NRC STAFF RESPONSE TO PUBLIC COMMENTS ON
DRAFT REGULATORY GUIDE DG-1334: GUIDANCE FOR IMPLEMENTATION OF
10 CFR 50.59, "CHANGES, TESTS, AND EXPERIMENTS"

On December 23, 2016, the NRC issued for public comment in the *Federal Register* (81 FR 94275) draft regulatory guide (DG), DG-1334, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments'" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML16089A381). Comments on the subject draft regulatory guide are available electronically at the U.S. Nuclear Regulatory Commission's (NRC's) electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html. From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents.

NRC staff received 7 comment submissions on DG-1334, as listed below, from the following individuals or organizations:

Letter No.	ADAMS Accession No.	Commenter Affiliation	Commenter Name
1	ML17038A003	No Known Affiliation	Anonymous
2	ML17048A163	No Known Affiliation	Anonymous
3	ML17048A164	No Known Affiliation	Anonymous
4	ML17059D068	No Known Affiliation	Kurt Schaefer
5	ML17059D075	No Known Affiliation	Daniel Cronin
6	ML17059D122	Nuclear Energy Institute (NEI)	Kati R. Austgen
7	ML17081A014	Exelon Generation Company, LLC	David Helker

This document lists each public comment by letter and comment number. For example, Comment 4-2 would be the second comment provided in Letter No. 4 listed in the table above. For each comment, the NRC has repeated the comment as written by the commenter and then provided the NRC's response. In some instances, the comment was broken down into segments for clarity.

Comment No. 1-1

NEI 96-07 Rev. 1 describes the "50.59" process as consisting of three phases:
(1) Applicability Determination - the 50.59 rule is applicable to an engineering design change if there are NO other more specific regulatory requirements for controlling the change
(2) Screening - Once it has been determined that the 50.59 rule is applicable to an engineering design change, the engineering design change is screened to determine (in part): (a) if the engineering design change is a modification of equipment needed for a design function, and (b) the change has any adverse effect on a design function
(3) Evaluation - If and only if the engineering design change has been determined to have any adverse effect on a design function, then the eight evaluation questions are answer and documented per the requirements of 50.59.

The vast majority of engineering design changes (for which 50.59 has been determined to be applicable), are not evaluated. Furthermore, NRC oversight is only applicable to evaluations and not screenings (i.e., no inspection procedures exist for screening). It is not clear however, what portion of engineering design changes do not modify equipment needed for a design function, and what portion do but are determined to have no adverse aspects.

The statements of consideration for the promulgation of the 50.59 rule (i.e., the ones that describe the definition of "change") only describe change as a modification to a design function; NEI 96-07 Rev. 1, added the guidance associated with "adverse".

Please add a regulatory position that all modifications:
(A) to equipment needed for a design function, or
(B) to other equipment or procedures that could adversely affect a design function, require an evaluation.

This position would effectively change the "and" between (2)(a) and (2)(b) above to an "or."

NRC Response

The NRC staff does not agree that, "NRC oversight is only applicable to evaluations and not screenings (i.e., no inspection procedures exist for screening)." For example, NRC Inspection Procedure 71111 Attachment 17T, "Evaluations of Changes, Tests, and Experiments," (ADAMS Accession No. ML16340A998) specifies that "If available as a potential sample selection, additional consideration should also be given to reviewing 6 to 12 evaluations and 12 to 25 screenings and/or applicability determinations for 10 CFR 50.59." Accordingly, NRC inspectors routinely review screenings of engineering design changes that modify equipment needed for a design function that licensees screen out as having no adverse effect.

The NRC staff does not agree with the commenter that all modifications to equipment or procedures needed for a design function should require a 50.59 evaluation, regardless of their impacts. As described in NEI 96-07, Rev. 1, Section 4.2.1,

> A 10 CFR 50.59 evaluation is required for changes that adversely affect design functions, methods used to perform or control design functions, or evaluations that demonstrate that intended design functions will be accomplished (i.e., "adverse changes"). Changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents or otherwise meet the 10 CFR 50.59 evaluation criteria.

Even if the guidance were modified such that all proposed changes received a 10 CFR 50.59 evaluation (i.e., even those changes that do not adversely affect a design function), evaluations of those changes that the guidance currently allows the licensee to screen out would always have the same result—the licensee would not be required to obtain a license amendment prior to implementation. Therefore, such evaluations may be screened out as described in NEI 96-07, Rev. 1. As described above, NRC inspection procedures provide guidance for NRC review of those changes that a licensee screens out of its 10 CFR 50.59 evaluation process.

No change was made to the regulatory guide in response to the comment.

Comment No. 2-1

I searched the NEI website and could not find a copy of NEI 96-07 Rev. I also searched ADAMS, and could not find the approved version in ADAMS.

Please ensure that NEI 96-07 Rev. 1 (the approved version) is available in ADAMS. Please include the ADAMS Accession number of the approved version in the RG and DG.

NRC Response

The approved version of NEI 96-07, Rev. 1, can be found in ADAMS under Accession No. ML003771157. This was added in the References section of the regulatory guide.

Comment No. 3-1

NEI 96-07, Rev. 1, only discusses the regulatory requirements for [maintenance] in terms of 10 CFR 50.65. There are other regulatory requirements for maintenance that should be described in the RG, for example:

10 CFR 50, Appendix A, states:
"…The development of these General Design Criteria is not yet complete. For example, some of the definitions need further amplification. Also, some of the specific design requirements for structures, systems, and components important to safety have not as yet been suitably defined. Their omission does not relieve any applicant from considering these matters in the design of a specific facility and satisfying the necessary safety requirements. These matters include:
…
(4) Consideration of the possibility of systematic, nonrandom, concurrent failures of redundant elements in the design of protection systems and reactivity control systems. (See Criteria 22, 24, 26, and 29.)
…
Criterion 22 Protection system-independence. The protection system shall be designed to assure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels do not result in loss of the protection function, or shall be demonstrated to be acceptable on some other defined basis. Design techniques, such as functional diversity or diversity in component design and principles of operation, shall be used to the extent practical to prevent loss of the protection function."

Therefore the design (at least for protections systems) must include provisions to ensure maintenance does not result in "the possibility of systematic, nonrandom, concurrent failures of redundant elements."

Please include a regulatory position that states: Where a requirement such as the one quoted above exists, Changes to these provisions must be evaluated under 50.59.

NRC Response

The NRC staff does not agree with the comment that, "NEI 96-07, Rev. 1, only discusses the regulatory requirements for [maintenance] in terms of 10 CFR 50.65." NRC finds NEI 96-07, Rev. 1, sufficiently addresses regulatory requirements for maintenance that are relevant for properly applying 10 CFR 50.59 and provides a sufficient description of why screening and evaluation under 10 CFR 50.59 are not required for certain maintenance.

NEI 96-07, Rev. 1, Section 1.2.1, "Relationship of 10 CFR 50.59 to Other Processes That Control Licensing Basis Activities," states:

> Maintenance activities, including associated temporary changes, are subject to the technical specifications and are assessed and managed in accordance with the

> Maintenance Rule, 10 CFR 50.65; screening and evaluation under 10 CFR 50.59 are not required. Together with 10 CFR 50.59, these processes form a framework of complementary regulatory controls over the licensing basis. To optimize the effectiveness of these controls and minimize duplication and undue burden, it is important to understand the scope of each process within the regulatory framework.

NEI 96-07, Rev. 1, Section 4.1.2, under "Control of Maintenance Procedures" states:

> Changes to procedures for performing maintenance are made in accordance with applicable 10 CFR Part 50, Appendix B, criteria and licensee procedures. Licensee processes should ensure that changes to plant configurations called for by procedures are consistent with the technical specifications. 10 CFR 50.59 does not apply to such changes because, like the maintenance activities themselves, changes to procedures for performing maintenance do not permanently alter the design, performance requirements, operation or control of SSCs.

NRC staff also does not agree that the regulatory guide should include a regulatory position that states, "Where a requirement such as [GDC 22] exists, Changes to these provisions must be evaluated under 50.59." NEI 96-07, Rev.1 addresses departures from the performance standards outlined in the GDC (Appendix A to Part 50) (see, e.g., NEI 96-07, Rev. 1, Section 2.0, "Defense In Depth Design Philosophy and 10 CFR 50.59," and NEI 96-07, Rev. 1, Section 4.3.2, "Does the Activity Result in More Than a Minimal Increase in the Likelihood of Occurrence of a Malfunction of an SSC Important to Safety?").

10 CFR 50.59 applies to proposed changes to the facility or procedures as described in in the UFSAR, which in turn describes how plants meet the GDC, including the maintenance provision in GDC 22. The guidance for criterion 10 CFR 50.59(c)(2)(ii) in NEI 96-07, Rev. 1, Section 4.3.2, states, "Further, departures from the design, fabrication, construction, testing and performance standards as outlined in the General Design Criteria (Appendix A to Part 50) are not compatible with a 'no more than minimal increase' standard." Therefore, if the maintenance activity involves a change to the facility or procedures described in the UFSAR that results in a departure from a standard outlined in the GDC, including maintenance provisions of GDC 22, this change would require prior NRC approval per criterion 10 CFR 50.59(c)(2)(ii).

No change was made to the regulatory guide in response to the comment.

Comment No. 4-1

The method of evaluation discussion is confusing. The discussion should include a specific statement such as:

> *A new method is "approved by the NRC for the intended application" if it is already NRC approved for the specific plant, plus, the NRC approval is for the type of analysis being conducted and the licensee satisfies applicable terms and conditions for its use.*

NRC Response

The NRC staff does not agree that the comment's proposed clarification to the method of evaluation discussion is needed, although NRC staff did make other clarifying edits to the method of evaluation discussion in the final version of RG 1.187, Rev. 1. The above comment

relates to NEI 96-07, Rev. 1, Section 4.3.8.2, Guidance for Changing from One Method of Evaluation to Another, which states,

> A new method is approved by the NRC for intended application if it is approved for the type of analysis being conducted, and applicable terms, conditions and limitations for its use are satisfied.
>
> NRC approval has typically followed one of two paths. Most reactor or fuel vendors and several utilities have prepared and obtained NRC approval of topical reports that describe methodologies for the performance of a given type or class of analysis. . . . The second path is the approval of a specific analysis rather than a more generic methodology.

The NRC staff finds the above excerpt from NEI 96-07, Rev. 1, sufficiently clear.

No change was made to the regulatory guide in response to the comment.

Comment No. 4-2

DG-1334 needs to address all the accident and event category errors in NEI 96-07. NEI 96-07, Rev. 1, erroneously lists transients, floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS), station blackout (SBO) and turbine missiles as "accidents." The current event categories are shown in SRP 15.0 Rev. 3. The NEI 96-07 position is inconsistent with the safety, design and licensing bases of all LWRs, the ASME Code, Reg. Guide 1.70, 10 CFR 50 App. A, Anticipated Operational Occurrence definition and GDC 10 and 15. As shown in SRP 15.0.3 Table 1, accidents have radiation doses as their acceptance criteria. Those other events have no or significantly lower dose acceptance criteria than for accidents. Treating those other events as accidents would be non-conservative, because this implies that the less restrictive accident success/acceptance criteria could be used in assessing changes to these events. (See SRP 15.0 and ESBWR DCD Tier 1 Section 15.0 for different event categories and their associated acceptance criteria.) NEI 96-07 [Rev. 1] correctly states that these events (as documented in a UFSAR) are within the scope of 10 CFR 50.59, however, changes to their UFSAR evaluations should be assessed against their event-specific acceptance criteria and not accident acceptance criteria.

NRC Response

The NRC staff does not agree with the comment. The NRC staff does not agree with the statement, "DG-1334 needs to address all the accident and event category errors in NEI 96-07. NEI 96-07, Rev. 1, erroneously lists transients, floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS), station blackout (SBO) and turbine missiles as 'accidents.'" The comment relates to NEI 96-07, Revision 1, Definition 3.2:

> Definition:
> Accident previously evaluated in the FSAR (as updated) means a design basis accident or event described in the UFSAR including accidents, such as those typically analyzed in Chapters 6 and 15 of the UFSAR, and transients and events the facility is required to withstand such as floods, fires, earthquakes, other external hazards, anticipated transients without scram (ATWS) and station blackout (SBO).
>
> Discussion:

> The term "accidents" refers to the anticipated (or abnormal) operational transients and postulated design basis accidents that are analyzed to demonstrate that the facility can be operated without undue risk to the health and safety of the public. *For purposes of 10 CFR 50.59*, the term "accidents" encompasses other events for which the plant is required to cope and that are described in the UFSAR (e.g., turbine missiles, fire, earthquakes and flooding). [emphasis added]

The NRC staff does not agree it is erroneous or non-conservative that NEI 96-07, Rev. 1, Section 3.2, states that for purposes of 10 CFR 50.59, the term "accidents" encompasses other events with which the plant is required to cope that may not considered "accidents" in the Standard Review Plan (SRP), NUREG-0800 (available electronically through the NRC Library on the NRC's public Web site https://www.nrc.gov/reading-rm/basic-ref/srp-review-standards.html). In the SRP, the NRC established acceptance guidelines for certain events that are considered of greater likelihood than the limiting accidents. For example, for a steam generator tube rupture, the SRP acceptance guideline is that the dose be less than or equal to a small fraction (i.e., 10 percent) of the 10 CFR Part 100 thyroid dose limit. The NRC staff finds that the set of SRP events that were chosen to have lower dose acceptance guidelines are acceptable. The NRC staff finds the NEI 96-07, Rev. 1, guidance for criteria 10 CFR 50.59(c)(2)(iii) and (iv) acceptable in evaluating dose increases against the SRP limits. Specifically, NEI 96-07, Rev. 1, Section 4.3.3, "Does the Activity Result in More Than a Minimal Increase in the Consequences of an Accident?" states the following:

> [F]or a given accident, calculated or bounding dose values for that accident would be identified in the UFSAR. These dose values should be within the GDC 19 or 10 CFR 100 limits, as applicable, as modified by SRP guidelines (e.g., small fraction of 10 CFR 100), as applicable. An increase in consequences from a proposed activity is defined to be no more than minimal if the increase (1) is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline value (10 CFR 100 or GDC 19, as applicable), and (2) the increased dose does not exceed the current SRP guideline value for the particular design basis event. . . .
>
> For some licensees the current calculated dose consequences may already be in excess of the SRP guidelines for some events. In such cases, *minimal increase* is defined as less than or equal to 0.1 rem. [emphasis in original]

No change was made to the regulatory guide in response to the comment.

Comment No. 4-3

DG-1334 and NEI 96-07 need to provide a definition with distinct criteria for an "accident of a different type." Accidents always result in a radiological consequence greater than a 10 CFR 20 allowable release limit. Therefore, for a change to create an accident of a different type, the change must be within the plant's 10 CFR 50.2 design bases criteria (e.g., within the single failure criterion), and must allow for a new failure with resulting radiological release of such safety significance (greater than the 10 CFR 20.1301(a)(1) 1 mSv (0.1 rem) dose limit) that, if the plant was being licensed for the first time, the failure would be included in the plant FSAR. Therefore, an accident of a different type must result in a new potential radioactive material release. The following definition and clarification should be added to the final regulatory guide revision.

A change that could result in an accident of a different type must (a) allow for or create a new fission product release path, (b) result in a new fission product barrier failure mode, and/or (c) create a new sequence of events that results in significant fuel cladding failures.

An accident of a different type is not applicable to an event with failures beyond the 10 CFR 50, Appendix A single failure criterion, except if the follow-on failures are a direct result of the initial failure or event.

Note; a change that only increases a radiological source term would not create an accident of a different type, but could result in an increase of a radiological consequence of an accident, which is covered by another 50.59 criterion.

NRC Response

The commenter used the term "accident" to refer to design basis accidents; however, in NEI 96-07, Rev. 1, the term "accident" includes both design basis accidents (DBAs) and transients (i.e., Anticipated Operational Occurrences - AOOs). See NRC response to Comment 4-2 for definition of "Accident previously evaluated in the FSAR (as updated)."

The NRC staff does not agree with the concept that a few (design neutral) specific criteria can be used in all cases (for both DBAs and AOOs). For certain older facilities, the term "design basis accident" was only applied to a very small set of events. That is, each nuclear power plant has its own safety analysis, and a comparison of any new accident with the plant-specific accident analysis must be considered in the licensee's determination of whether the new accident should be considered an accident of a different type when performing 10 CFR 50.59 evaluations. The NRC staff finds the explanation in NEI 96-07, Revision 1, Section 4.3.5, appropriate and sufficient:

> The terms accidents and transients are often used in regulatory documents (e.g., in Chapter 15 of the Standard Review Plan), where transients are viewed as the more likely, low consequence events and accidents as less likely but more serious. . . . This criterion deals with creating the possibility for accidents of similar frequency and significance to those already included in the licensing basis for the facility.

Regarding the suggested statement related to "single failure criterion," the NRC staff finds NEI 96-07, Rev. 1, Section 4.3.5, appropriate and sufficient:

> The possible accidents of a different type are limited to those that are as likely to happen as those previously evaluated in the UFSAR. The accident must be credible in the sense of having been created within the range of assumptions previously considered in the licensing basis (e.g., random single failure, loss of off-site power, etc.).

See also response to comment No. 5-1.

No change was made to the regulatory guide in response to the comment.

Comment No. 5-1

The current 50.59 rule and associated guidance is well established and well understood. It has served the industry and regulator well for two decades. Given this track record, any proposed

changes should be carefully scrutinized for potential unintended negative consequences. With this in mind, my comments are as follows:

No objective evidence is provided to justify the need for the proposed changes to RG-1.187.

The staff is attempting to change the interpretation and revise the words of NEI 96-07 in DG-1334. This is an inappropriate use of the Regulatory Guide process.

The new interpretation and attempted rewording of the NEI guidance fails to clarify any "potentially misleading statements". In fact, the proposed changes undermine and muddle the well-established and well-understood wording that has been in place for two decades.

The current wording in Sections 4.3.5 and 4.3.8 of NEI 96-07 are applicable to non-power reactors and provide valuable and well-understood 50.59 guidance to the non-power reactor community. In contrast, the wording changes proposed in DG-1334 eliminate or muddle the applicability to non-power reactors and create confusion thereby greatly increasing the likelihood of misinterpretation.

What is an "effect on the plant that is different"? This proposed change is vague, misleading, and undefined.

NRC Response

This revision to RG 1.187 clarifies certain ambiguous language in NEI 96-07, Revision 1, which NRC staff determined could be interpreted inconsistently with 10 CFR 50.59 requirements. The staff agrees with the commenter that as originally proposed, the DG did not clearly indicate that the planned revision simply clarified an ambiguity and was not intended to change the NRC staff's previous interpretation of the underlying regulations. The final regulatory guide includes a number of revisions to address this concern.

The NRC staff also agrees that the phrase "effect on the plant that is different" is vague. Changes were made to Sections B and C of the regulatory guide that deleted the sentences containing the phrase.

Comment No. 6-1

A. Introduction, Purpose and Applicable Regulations (first bullet), Page 1, Paragraphs 1 & 3

Both of these paragraphs omit the "tests or experiments not described in the FSAR (as updated)" portion of the regulation.

Revise the Purpose statement as follows:

"… may make changes to their facilities and procedures as described in the final safety analysis report (FSAR) (as updated), and conduct tests or experiments not described in the FSAR (as updated), without prior NRC approval, under certain conditions."

Revise the first bullet under Applicable Regulations as follows:

"... may make changes to their facilities and procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated) without prior NRC approval."

NRC Response:

The NRC staff agrees with the comment because the wording is in the 10 CFR 50.59 regulation.

Changes were made to the regulatory guide as stated in the proposed wording.

Comment No. 6-2

B. Discussion, Background, Page 3

The first sentence should be revised to clearly reflect the language of 10 CFR 50.59(c)(1).

Revise as follows:

"Under 10 CFR 50.59, licenses are allowed to make changes in the facility and procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without prior NRC approval provided specific criteria are met.

NRC Response:

The NRC staff agrees with the comment because the wording is in the 10 CFR 50.59 regulation.

A change was made to the regulatory guide as stated in the proposed wording.

Comment No. 6-3

B. Discussion, Background, Departure from a Method of Evaluation, Page 3, 3rd paragraph

The final sentence quoting of Criterion (viii) is incomplete.

Revise as follows:

"Criterion (viii) states, "Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.""

NRC Response:

The NRC staff agrees with the comment because the wording is in the 10 CFR 50.59 regulation.

A change was made to the regulatory guide as stated in the proposed wording.

Comment No. 6-4

B. Discussion, Background, Departure from a Method of Evaluation, Pages 3 and 4

There are typos in the quote of the definition in 10 CFR 50.59(a)(2) on page 3 and in the paragraph following the Section 4.3.8 excerpt in the middle of page 4: "(as update)" should be "(as updated)."

Correct "(as update)" to "(as updated)" throughout.

Response:

The NRC staff agrees with the comment because the wording is in the 10 CFR 50.59 regulation.

A change was made to the regulatory guide as stated in the proposed wording.

Comment No. 6-5

B. Discussion, Background, Departure from a Method of Evaluation, Page 4, 1st paragraph

This paragraph is intended to instruct the 50.59 performer to compare the results of the analysis using the current method against the results of same method with the changed elements; however, this is not what it says. Instead, the paragraphs states, "...consists of comparison between: (1) the results of the analysis using the method of evaluation described in the FSAR (as updated), and (2) the results of the analysis using the current method described in the FSAR (as updated) that has been revised by the proposed change to any of the elements of the method."

At first read, (1) and (2) appear to be the same statement phrased slightly different. The confusion may be caused by the term "that has been revised."

To provide a clearer distinction between the current UFSAR described methodology and the methodology that is proposed with the changed elements, revise (2) as follows:

"(2) the results of the analysis using the same method described in the FSAR (as updated) that is being revised by the proposed change to any of the elements of the method."

NRC Response:

While the NRC staff agrees with the comment that this language in the regulatory guide should be clarified, NRC staff decided to remove this text because the same concept is restated more clearly at the end of the discussion of Departure from a Method of Evaluation in RG 1.187, Revision 1.

Comment No. 6-6

B. Discussion, Background, Departure from a Method of Evaluation, Page 4, 2nd to last paragraph

The paragraph beginning, "The above excerpt ...," appears to mix the potential misinterpretation with the intended clarification and seems to confuse the issue further.

Specifically, is the second to last sentence, "Licensees may document a methodology revision as a change from a method described in the FSAR (as update) to another method and would not require a license amendment if the licensee can demonstrate and document that the revised

method has been previously accepted by NRC through issuance of an SER for the intended application," intended as 1) continued explanation of potential misinterpretation by licensees, 2) an allowance for 50.59 implementation, or 3) a requirement for implementation of 50.59?

Although this language in DG-1334 is confusing, NRC's March 6, 2015 Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (ML15015A419) provided a discussion that is clear. DG-1334 should use the clear discussion from the lessons learned report on this issue.

Consider separating the discussion of the potential misinterpretation and the intended clarification. Clarify this discussion by replacing "Licensees may..." with language from the lessons learned report. Specifically, the report states with respect to NEI 96-07:

- *It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "the previous revision of the same methodology" instead of being compared to the revision currently specified in the FSAR which may be an earlier revision than the "previous revision"; and*

- *It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "another methodology previously accepted by NRC through issuance of an SER" instead of being compared to the methodology currently specified in the FSAR.*

NRC Response:

The NRC staff agrees with the comments.

The regulatory guide background section was changed to refer to the NRC Report "Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event," dated March 6, 2015. In addition, the regulatory guide was changed to remove the detailed discussion of the language in NEI 96-07, Revision 1, and to add a clear, concise discussion. Specifically, this discussion explains that guidance in Section 4.3.8 of NEI 96-07, Revision 1, appears to merge the concepts in 10 CFR 50.59(a)(2)(i) and (ii), which, correctly interpreted, are two distinct provisions.

Comment No. 6-7

B. Discussion, Background, Accident of a Different Type, Page 5, 4th paragraph from the bottom and C. Staff Regulatory Guidance, 1. NEI 96-07, a. Section 4.3.5. Page 6, last paragraph

There is a typo in the modified paragraph and "of" should be added to the third sentence.

Revise the third sentence as follows:

"*The UFSAR evaluates a broad spectrum of transients and accidents, or initiating events. Initiating events are categorized according to expected frequency of occurrence and by type. The type of accident is defined by its effect on the plant. Categorization of initiating events by type provides a basis for comparison between events, which makes it possible to identify and evaluate in detail the limiting cases (i.e., the cases that can challenge the analysis acceptance criteria) and eliminate non-limiting cases from further consideration. Accidents that are non-limiting cases are not discussed in the UFSAR. For example, a postulated pipe break in a small line may not be specifically evaluated in the UFSAR because it has been determined to be less*

limiting than a pipe break in a larger line in the same area. Therefore, if a proposed design change would introduce a small high energy line break into this area, postulated breaks in the smaller line need not be considered an accident of a different type."

NRC Response:

The comment is referring to the third sentence that stated, "The type [of] accident is defined by its effect on the plant," which was missing the word "of" as noted. The NRC staff agrees with the comment. The third sentence was removed.

Comment No. 6-8

B. Discussion, Background, Accident of a Different Type, Page 5, 3rd paragraph from the bottom

The draft guidance states "(i.e., a different accident analysis would be needed for this different type of accident)."

The meaning of "different accident analysis" is the major point of this clarification. It is intended to mean that an entirely new event has been "created" and thus an entirely new analysis must be developed.

This possibility is remote and was not directly included in NEI 96-07, but it was considered during the development of the statement of consideration. From 64 FRN 53593:

> *Allowing changes that result in an accident of a different type (even if the result has previously been analyzed) appears inconsistent with the criterion in § 50.92.*

The context of the statement above is that the 1999 revision to 10 CFR 50.59 does not allow a licensee to avoid the license amendment process for changes that result in an accident of a different type. For purposes of the guidance, the NRC should clarify that:

- *An accident of a different type does not have to have non-bounded results.*
  - *Since it is a "new event," being bounded by something that doesn't exist is not possible.*

NEI 96-07, section 4.3.5 attempted to describe what an "accident of a different type" was not.

This clarification more completely describes what characteristics such an accident sequence must have to be a "different type".

Further clarify the NRC's proposed modification of the last sentence in Section 4.3.5 as follows:

"Accidents of a different type are credible accidents that the proposed activity could create that have an effect on the plant that is different than any previously evaluated in the UFSAR (i.e., a different accident analysis, not simply a revision of an existing analysis, would be needed for this different type of accident)."

An additional clarifying paragraph should be added as follows:

"Accidents of a different type would generate a revised event categorization, which then would require a completely new accident analysis. If a tube rupture could be experienced in multiple

steam generators, then it would be categorized as a separate event as described above. The existing accident analysis would not be adequate. This would be in contrast to higher flowrates from a single tube failure within a single steam generator. These would only involve revisions to the existing analyses governed by the other 10 CFR 50.59 criteria."

NRC Response:

The NRC staff agrees that the language in the draft guide could be enhanced regarding the term "bounded" to better clarify how licensees should apply Section 4.3.5 of the NEI 96-07, Revision 1, guidelines to satisfy the requirements of 10 CFR 50.59. Section B of the regulatory guide was revised to specify that the statement of considerations for the 1999 final rule for 10 CFR 50.59 states, "the Commission had in mind creation of accidents of the likelihood and significance" but does not mention "bounded" as a consideration. Section B of the regulatory guide was also revised to specify that the bounding criterion is not applicable for those new accidents which have no related events analyzed in the UFSAR.

However, the NRC staff did not insert into the regulatory guide the comment's proposed clarifying paragraph regarding steam generator tube failures. NEI 96-07, Rev. 1, Section 4.3.5, is sufficiently clear, stating, "if a change or activity is proposed such that a scenario such as a multiple steam generator tube rupture becomes credible, the change or activity could create the possibility of an accident of a different type."

Comment No. 6-9

B. Discussion, Background, Accident of a Different Type, Page 5, 2nd paragraph from the bottom

The major characteristic of classifying a newly created sequence as an "accident of a different type" is not the analyzed results.

- *An "accident of a different type" does not have to have non-bounded results.*
- *Simple logic demands that if an accident is of a "different type," then being bounded by a prior analysis is impossible.*

Revise as follows:

"This NRC clarification ensures the last sentence would not be inappropriately interpreted to mean that the accident types described in the current UFSAR accident analyses could be used to evaluate the effect on the plant of the newly created, but distinct and dissimilar, accident sequence."

NRC Response:

The NRC staff agrees with the comment regarding the proposed sentence. The regulatory guide discussion was revised to incorporate language similar to this proposed sentence. See NRC Response to Comment No. 6-8 regarding the term "bounded."

Comment No. 6-10

10. C. Staff Regulatory Guidance, 1. NEI 96-07, a. Section 4.3.5, Page 7

Revise the italicized text following "The last sentence...should be read as:" to reflect the corresponding statement in the preceding section, B. Discussion, Background, Accident of a Different Type

Further clarify the NRC's proposed modification of the last sentence in Section 4.3.5 and align with the same earlier statement as follows:

"Accidents of a different type are credible accidents that the proposed activity could create that have an effect on the plant that is different than any previously evaluated in the UFSAR (i.e., a different accident analysis, not simply a revision of an existing analysis, would be needed for this different type of accident)."

NRC Response:

A change was made to Sections B and C of the regulatory guide that deleted the sentence described in the comment.

Comment No. 6-11

11. C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, a., Page 7

It appears this NRC staff clarification is intended to be consistent with the historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance as discussed in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.5.

However, the same confusion noted in the corresponding statement in the preceding section B. Discussion, Background, Departure from a Method of Evaluation, exists. NRC's March 6, 2015 Review of Lessons Learned from the San Onofre Steam Generator Tube Degradation Event (ML15015A419) provided a discussion that is clear. DG-1334 should use the clear discussion from the lessons learned report on this issue.

Consider separating the discussion of the potential misinterpretation and the intended clarification. Clarify this discussion by replacing "Licensees may ..." with language from the lessons learned report. Specifically, the report states with respect to NEI 96-07:

- *It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "the previous revision of the same methodology" instead of being compared to the revision currently specified in the FSAR which may be an earlier revision than the "previous revision"; and*

- *It [NEI 96-07] could be read to infer that "methodology revision" results could be compared to "another methodology previously accepted by NRC through issuance of an SER" instead of being compared to the methodology currently specified in the FSAR.*

Alternately, remove discussion of the potential misinterpretation and focus on the clarification only in C.1.b.a.

NRC Response:

The NRC staff agrees with the comment.

See NRC Response to Comment 6-6 above.

Comment No. 6-12

C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, b., Page 7

This NRC staff clarification contains conditional language, i.e., "could be ...," and should be more direct. A direct statement that the "previous revision" must be the licensee's previously described method is consistent with the historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance as discussed in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.22.

For clarity, replace C.1.b.b as follows:

"10 CFR 50.59(a)(2)(i) controls when a licensee implements a change to a "previous revision" of a methodology that was "described in the FSAR (as updated)" and no NRC SER exists for the revised methodology."

NRC Response:

The NRC staff agrees with the comment.

See NRC Response to Comment 6-6 above.

Comment No. 6-13

C. Staff Regulatory Guidance, 1. NEI 96-07, b. Section 4.3.8, b., Page 7

This NRC staff clarification should be more direct to reflect the two possibilities for a "departure." As written, it appears inconsistent with the historic NRC/ industry understanding of 1) demonstration of the new method's applicability and 2) determination that the "new method" is specific to the "intended function" as approved through an NRC SER.*

It is our understanding that Attachment 4 to NRC's Summary of November 2, 1999 Meeting with NEI on Revision to NEI 96-07 on Implementation of 10 CFR 50.59 - Methods of Evaluation (ML993260078) provides the NRC Staff historic view of the steps necessary to take in determining the new method's applicability and the determination of meeting the "intended application" criteria.

The historic industry understanding of this portion of NEI 96-07, Revision 1, Section 4.3.8 guidance is provided in the "Questions and Answers on 10 CFR 50.59 and NEI 96-07, Revision 1" document dated April, 2001 (enclosed); Q&A E.16.

**DG-1334 C.1.b.c states "intended function" and we believe this was meant to be "intended application."*

For clarity, replace C.1.b.c as follows:

"10 CFR 50.59(a)(2)(ii) controls when a licensee replaces the methodology as currently specified in the FSAR (as updated) with another methodology not used at the licensee's plant.

The basis for determining that there is no departure under 10 CFR 50.59 shall ensure that the demonstration of applicability of the new methodology becomes part of the licensing basis for the licensee's facility and is specific to the intended application as approved through an NRC SER."

NRC Response:

The NRC staff agrees with the comment that the regulatory guide needs to be more direct. A new paragraph was added that more directly reflects the wording in 10 CFR 50.59(a)(2).

Comment No. 6-14

C. Staff Regulatory Guidance, 5. Applicability to 10 CFR 72.48 Evaluations, Page 8

NEI 96-07, Appendix B is the current NRC approved implementation guidance for 10 CFR 72.48. This approval is documented in RG 3.72. Efforts are underway to supersede NEI 96-07, Appendix B with NEI 12-04 and we expect to see a corresponding revision to RG 3.72.

Specific 10 CFR 72.48 implementation guidance endorsement through NRC Regulatory Guide 3.72 should be referred to in this section in addition to the general applicability of NEI 96-07, Revision 1.

NRC Response:

The NRC staff agrees with this comment that efforts are underway to supersede NEI 96-07, Appendix B.

The discussion in Section C.5 was deleted and RG 3.72 was referenced in the discussion of "Related Guidance" in section A.

Comment No. 7-1

Section C.1.b.a

Exelon believes that the guidance should be revised to make it clear that the "conservative or essentially the same" criteria only apply when making changes to elements of an existing methodology that the licensee is currently licensed to as described in the Updated Final Safety Analysis Report (UFSAR). These criteria do not apply when changing to another method that is not part of a licensee's current licensing basis as described in the UFSAR, but that has been approved by the NRC through issuance of a Safety Evaluation Report (SER) for the intended application.

Exelon recognizes the NRC's use of the wording "methodology revision" in its guidance since this wording is used in the subject NEI 96-07, Revision 1 statement; however, Exelon believes the use of this wording is confusing since a "revision" is typically thought of as a change to an existing methodology and not a change from one method to another method. Exelon recommends the following clarification to the last sentence in the first paragraph of Section C.1.b.a:

Although a "methodology revision" is typically thought of as a change to an existing methodology in the licensee's current licensing basis, Licensees may document a "methodology revision" as a change from a method described in the FSAR to another method which would not require a license amendment if the licensee can demonstrate that the other method has been previously accepted by NRC through issuance of an SER for the intended application. However, the "conservative or essentially the same" criteria do not apply when changing from one method to another method.

NRC Response:

The NRC staff agrees with the comment regarding clarifying the use of the term "methodology revision." The subject paragraph was rewritten.

Comment No. 7-2

Section C.1.b.b

Exelon believes that the proposed guidance does not provide sufficient discussion in this section to clearly explain that the statement "previous revision of the same methodology" is a reference to the revision of the methodology that the licensee is currently licensed to as described in the UFSAR. The determination of whether a change to an element of a methodology produces results that are conservative or essentially the same is based on a comparison with the methodology of record as described in the UFSAR (i.e., the current licensing basis).

NRC Response:

The NRC staff does not agree with the comment. NEI 96-07, Revision 1, and the definition in 10 CFR 50.59(a)(2) uses the phrases "Departure from a method of evaluation *described in the FSAR (as updated)*," "Changing any of the elements of the method *described in the FSAR (as updated)*," and "Changing from a method *described in the FSAR* to another method" (emphasis added). However, NEI 96-07, Revision 1, and the definition in 10 CFR 50.59(a)(2), do not use "methodology of record as described in the UFSAR" or "the current licensing basis."