such an assessment, the regulatory analysis should contain, to the extent practicable, a best estimate of the costs and benefits of the regulation under consideration. These results would serve as the basis for the staff's recommendations to the Commission. Careful attention is needed when PRA techniques are used to give partial or no credit to industry initiatives, because risk estimates from PRAs are based on existing conditions that typically include credit for any industry initiative that may be in place. When the PRA is modified to eliminate or reduce credit for industry initiatives, the reviewer needs to ensure that these changes are properly reflected in the details of 40 the PRA model. ~~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 "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~~

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			~~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.~~
5-12	Table 5-1	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?	
5-15	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 be the basis for the update and what is the plan for updating this table? Please clarify the intended use of this table.	
A-1	7	*"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's) 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 like "intangible" or "less quantifiable" would be more appropriate.	
A-1	6-34	First two paragraphs stress importance of qualitative factors, describing the use of qualitative information has "essential	**Appendix A** **A.1 Purpose**

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		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	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's) regulatory, backfit, and environmental analyses. 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, stakeholders, and the general public can understand. The methods described in this Appendix should be used only when quantification is not practical or possible; they are not a substitute for collecting accurate information to develop

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		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 (Sept. 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 in tension with the idea the qualitative information can be important in limited circumstances, we suggest the	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 decisionmakers 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 that 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 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~~

Page	Lines	Comment	Suggested Wording Change
		revisions to Appendix A detailed in the column to the right.	~~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.~~
A-2	11	*"Intangible costs and benefits do not easily lend themselves to direct, quantitative measures. In 10 other words, these types of attributes: (1) do not have readily available standard measurement 11 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.	
A-2 A-3		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 10 different methods without any guidance on how to consistently choose the appropriate method.	Please clarify what is meant by "Need for Consistent Methods".
App. D		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 an ASME BPV or OM code provision and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code.	

Page	Lines	Comment	Suggested Wording Change
		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.	
App. E E-2 – E-4		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.	
E-4	29-30	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 section 50.109(a)(4)(i). Although the staff is not required to perform the full analysis required pursuant to section 50.109(a)(3) and the extent to which costs must be considered is unclear, the statement in the above-quoted	"This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4)(ii) and (iii). 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)."

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		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 protection exceptions to the backfitting rule.	
E-9 – E-10	Footnotes b, c, d 1-18; 1-28	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.	

Modified Version of Figure 2-2 Mentioned in NEI Comment on Page 2-19

Figure 2-2 of NUREG/BR-0058