

April 11, 2016

MEMORANDUM TO: Eric R. Oesterle, Acting Branch Chief
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Division of Safety Systems
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SUBJECT: RESPONSE TO PUBLIC COMMENTS ON DRAFT REGULATORY
ISSUE SUMMARY 2015-##, "CLARIFICATION OF 10 CFR 50.46
REPORTING REQUIREMENTS AND RECENT ISSUES WITH
RELATED GUIDANCE NOT APPROVED FOR USE BY THE NRC"

A notice of opportunity for public comment on a draft of the subject regulatory issue summary was published in the *Federal Register* (80 FR 44160) on July 24, 2015. Comments were received from the Nuclear Energy Institute (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15268A089), AREVA Inc. (ADAMS Accession No. ML15268A090), Southern Nuclear Operating Company (ADAMS Accession No. ML15271A085), GE Hitachi Nuclear Energy (ADAMS Accession No. ML15271A087), STP Nuclear Operating Company (ADAMS Accession No. ML15287A392), Virgil C. Summer Nuclear Station (ADAMS Accession No. ML15292A212), STARS Alliance LLC (ADAMS

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Accession No. ML15292A215), Westinghouse Electric Company (ADAMS Accession No. ML15293A418), and Exelon Generation Company, LLC (ADAMS Accession No. ML15310A047). Enclosed are the U.S. Nuclear Regulatory Commission's responses to all public comments.

Enclosure:

1. U.S. Nuclear Regulatory Commission
Responses to Public Comment
2. List of All Submitted Comments

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Accession No. ML15292A215), Westinghouse Electric Company (ADAMS Accession No. ML15293A418), and Exelon Generation Company, LLC (ADAMS Accession No. ML15310A047). Enclosed are the U.S. Nuclear Regulatory Commission’s responses to all public comments.

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**NRC RESPONSE TO PUBLIC COMMENTS ON
DRAFT U.S. NUCLEAR REGULATORY COMMISSION
REGULATORY ISSUE SUMMARY 2015-##
“CLARIFICATION OF 10 CFR 50.46 REPORTING REQUIREMENTS AND RECENT ISSUES
WITH RELATED GUIDANCE NOT APPROVED FOR USE BY THE NRC”**

Comments on the subject draft regulatory issue summary (RIS) (ADAMS Accession No. ML15057A346) 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. Comments were received from the following individuals or groups:

Table 1. Commenters on Draft RIS

Letter No.	ADAMS Accession No.	Commenter Affiliation	Commenter Name
1	ML15268A089	Nuclear Energy Institute (NEI)	Gordon A. Cleifton
2	ML15268A090	AREVA, Inc. (AREVA)	Pedro Salas
3	ML15271A085	Southern Nuclear Operating Co. (SNC)	C. R. Pierce
4	ML15271A087	GE Hitachi Nuclear Energy (GEH)	James F. Harrison
5	ML15287A392	STP Nuclear Operating Co. (STPNOC)	Michael P. Murray
6	ML15292A212	Virgil C. Summer Nuclear Station (VCSNS)	Anonymous
7	ML15292A215	STARS Alliance LLC (STARS)	Scott A. Bauer
8	ML15293A418	Westinghouse Electric Co. (WEC)	James A. Gresham
9	ML15310A047	Exelon Generation Co., LLC (Exelon)	David P. Helker

Table 1, “Commenters on the draft RIS,” lists each public comment by letter number. Each comment is referred to below by letter number, and a sequential number for each comment within the letter. In some instances, the comment was broken down into segments for clarity. Table 2, “List of All Submitted Comments,” at the end of this document, shows how each comment was broken down and categorized by topic, as applicable.

The following comments endorsed the comments submitted by NEI: SNC 3-01.A, SNC 3-01.B, SNC 3-01.C, SNC 3-01.D, SNC 3-02, SNC 3-03, STARS 7-01, Exelon 9-01. For brevity, these comments were not addressed individually, and the NRC’s responses to the NEI comments also serve as the NRC responses to these comments.

During NRC review of the public comments submitted on the subject draft RIS, the NRC staff identified four recurring topics. This comment response document was structured to address the recurring topics first, then individual comments were repeated and addressed.

The recurring topics were identified as follows:

1. The relationship between the RIS and proposed 10 CFR 50.46c rule (NEI 1-03, NEI 1-06.B, NEI 1-07)

2. The definition of the term “application” (NEI 1-04, NEI 1-06.C, NEI 1-12, AREVA 2-02, SNC 3-02)
3. The definition of the terms “input” and “evaluation model” (NEI 1-13, AREVA 2-01, AREVA 2-02, SNC 3-01.C, SNC 3-03, GEH 4-01, GEH 4-02, VCSNS 6-01)
4. The NRC interaction with the industry to develop guidance (SNC 3-05, STPNOC 5-02)

Recurring Topic Comment Responses

The recurring topics identified above are summarized, with the NRC response provided directly after.

Topic 1: The Relationship Between the RIS and Proposed Rule 10 CFR 50.46c

Language should be provided in the RIS regarding changes to reporting requirements under proposed rule 10 CFR 50.46c. Additionally, clarification needs to be provided regarding the reporting requirements language used in proposed rule 10 CFR 50.46c and current regulation. A 5-year time frame for review of the RIS for efficacy is not reasonable if outstanding items that require clarity are identified, affect reporting, and are not resolved. (NEI 1-03, NEI 1-06.B, NEI 1-07)

NRC Response

The NRC disagrees with this comment. The NRC staff responsible for developing the RIS coordinated the content with the NRC’s 10 CFR 50.46c working group, in order to avoid providing guidance in the RIS that would be invalidated by the 10 CFR 50.46c rulemaking activity. However, the RIS pertains to reporting requirements presently contained in 10 CFR 50.46(a)(3). The proposed reporting requirements contained in 10 CFR 50.46c¹ are pre-decisional, such that issuing a generic communication about them would be inappropriate. Furthermore, not all licensees and applicants will be required to comply with proposed rule 10 CFR 50.46c requirements immediately upon publication of the final rule. Some licensees and applicants may defer implementation of proposed rule 10 CFR 50.46c for up to 84 months after the rule’s final issuance. Should the Commission decide to issue proposed rule 10 CFR 50.46c, the NRC staff will review generic communications affected by the rulemaking to decide which communications, if any, would require rescission or revision. The NRC staff did not revise the draft RIS in response to these comments because of the following:

1. The authors of the draft RIS coordinated with the 10 CFR 50.46c working group
2. The RIS pertains to existing reporting requirements contained in 10 CFR 50.46(a)(3)
3. The requirements contained in 10 CFR 50.46(a)(3) will remain applicable for up to 84 months following issuance of 10 CFR 50.46c

¹ Available in ADAMS at Accession No. ML15281A011

4. the NRC staff will re-visit the need to rescind or revise this RIS, along with other generic communications potentially affected by proposed rule 10 CFR 50.46c, once it is issued.

Topic 2: The Definition of the Term “Application”

The definition of the term “application” in the draft RIS is both incorrect and inconsistent with the SOC regarding the 10 CFR 50.46(a)(3) reporting requirements that were adopted on September 16, 1988 (1988 ECCS Rule SOC), and has no basis in any regulations or guidance. The definition of “application” as “the range of applicability” of an evaluation model, as used in NEI 07-05, “10 CFR 50.46 Reporting Requirements,” is based on the 1988 ECCS Rule SOC, and should be adopted by the NRC staff. (NEI 1-04, NEI 1-06.C, NEI 1-12, AREVA 2-02, SNC 3-02)

NRC Response

The NRC staff disagrees with the comment because the scope of the term “application” is generally applied more broadly by the NRC in the regulations and their supporting documentation. Nevertheless, the NRC staff also recognizes that if only a single public comment from the 1988 ECCS Rule SOC is used to infer a definition of the term “application,” that definition may align with NEI 07-05. However, the background information provided in the draft RIS summarizes other discussion regarding the reporting requirements, which also appeared in the 1988 ECCS Rule SOC. These additional passages identify that the NRC staff needs to remain cognizant of changes and corrections. The definition of “application” provided in NEI 07-05 is inconsistent with the additional discussion because it leads to the exclusion of numerous types of changes to or errors in the applications of ECCS evaluation models from reporting, and thus could prevent the NRC staff from being able to make safety decisions regarding the updated information.

To add further clarity, the NRC staff revised the draft RIS to indicate the consistency of the definition of the word “application” with the general discussion in the 1988 ECCS Rule SOC, and also to show that the NEI 07-05 definition of “application” is inconsistent with the general discussion in the 1988 ECCS Rule SOC. The following changes were made to Section A of the subject RIS:

...While the NEI 07-05 definition of “application” may appear consistent with certain portions of the NRC’s comment response in the 1988 ECCS Rule SOC, it is inconsistent with the general discussion on the reporting requirements in the 1988 ECCS Rule SOC...

The NRC staff is aware of at least one other third-party guidance document, written in 1992, which defines “application” more consistently with the definition discussed in the draft RIS. This third-party guidance document also claimed to be based on the same 1988 ECCS Rule SOC discussion, further suggesting that the NEI 07-05 definition was too narrow.

Topic 3: The Definition of the Terms “Input” and “Evaluation Model”

The definitions from 10 CFR 50.46, “Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,” and 10 CFR 50.2, “Definitions,” do not support the position taken in the draft RIS that plant-specific inputs and input parameters are a part of the evaluation model. The definition of evaluation model used in the draft RIS means that each plant effectively has its own evaluation model, which is an expansion of the intent expressed by the NRC in the 1988 ECCS Rule SOC. The NRC should clarify in the RIS what input changes would be considered changes to the evaluation model, what changes and errors should be reported, and what may be changed without notifying the NRC. (NEI 1-13, AREVA 2-01, SNC 3-01.C, SNC 3-03, GEH 4-01, GEH 4-02, VCSNS 6-01)

NRC Response

The NRC staff disagrees with the comment that the definition provided in 10 CFR 50.46(c)(2) does not support the position taken in the draft RIS. In the draft RIS, the NRC staff reviewed the 10 CFR 50.46(c)(2) definition of evaluation model. The definition is as follows:

An evaluation model is the calculational framework for evaluating the behavior of the reactor system during a postulated [loss of coolant accident (LOCA)]. It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

The discussion identifies several clauses of the definition that include plant-specific information. Most notably, the definition identifies “all other information necessary for application of the calculational framework to a specific LOCA.” On page 6 of the draft RIS, the NRC staff identified several categories of information that might contain plant-specific information, or “input information” as defined in NEI 07-05. In order to demonstrate the long-standing consistency of the NRC staff position, the NRC staff also considered the interpretive discussion published in the *Federal Register* on June 1, 2000². The draft RIS reflects consideration of this discussion on pages 3–4 and on pages 6–7.

One of the comments received regarding the draft RIS stated that the definition of evaluation model used in the draft RIS would mean that each plant effectively has its own evaluation model and that such an interpretation is an expansion of the intent expressed by the NRC in the 1988 ECCS Rule SOC. However, the draft RIS does not assert or interpret a new definition of evaluation model, as suggested by the comment. Rather, the draft RIS restates the definition that is provided in 10 CFR 50.46(c)(2). The NRC staff also considered, in identifying examples to support the discussion in the draft RIS, previous information published in the *Federal Register* on June 1, 2000. This information identified items that the NRC staff determined were part of the ECCS evaluation model, and were subject to reporting under 10 CFR 50.46(a)(3). Based on the NRC staff review of the definition of evaluation model, including prior discussions

² 65 FR 34913; June 1, 2000

published in the *Federal Register* on June 1, 2000, the NRC staff disagreed that the draft RIS offered an interpretation of evaluation model that expands the intent beyond that discussed in the 1988 ECCS Rule SOC. As discussed below, clarifying text has been added to the RIS in response to these comments.

Based on several comments received in response to the draft RIS, regarding both the regulatory definition of evaluation model and the meaning of the phrase “or in the application of such a model,” the NRC staff has added a passage to Section B of the RIS. The passage discusses items considered part of an evaluation model, and items considered part of the application of an evaluation model. The passage concludes that both examples discussed in the draft RIS would be reportable, either as a change to the evaluation model, or as a change to the application of an evaluation model:

The NRC recognizes that there may be some overlap between the information identified as part of an evaluation model, as defined in 10 CFR 50.46(c)(2), and the information that would be considered part of the application of an evaluation model. Two examples are discussed below.

First, some plant- and cycle-specific core design parameters, such as peaking factors, are included in the definition of evaluation model, but are also part of the plant-specific application of the evaluation model. This first example indicates some overlap between the evaluation model and its application.

Second, some best-estimate evaluation models that rely on random sampling to perform adjustments to values of parameters, such as correlation coefficients, use a multiplier that varies randomly from case-to-case. The nominal value of the parameter and the sampling range or probability density function from which the parametric multiplier is determined would generally be considered part of the evaluation model, but the specific value that is used in a particular case would be considered part of the application of the evaluation model. In this second example, there is a distinction between information that belongs to the evaluation model, and information that is considered part of the application of the evaluation model.

Changes to any of the parameters identified in the two examples above that affect the PCT [peak cladding temperature] calculation would be considered reportable. Changes to the core design parameters, the nominal values of correlation coefficients, or the probability density functions for correlation coefficients would be reportable as changes to the evaluation model. Changes to core design parameters, or a specific value of a correlation coefficient used as part of a plant-specific analysis would be considered reportable as changes to the application of an evaluation model. However, because the reporting requirements are the same for either type of change, neither the specific distinction, nor the occurrence of overlap between the two, is important.

One commenter on the draft RIS asked the NRC staff to clarify what may be changed in an ECCS evaluation model without notifying the NRC. The NRC staff believes that only changes

that do not affect the cladding temperature calculation may be made to ECCS evaluation models, or applications thereof, without triggering reporting under 10 CFR 50.46(a)(3).

Topic 4: The NRC Interaction with the Industry to Develop Guidance

The RIS is not necessary, and it is recommended it be withdrawn. Instead, the NRC is encouraged to engage and work with the industry to develop guidance for the identified issues. (SNC 3-05, STPEGS-02)

NRC Response

The NRC staff disagrees with the comment. The RIS identifies issues that are current, and is the appropriate regulatory vehicle to clarify these issues. Specifically, Management Directive (MD) 8.18, "NRC Generic Communications Program," states, in part:

A regulatory issue summary (RIS) is used to communicate with the stakeholders on a broad range of matters that do not involve a request for action or information (unless strictly voluntary).

Additionally, MD 8.18 states that a RIS may, among other things, "communicate staff technical or policy positions on matters that have not been communicated to or are not broadly understood by the nuclear industry," and may not, among other things, "provide guidance for the implementation of rules and regulations," nor, "provide guidance to NRC staff on regulatory or technical matters." Therefore, the NRC staff may only use a RIS to communicate and clarify existing NRC positions on regulatory matters.

Should the industry choose to develop a consensus-based guidance document, and submit it for NRC staff review and approval for use or endorsement, the NRC would consider reviewing such a document.

No revision was made to the draft RIS in response to these comments.

Other Topics in Individual Comment Responses

The remainder of this document address public comments received by the NRC that were on other topics than the recurring topics listed above (see Table 2 at the end of this document for further information on the individual comments).

NEI 1-01.A:

Regulation 10 CFR 50.46 has two primary functions: 1) to provide reporting requirements in paragraph (a)(3) and 2) provide acceptance criteria in paragraph (b).

10 CFR 50.46 is not a change control rule. 10 CFR 50.59 provides criteria for making changes to methods of evaluation and when NRC approval is required. In comparison, 10 CFR 50.46 does not provide such criteria.

NRC Response

The NRC staff agrees in part with the comment, in that 10 CFR 50.46 does not explicitly contain criteria to determine whether or not prior NRC approval is required to make changes to ECCS evaluation models or applications thereof. However, the purpose of some of the criteria in 10 CFR 50.46 is to determine the actions required of the licensee as a result of such changes. There are changes described in 10 CFR 50.46 that meet 10 CFR 50.59(c)(4), which states, "The provisions in this section [10 CFR 50.59] do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes." Accordingly, the provisions of 10 CFR 50.59 do not apply for changes to the facility or procedures when 10 CFR 50.46 establishes more specific criteria than those in 10 CFR 50.59 for accomplishing such changes.

Overall, the relationship between 10 CFR 50.59 and 10 CFR 50.46 involves determining:

- (a) The types of changes to the facility or procedures covered by 10 CFR 50.46
- (b) The more specific criteria for evaluating those changes in 10 CFR 50.46
- (c) The actions required when the criteria in 10 CFR 50.46 are exceeded

There are several sets of related changes, criteria, and actions embedded in 10 CFR 50.46. For example, 10 CFR 50.46(a)(3)(ii) covers "change[s] to or error[s] discovered in an acceptable evaluation model or in the application of such a model". The criterion for evaluating these covered changes is whether or not such changes or errors, "affect the temperature calculation," which is more specific than the criteria provided in 10 CFR 50.59(c)(2). Finally, when such a change is made or error discovered, the applicant or licensee is required by 10 CFR 50.46(a)(3)(ii) to, "report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4 or § 52.3 of this chapter, as applicable."

Ultimately, 10 CFR 50.46 acts as a change control rule for certain changes to ECCS evaluation models or applications thereof. Facility changes that result in modifications to an ECCS evaluation model or its application, or changes made to ECCS evaluation models or applications thereof independently of facility changes, should be evaluated for the need for a license amendment under 10 CFR 50.59 and for reportability under 10 CFR 50.46(a)(3). This is discussed in further detail in the NRC response to NEI 1-06. No additional changes were made to the draft RIS in response to this comment.

NEI 1-01.B

In the guidance for the implementation of 10 CFR 50.59 in Revision 1 of NEI 96-07,³ as endorsed by Regulatory Guide 1.187, there is a clear distinction between an input parameter and an element of the method of evaluation. 10 CFR 50.46 does not provide such a distinction.

³ Available in ADAMS at Accession No. ML003771157.

NRC Response

The NRC agrees, in part, with the comment. The definition of evaluation model in 10 CFR 50.46(c)(2) states that it includes “values of parameters,” which would include input parameters. Revision 1 of NEI 96-07, “Guidelines for 10 CFR 50.59 Implementation,” Section 3.8, definition of “Input Parameters” states:

Input parameters are those values derived directly from the physical characteristics of SSC or processes in the plant, including flow rates, temperatures, pressures, dimensions or measurements (e.g., volume, weight, size, etc.), and system response times.

Discussion:

The principal intent of this definition is to distinguish methods of evaluation from evaluation input parameters. Changes to methods of evaluation described in the UFSAR (see Section 3.10) are evaluated under criterion 10 CFR 50.59(c)(2)(viii), whereas changes to input parameters described in the FSAR are considered changes to the facility that would be evaluated under the other seven criteria of 10 CFR 50.59(c)(2), but not criterion (c)(2)(viii).

That such a distinction exists in the implementation guidance for 10 CFR 50.59 but not in 10 CFR 50.46 is primarily due to the fact that the 10 CFR 50.46 reporting requirements apply to changes to and errors found in an ECCS evaluation model or an application of such a model. Furthermore, it is important to note that 10 CFR 50.46(c)(2) defines “evaluation model” whereas 10 CFR 50.59 and NEI 96-07, collectively, define “method of evaluation”, rather than “evaluation model”. Owing to these considerations, changes to both elements of an ECCS evaluation model and “input parameters” are equally reportable under 10 CFR 50.46. The response to Topic 3, above, provides a more detailed discussion of this subject.

Furthermore, to underline the possible applicability of both 10 CFR 50.59 and 10 CFR 50.46, to a particular situation, NEI 96-07, Rev. 1, provides an explicit example of a change to an input parameter to an evaluation model as Example 2 in Section 4.3.7, as follows:

Example 2

The heat transfer capability of an RHR [Residual Heat Removal] heat exchanger tube bundle has degraded, and it is proposed to accept the condition “as-is.”

Identification of design basis limits

The effects of the reduced heat transfer capability would be reviewed. The direct effect would include the increased temperature of the suppression pool or containment sump [BWR or PWR, as applicable]. The indirect effects would include increasing the peak containment post-accident pressure and increased enthalpy of ECCS flow. The increased ECCS enthalpy would also affect peak clad temperature (PCT). Thus, the proposed activity affects two design basis limits: containment pressure and PCT. In this example, the design basis limits

would most likely serve as the acceptance criteria for the two parameters in the LOCA analysis described in the UFSAR. (Most licensees use containment design pressure and 2200 degrees F for those values.)

Exceeded or altered

Any increase in peak containment post-accident pressure would be compared to the design basis limit, in this case, containment design pressure. If the revised peak post-accident containment pressure exceeded the design basis limit, then a license amendment would be required.

On the other hand, PCT is governed by a more specific regulation, 10 CFR 50.46. Therefore, the evaluation under this criterion would not address the impact on this parameter. Rather, any changes or corrections to an acceptable evaluation model or application of such a model that affects the PCT calculation would be evaluated per the requirements of 10 CFR 50.46(3)(ii). [emphasis added]

In this example, the design basis limit for containment pressure is not being altered. Therefore, this element of the review is not applicable.

Although NEI 96-07 might distinguish between an input parameter and an element of the method of evaluation, the *reportability* of a change to an input parameter to an ECCS evaluation model or the application thereof is determined under the requirements of 10 CFR 50.46. No changes were made to the draft RIS in direct response to this comment. However, the NRC response to NEI 1-06.C discusses revisions made to the draft RIS on the interface between 10 CFR 50.59 and 10 CFR 50.46. These revisions also reflect consideration of this comment.

NEI 1-01.C:

10 CFR 50.46 uses the term "Acceptable Evaluation Model" several times. The rule provides no clear definition of the process for acceptance of an Evaluation Model or acceptance of changes to an Evaluation Model. The only reference to a process may be in paragraph (a)(2) that refers to "...evaluations of ECCS cooling performance submitted..."

NRC Response

The NRC staff interpreted this comment to refer to the "acceptable evaluation model" language contained in 10 CFR 50.46(a)(1)(i), and to suggest that further clarification should be provided regarding appropriate processes that may be used to obtain acceptance for a particular evaluation model. Since the intent of the RIS is to clarify reporting requirements, rather than discuss the processes and attributes that make an "evaluation model" an "acceptable evaluation model," the NRC staff determined that the comment is out of scope. For additional clarification regarding acceptable attributes of evaluation models, refer, for example, to NRC Regulatory Guide 1.157, "Best-Estimate Evaluations of Emergency Core Cooling System Cooling Performance," and to Appendix K to 10 CFR 50, "ECCS Evaluation Models."

NEI 1-01.D:

While not formally defined in 10 CFR 50.2, "Definitions", paragraph (c)(2) of 10 CFR 50.46 describes or "defines" an Evaluation Model as being the "calculational framework" and the "calculation procedure". This description implies that the Evaluation Model is a process. Paragraph (c)(2) uses the expression "... procedure for treating input and output information..." Again, this describes a process, not values of plant-specific inputs or input parameters. Paragraph (c)(2) also uses the expression "values of parameters" as being part of the Evaluation Model. This expression has been a source of confusion. It is not clear from the definition of an Evaluation Model in paragraph (c)(2) what is meant by a "parameter". Mathematically, a parameter is a quantity that influences the behavior of a mathematical function. An example would be the coefficients in the Baker-Just equation for calculating the metal-water reaction rate as described in 10 CFR 50, Appendix K. In this case, the parameters (coefficients) would be considered part of the Evaluation Model. This is analogous to an element of a method of evaluation in 10 CFR 50.59 as opposed to an input or input parameter.

The concept of an "Acceptable Evaluation Model" is not clear. Acceptance of models (or methods of evaluation as referred to in 10 CFR 50.59) is typically through the issuance of a Safety Evaluation Report (SER) by the NRC whereby the NRC approves the method for an intended application as in 10 CFR 50.59(a)(2)(ii). Such methods are typically submitted as topical reports by vendors to the NRC for review and acceptance/approval. In the topical reports, as well as in the review and acceptance process, plant-specific inputs or parameters are not typically included. Therefore, plant-specific inputs or parameters cannot be considered part of the Evaluation Model.

NRC Response

The NRC staff disagrees in part with this comment. While the NRC staff agrees that "evaluation model" is defined in 10 CFR 50.46(c) rather than 10 CFR 50.2, as the comment noted, the NRC staff disagrees with the assertion in this comment that the definition provided in § 50.46(c) suggests that the evaluation model, as a whole, is a process. Rather, as noted in the comment and as defined in § 50.46(c)(2), an evaluation model may include certain processes, such as those used for treating the input and output information. The NRC also disagrees that, simply because any particular constituent process within the evaluation model may not specifically include plant-specific inputs or input parameters, the definition of evaluation model, as a whole, specifically excludes plant-specific inputs or input parameters. Since evaluation model is defined within 10 CFR 50.46(c)(2), and clarification on this topic is already provided within the draft RIS, the NRC staff did not revise the draft RIS in response to this portion of the comment.

As discussed more generally in the response to Topic 3, above, the NRC staff has considered the comment pertaining to values of parameters and added additional, clarifying discussion to Section B of the draft RIS. This discussion was based on review of the correspondence between NEI and the NRC during the 1999-2000 rulemaking that resulted in the revision to 10 CFR 50.46 and 10 CFR Part 50, Appendix K. Refer to the response to NEI 1-01.E, below, for additional detail. Hence, the NRC agrees with the portion of this comment which notes that the phrase "values of parameters" has been a source of confusion.

Regarding the concept of an acceptable evaluation model, refer to the response to NEI 1-01.C, above.

NEI 1-01.E:

In the proposed rulemaking (64 FR 53270, October 1, 1999) related to the revision of 10 CFR 50, Appendix K of NEI submitted comments on the proposed rulemaking in a letter dated December 15, 1999 (ML003671779). NEI Comment 8 addressed the following statement in the Section-by-Section Analysis of the proposed change: "Estimated changes in ECCS performance due to revised analysis inputs are reported under 10 CFR 50.46 (a)(3), at least annually."

NEI sought to clarify the applicability of the reporting requirements in paragraph (a)(3). In particular, NEI argued that paragraph (a)(3) does not apply to changes in the Peak Clad Temperature (PCT) resulting from plant specific analysis input parameter values. NEI proposed revised rule language to clarify this.

In the publication of the final rule, the NRC disagreed with the NEI proposal and took the position that "... the ECCS evaluation model is comprised of the computer code or codes, the input parameters (including plant specific design parameters), and the calculational results." (65 FR [34913], June 1, 2000).

This position further indicates continued disagreement on what constitutes an Acceptable Evaluation Model. As discussed previously, the definition in paragraph (c)(2) does not include plant-specific information. Further, contrary to the statement above from 65 FR 34918, the definition in paragraph (c)(2) does not include calculational results.

[Proposed Resolution to NEI 1-01.A-E]

Consider clarification within the RIS of the use of an evaluation model to ensure consistency with definitions in 10 CFR 50.46(c)(2).

NRC Response

The NRC disagrees with this comment. In NEI comments regarding the 2000 revision to 10 CFR 50.46 and 10 CFR Part 50, Appendix K, NEI requested⁴ that the NRC revise the rule language contained in 10 CFR 50.46(a)(3) to clarify that reporting is required for changes to, or errors in, model parameters, but not to plant design parameters. The NRC disagreed⁵ with NEI. The NRC further stated that, based on the definition provided in 10 CFR 50.46(c)(2), the ECCS evaluation model includes input parameters (including plant-specific design parameters). The NRC also stated, as noted in the draft RIS, that the NRC did not accept NEI's distinction between "model parameters" and "design parameters." Therefore, the NRC acknowledges that the NEI has a different position than the NRC. NEI requested that the NRC

⁴ ADAMS Accession No. ML003671779.

⁵ 65 FR 34913, June 1, 2000

change the rule language, and the NRC declined to do so. Nevertheless, as discussed in the response to NEI 1-01.D above, the NRC agrees that the meaning of "values of parameters" has been a source of confusion on the part of the industry.

NEI 1-02:

The Draft RIS would benefit by better organization of the information. The use of "NRC Staff Position" is unclear whether it was previously stated or is being repeated herein. For example, "NRC Staff Position" is used on page 3 of 9 prior to the section that describes the NRC Staff Position. Even more, the NRC Staff Position is intermingled with the Summary of the Issue. Separation of these would provide better clarity. Finally, the last paragraph in the Background Information would be better placed after the first paragraph in that section.

[Proposed Resolution]

Reorganize the RIS to provide improved clarity and cite specific docketed examples of "NRC Staff Position".

NRC Response

The NRC disagrees with this comment. The citation of "NRC staff position" from the 1988 ECCS Rule SOC on page 3 of 9 of the draft RIS is one example where the long-standing NRC position was documented. The NRC staff considers this citation as appropriate background information for the RIS. The remainder of the suggestions in the comment were considered editorial only. No changes were made to the draft RIS as a result of this comment.

NEI 1-05:

The following items are not addressed in the Draft RIS:

- The wording of the rule (i.e., "acceptable evaluation model," "last acceptable model," "proposed schedule for providing a reanalysis,") is frequently and inappropriately inferred to require regulatory action that is not required by any rule.*
- Ambiguous characterization of a "change to or error discovered in ... a model that affects the temperature calculation." Is reporting required for changes/errors that have no effect on the PCT calculation result?*
- Treatment of offsetting changes as compared to the last acceptable analysis (e.g., changes due to installation and removal of lead test assemblies, as discussed in the public meeting).*
- What constitutes the "last acceptable model," - last NRC SE, last biannual report, last 30-day report or other?*
- Repeated 30-day reports for inconsequential changes due to the "sum of the absolute magnitudes" exceeding 50 °F.*

[Proposed Resolution]

Recommend clarification on these bullet points be provided within the RIS.

NRC Response

The intent of this RIS is to clarify reporting requirements provided in 10 CFR 50.46(a)(3). This comment, by contrast, identifies items that were not discussed in the draft RIS. Since the intent of the RIS is to clarify 10 CFR 50.46 reporting requirements, the NRC staff determined that the comment is out of scope.

NEI 1-06.A:

The stated intent of the Draft RIS is to provide clarification with regards to the language in 10 CFR 50.46(a)(3). The Draft RIS was initiated in response to "recent inspection and review activities." Additional clarification [is] needed within the Draft RIS to complete this endeavor.

NRC Response

The NRC agrees with this comment. The discussion regarding "recent inspection and review activities" appearing in the BACKGROUND INFORMATION section of the RIS was revised, in particular, to provide a more narrative discussion of the inspection experience that, in part, led to the development of this RIS.

NEI 1-06.C:

Within the Draft RIS the arguments for some language are inconsistent. With regards to "application", the discussion on page 4 of 9 of the Draft RIS rebuts the use of application to mean analysis of facility changes and indicates that it is the extension of the (evaluation) model beyond the range intended. Whereas, the discussion on page 5 of 9 of the Draft RIS clearly states that "application" is "...the act of putting an evaluation model to use." (Note: the Draft RIS does not provide a basis for the "broader, plain-language definition.") These are clearly different meanings to the use of application.

[Proposed Resolution to NEI 1-06.A-C]

Provide clarity to these identified items within the RIS.

NRC Response

Although this comment falls under Topic 2, above, additional discussion on information specific to this comment is provided below.

The sentence in question on page 4 of the draft RIS is repeated as follows, "Changes to, and errors in, ECCS evaluation models, or applications thereof, made as a result of facility changes made under 10 CFR 50.59 are reportable under 10 CFR 50.46(a)(3)." The NRC staff revised this sentence in response to this portion of the comment, and the following sentence, as follows, "Changes to, or errors in, evaluation models, or in the applications thereof, that affect the PCT

calculation and are a result of facility changes made under 10 CFR 50.59, must be reported under 10 CFR 50.46(a)(3). The NRC maintains that each change to, or error in, an evaluation model, or in the application thereof, that affects the PCT calculation, is reportable under 10 CFR 50.46(a)(3).”

There is no discussion in the draft RIS concerning the analysis of facility changes, and the draft RIS provides further discussion regarding the meaning of the phrase “or in the application of such a model” in the section following. Notwithstanding the revision noted above, the NRC staff disagrees with the comment that the draft RIS uses differing or inconsistent meanings of the term “application.”

NEI 1-08:

[Regarding “Background Information,” page 1 of 9, footnote 1]

10 CFR 50.46 and Draft RIS do not provide clear and complete direction with regard to when the 30-day reporting period begins for certain significant changes to Emergency Core Cooling System (ECCS) Evaluation Models, specifically those that arise from discretionary plant design modifications.

In the case referenced in the Draft RIS, the NRC determined that the 30-day reporting period began at discovery, which corresponded with initiation of a documented Condition Report (CR) within the licensee's corrective action process. This determination is analogous to the concept of discovery for 10 CFR Part 21 reporting practices and is not in dispute. However, given the NRC's position in the Draft RIS that certain plant-specific inputs and design parameters are, by definition, part of ECCS Evaluation Models or applications thereof, the implication of this position is that certain significant changes to ECCS Evaluation Models and their applications may also arise from discretionary plant design modifications that are planned, controlled, and executed outside a licensee's corrective action process, and which are in no way corrective actions pursuant to 10 CFR 50, Appendix B, Criterion XVI. In such cases, the concept of discovery as the starting point for a 30-day report is not defined by either 10 CFR 50.46 nor the Draft RIS.

For example, a licensee may decide to implement a design modification that will add heat sinks to a containment building and thereby affect calculated PCT for a postulated Loss of Coolant Accident (LOCA). If that design modification does not otherwise require prior NRC review and approval, then that licensee would not submit a License Amendment Request (LAR) pursuant to 10 CFR 50.90 and instead would report the change pursuant to 10 CFR 50.59 (if only because of the impact of the new heat sinks on calculated post-accident containment pressures and temperatures or containment subcompartment analyses). If reanalysis with an acceptable ECCS Evaluation Model revealed that the calculated PCT would change by 50°F or more, or that the cumulative sum of absolute magnitudes of Δ PCT estimates would change by 50°F or more once the effects of prior changes/errors were taken into account, then the position in the Draft RIS would require that this discretionary plant design modification be reported within 30 days pursuant to 10 CFR 50.46(a)(3)(ii). If the plant design modification is not itself a corrective action for some other deviation, deficiency, or nonconformance, then implementation of the

modification would occur outside the corrective action process. In such a case, neither 10 CFR 50.46 nor the Draft RIS define when the 30-day reporting period would begin.

[Proposed Resolution]

It is recommended to expand the discussion of reporting requirements in the RIS to state the policy with regard to reporting of discretionary plant design changes.

The need for consistent guidance is particularly acute for major modifications that have significant effects on PCT pursuant to 10 CFR 50.46(a)(3)(ii), but are planned, controlled, and executed outside of a licensee's corrective process. In such cases, the traditional concept of "discovery" such as that used for errors and their corrective actions would not necessarily apply to determine the start of a 30-day reporting period. It is recommended that policy and guidance also be provided for minor modifications that have non-significant effects on PCT and which may be reported in annual reports pursuant to 10 CFR 50.46(a)(3)(ii).

It should be recognized that, without such guidance, licensees may interpret 10 CFR 50.46 in a non-consistent manner and may select different start dates for reporting of discretionary plant design modifications, such as upon management approval of funding, approval of a contract with a vendor, completion of design paperwork, 90% design review, beginning or end of physical installation of a modification, turnover to plant operations personnel, etc. For consistency with other licensing requirements, it is recommended that the reporting requirements would start only after both of the following occur: (1) partial or complete physical installation of a modification in the plant; and (2) when the plant's ECCS is determined to be or declared OPERABLE in accordance with that plant's Technical Specifications.

NRC Response

The NRC agrees in part with the comment, specifically that 10 CFR 50.46 does not define when the reporting period for changes and errors begins. The NRC infers that by "discretionary plant design modifications," the comment is referring to "changes to the facility as described in the final safety analysis report (as updated)," as set forth in 10 CFR 50.59. Such changes require evaluation for 10 CFR 50.59 applicability. As part of this process, the licensee must consider whether the change affects predicted ECCS performance in accordance with 10 CFR 50.46. If the plant change is determined to affect the ECCS performance, as predicted using an acceptable evaluation model, the effect of the change should be estimated according to the requirements in 10 CFR 50.46(a)(3). Regarding the timing for a report, if the estimated effect of the change is not significant, then it would be appropriate for inclusion in an annual report. For a significant change in predicted ECCS performance, the comment suggested, among other things, that the timing for the 30-day report should coincide with complete installation of a modification at the plant, or a subsequent declaration of ECCS operability in accordance with the facility technical specifications. The NRC staff reviewed the comment in accordance with the stated intent of the reporting requirements of ensuring staff cognizance of changes in ECCS performance, as discussed in the 1988 ECCS Rule SOC, and determined that either of these options would satisfy the intent of the rule. However, as the topic of the RIS relates more closely to the determination of which changes to and errors in ECCS evaluation models and applications thereof are reportable, rather than the timeliness of such reports, the NRC staff did not expand the scope of the RIS, and did not revise the draft RIS in response to this comment.

NEI 1-09:

[Regarding "Background Information," page 3 of 9]

10 CFR 50.46 and Draft RIS do not provide clear and complete direction with regard to reporting requirements for certain non-significant changes to, and errors discovered in, Emergency Core Cooling System (ECCS) Evaluation Models.

Specifically, if a licensee docketed a 30-day report pursuant to 10 CFR 50.46(a)(3)(ii) for a significant change or error that had a 50°F or greater effect on calculated PCT, along with a proposed schedule for providing a reanalysis, and later discovered another non-significant change or error before that reanalysis was complete, it is not clear what actions the NRC would require of the licensee.

The 1988 Statement of Considerations (SOC), quoted on page 3 of the Draft RIS, suggests that non-significant changes and errors would not normally be of immediate concern to the NRC, and thus could be reported in the licensee's next annual report pursuant to 10 CFR 50.46(a)(3)(ii). However, if a licensee had not yet completed corrective action (reanalysis) in accordance with a 30-day report, another interpretation of the regulation may require the licensee to cumulate the absolute magnitude of the effect on PCT for a newly discovered, non-significant change/error with any previously reported changes/errors, thereby effectively reclassifying the new change/error from non-significant to significant and triggering another 30-day report (or an update to the previous 30-day report). Such an interpretation would have the consequence of requiring certain non-significant changes/errors, with a 0°F effect on calculated PCT, to be treated as significant and reported within a 30-day period of discovery because of how cumulative sums are calculated pursuant to 10 CFR 50.46 and the 1988 Statement of Considerations (SOC).

[Proposed Resolution]

It is recommended to expand the discussion of reporting requirements in the Draft RIS to state its policy with regard to reporting of non-significant changes/errors that are discovered following a 30-day report, but prior to completion of corrective action (reanalysis).

It is further recommended that a statement be added to the RIS that licensees have three options in such a case, as follows: (1) if the reanalysis will not be complete prior to the licensee's next annual report, include the newly discovered non-significant change/error in that next annual report along with its estimated effect on PCT; (2) if the reanalysis will be complete prior to the licensee's next annual report and the newly discovered change/error will not be resolved as part of that reanalysis, then include the newly discovered non-significant change/error in the next annual report along with its estimated effect on PCT; or (3) if the reanalysis will be complete prior to the licensee's next annual report and the newly discovered change/error will be resolved as part of that reanalysis, then describe the newly discovered non-significant change/error in the next annual report but report its estimated effect on calculated PCT as "Not Applicable" because its impact has already been addressed through reanalysis.

It is recommended to state in the RIS that a licensee will not be required to docket a 30-day report pursuant to 10 CFR 50.46(a)(3)(ii) for a change/error that has a 0°F effect on PCT. Such a policy would provide a reasonable balance between the needs of NRC Staff to maintain cognizance with respect to licensee activities and the licensee's burdens associated with reporting requirements.

NRC Response

The intent of this RIS is to clarify reporting requirements provided in 10 CFR 50.46(a)(3). This comment, by contrast, inquires about the NRC providing guidance on certain non-significant changes. Since the intent of the RIS is to clarify reporting requirements, the NRC staff determined that the comment is out of scope.

NEI 1-10:

[Regarding "NRC Staff Position," page 3 of 9]

The "NRC Staff Position" contained in Draft RIS does not, but should, recognize that there may be differences between a bounding or limiting plant configuration that has been analyzed with an acceptable Emergency Core Cooling System (ECCS) Evaluation Model, and an actual as-built or physical plant configuration. This is important because 10 CFR 50.46 requires reporting of certain changes, but does not explicitly define what a "change" is, unlike 10 CFR 50.59.

A closer examination of how the word "change" is used in 10 CFR 50.46 suggests that licensees do have some latitude to modify their actual plants without necessarily triggering any reporting requirement pursuant to 10 CFR 50.46. Given the positions described in the Draft RIS, it logically follows that only plant modifications that affect the bounding or limiting inputs used in ECCS performance analyses should be of regulatory interest to the NRC pursuant to 10 CFR 50.46, although certain other reporting requirements (e.g., 10 CFR 50.59) may also apply for such modifications.

[Proposed Resolution]

It is recommended to expand the discussion of reporting requirements in the RIS to state the policy with regard to what constitutes a "change" for the purposes of reporting.

This comment is loosely related to the concepts of "margin management" and "margin ownership." Clearly, the acceptance criteria adopted in 10 CFR 50.46 (e.g., 2200°F PCT) represent limits that licensees must not violate, and the NRC is the sole owner of any margin between that acceptance criteria and the ultimate cladding performance limit. Licensees, however, should be the sole owners of any discretionary margins between actual plant configurations and analyzed (bounding or limiting) plant configurations. Thus, a modification of the plant configuration or reload core design practices should not be construed as a "change" for the purposes of 10 CFR 50.46 reporting requirements.

NRC Response

The NRC disagrees with this comment. The language in 10 CFR 50.46(a)(3) requires licensees to estimate the effects of changes to, or errors in, acceptable ECCS evaluation models, or in applications thereof, and submit reports to the NRC. The NRC recognizes that some plant configuration changes are possible, which may affect the performance of the ECCS, or of the reactor system during a LOCA, but which would be bounded by the existing ECCS performance evaluation. For example, a change could be made to cycle-specific peaking factors that remains bounded by the existing ECCS performance evaluation. In such a case, reporting pursuant to 10 CFR 50.46(a)(3) would not be required, because despite that a change was made to the cycle-specific core design, there was no change made to the ECCS evaluation model, or to its plant-specific application. The draft RIS does not suggest otherwise, and as such, the NRC disagrees that the draft RIS, "does not, but should, recognize that there may be differences between a bounding or limiting plant configuration that has been analyzed... and an actual as built or physical plant configuration." Thus, the NRC did not revise the draft RIS in response to this comment.

NEI 1-11:

[Regarding "Summary of Issue," page 4 of 9]

Footnote 8 on page 4 indicates that the RIS has a narrow focus. Use of the phrase "all potential issues associated with the NEI guidance document" indicates that other issues may exist but are not being pursued.

[Proposed Resolution]

If the other potential issues exist, they should be in the scope of the RIS. If there are no additional specific issues with NEI 07-05 identified, the footnote should be modified to remove this phrase.

NRC Response

The NRC staff disagrees with the comment. Since NEI 07-05 was not submitted to the NRC for review and approval for use or endorsement, the NRC has not completed a detailed review of NEI 07-05. The issues with NEI 07-05 that are discussed in the RIS are currently the only ones identified. Since a RIS is not the appropriate regulatory vehicle to fully review an industry guidance document, it is not appropriate to expand the draft RIS. To underscore the significance of the review status of the NEI guidance document, the footnote on which this comment was based was moved to the body text.

NEI 1-13:

[Regarding definition of "Input Information," page 5 through 7 of 9]

The terms "input", "parameter", "input parameter", "input information", "design input", "model input", have been used in Federal Register Notices, Regulation, and industry guidance. These terms seem to be used interchangeably. Regardless of the term used, if the value of such a

quantity is part of the Evaluation Model submitted to the NRC for review and acceptance, and formed the basis for acceptance and documented as a condition for the use of the Evaluation Model in an SER, it would be considered part of the Evaluation Model. However, if the value of such a quantity does not meet this criterion and is plant-specific, it would not be considered part of the Evaluation Model.

[Proposed Resolution]

Recommend the definition of "input information" in NEI 07-05 be incorporated and endorsed within the RIS. This definition provides a clear distinction between quantities that are and are not part of the Evaluation Model and, therefore, are or are not subject to the reporting requirements of 10 CFR 50.46(a)(3).

NRC Response

Although this comment falls under Topic 3, above, additional discussion on information specific to this comment is provided below.

The NRC disagrees with the portion of the comment recommending that the NRC endorse the definition of "input information" in NEI 07-05. However, the NRC staff agrees that the items included in the NEI 07-05 definition would reasonably be considered as types of "input information." More importantly, the passage within NEI 07-05, which suggests that changes to such information are not reportable, may erroneously lead licensees to refrain from reporting changes to or errors in ECCS evaluation models, or in applications thereof, that affect the PCT calculation.

In consideration of this comment, the NRC revised the section discussing "input information" in the draft RIS. This revision shifts the focus from specific aspects of the NEI 07-05 definition, with which the NRC disagrees, to focus on the reportability of, and the consequence of failing to report, such information. In particular, the concluding paragraph of the section was revised to state the following, in order to clarify the safety and regulatory implications of applying the guidance for "input information" contained in NEI 07-05:

In summary, the NRC's interpretation of the reportability of "input information" ensures that changes to, or errors in, evaluation models or applications thereof, which affect the PCT calculation, are reported to the NRC. Licensees who adopt the view that plant-specific "input information" is not reportable, as described in NEI 07-05, may erroneously exclude certain changes to, or errors in, evaluation models or applications thereof from reporting under 10 CFR 50.46(a)(3). By not reporting to the NRC, licensees impact the ability of the NRC to determine the safety significance of each error or change, which may be inconsistent with the NRC's prior safety review and approval.

NEI 1-14:

[Regarding Section C, page 7 of 9]

The interpretation of the relationship between 10 CFR 50.46 and 10 CFR 50.59 provides the NRC's perspective from a 10 CFR 50.46 view point and seems to interject the term "reporting" when the subject is determination of change.

[Proposed Resolution]

Clarify if both 10 CFR 50.59 and 10 CFR 50.46 can apply to a change and what that means for the Applicability Determination process used as the pre-screen in 10 CFR 50.59 application.

NRC Response

Regarding the assertion that the NRC position expressed in the draft RIS "interject[s] the term 'reporting' when the subject is determination of change", the response to NEI 1-01.A clarifies the distinction between the requirements of 10 CFR 50.46 and 10 CFR 50.59, and clarifies how the changes, criteria, and actions required by the two sections interact.

Regarding the 10 CFR 50.59 Applicability Determination process, the NRC position is that both 10 CFR 50.59 and 10 CFR 50.46 can apply to a change. This is explicitly illustrated in the NEI 96-07 Example 2 discussed in the response to NEI 1-01.B above, which involves a change in heat transfer capability of an RHR heat exchanger tube bundle. In the example, a change in peak containment post-accident pressure would be evaluated using 10 CFR 50.59 while a change in PCT would be governed by 10 CFR 50.46. As discussed in response to NEI 1-06.C, the NRC staff modified language in the draft RIS to reflect this consideration more clearly.

NEI 1-15:

[Regarding Section C, page 7 of 9]

The Draft RIS discussion fails to address the distinct differences in the intent of these two rules (10 CFR 50.46 and 10 CFR 50.59). 10 CFR 50.46 does not include requirements for regulatory review of changes to the ECCS analysis. It establishes requirements for the initial calculated cooling performance of the ECCS, and provides guidance for reporting of changes to or errors in that analysis subsequent to "acceptance" by the Staff. The main objective of 10 CFR 50.59 is to allow changes under licensee control if certain criteria are met. The reporting requirements of 10 CFR 50.59 are only ancillary to the main objective, and require only a summary of changes made under the rule. In the last paragraph of the Draft RIS on page 7 of 9, applying the provisions of 10 CFR 50.59(c)(4) to compare the decision making mechanism provided in 10 CFR 50.59 to the reporting requirements of 10 CFR 50.46 is an inappropriate comparison. Both the position attributed to NEI 07-05 and the interpretation provided in the Draft RIS are incorrect for the following reasons:

1. *As stated in the Draft RIS "changes to, and errors in, ECCS evaluation models, or applications thereof, made as a result of facility changes under 10 CFR 50.59 are reportable*

under 10 CFR 50.46(a)(3). Acceptability of the change under licensee control and satisfaction of other reporting requirements (both from 10 CFR 50.59) do not relax this requirement.

2. Changes to the evaluation model or its application are subject to 10 CFR 50.59 review to the extent that they are described in the UFSAR. That may involve either a change to the evaluation model (method of evaluation, 10 CFR 50.59(c)(2)(viii) or changes to inputs resulting from design modifications or analytical input (10 CFR 50.59(c)(2)(i - vii)). Regardless of 10 CFR 50.46 other requirements, such changes are subject to the two-year summary reporting requirements of 10 CFR 50.59(d)(2), contrary to the conclusion drawn in the Draft RIS.

[Proposed Resolution]

The referenced passages in the RIS should be changed to correctly address the relationship between the two rules, in that they address different aspects of regulatory requirement and that based on the nature and the effect of a particular change to ECCS model, both rules should be independently applied on their own merits.

NRC Response

The NRC agrees with this comment. Section C of the draft RIS was revised to focus more on the specific requirements of 10 CFR 50.46 in relation to 10 CFR 50.59, rather than to discuss both rules more generally. In addition, the commenter's suggestion that both rules should each be independently applied on their own merits was incorporated into the RIS. Finally, the discussion also acknowledges that NEI 96-07 is an NRC-endorsed guidance document for implementing 10 CFR 50.59 requirements.

NEI 1-16:

[Regarding Section 3, page 7 of 9]

The Draft RIS states, "...that by not providing timely reporting of all changes and errors to evaluation models, or applications thereof, which results in changes to the PCT of more than 50[] [degrees F], licensees impact the ability of the NRC to determine the safety significance of each error or change." Licensees have been cited for inconsistent implementation of other aspects of reporting under 10 CFR 50.46.

10 CFR 50.46(a)3(i) establishes "...a significant change or error is one which results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F."

The Draft RIS does not address what actions allow a re- set of the cumulation of changes and errors. For example:

- Does the submittal of an annual report that shows the complete list of changes and errors allow a re-zero of the cumulation?*

- *Is a licensee required to maintain the cumulation since the last 30-day report for exceeding 50 F, which could have been 4 years ago?*

The Draft RIS does not address how to evaluate the impact of a temporary EM change when it is no longer applicable and whether it needs to be counted against the cumulation upon the final removal of the change.

For example, consider the assessment of a + 14 [degrees F] PCT for introduction of a new fuel product when in a transition core with the current fuel product. This PCT impact is not applicable for a full core of the new fuel. The PCT penalty is added in cycle N for the first mixed core of the two fuel types. For cycle N+3, a full core of the new fuel is in place and the + 14 [degrees F] is no longer applicable to the Evaluation Model. The PCT cumulation had included +14 F during the transition cores. In this instance, to reflect the full core of the new fuel product, should the plant now have to take a -14 [degrees F] against the cumulation of changes? With this approach, this fuel transition has an absolute change of 28 [degree F] to PCT but no actual change to the Evaluation Model by the end of the fuel transition.

For plants that track the cumulation of changes since the last 30-day report (which could have been before the fuel transition started), this 28 [degrees F] and other changes or errors could trigger an unnecessary 30-day report.

[Proposed Resolution]

The RIS should provide guidance on the cumulation of changes and errors.

NRC Response

The intent of this RIS is to clarify reporting requirements provided in 10 CFR 50.46(a)(3). This comment, by contrast, requests guidance regarding the cumulation of changes and errors. Since the intent of the RIS is to clarify reporting requirements, the NRC staff determined that the comment is out of scope.

SNC 3-04:

[Regarding The Interpretation of the Relationship Between 10 CFR 50.46 and 10 CFR 50.59 (Draft RIS page 7-8 of 9)]

Comparison of attributes of 10 CFR 50.46 and 10 CER 50.59 has been discussed extensively in the General Comments section and will not be debated further here. However, some additional comments are provided.

As discussed previously, the issues regarding the relationship between the two rules go back to the debate over what constitutes an "acceptable evaluation model" and the treatment of plant-specific inputs or parameters. Universal agreement on these is necessary to clarify the relationship between the two rules.

NRC Response

Refer to the response to NEI 1-01.A, NEI 1-01.B, and NEI 1-15, above.

SNC 3-05:

The issues identified in the draft RIS are not unique to NEI 07-05. The issues have existed for many years and have been the subject of debate both with respect to the current 10 CFR 50.46 rule as well as the proposed 10 CFR 50.46c rule. It is noted that the proposed 10 CFR 50.46c rule is not the subject of the draft RIS.

The issues are centered on the lack of a clear definition of what constitutes an “acceptable evaluation model.”

The industry has attempted on multiple occasions to engage the NRC in discussion on industry-developed reporting guidance for NRC endorsement. Two such guidance documents are WCAP 13451, “Westinghouse Methodology for Implementation of 10 CFR 50.46 reporting,” (October 1992) and NEI 07-05 (July 2008). While discussions with the NRC had taken place during the development of these documents, the NRC chose not to endorse either of these documents.

In light of the issues and remaining ambiguities, it is recommended that the draft RIS be withdrawn. Instead, the NRC is encouraged to engage in discussions with the industry with the goal to establish uniform guidance on the issues discussed above. As an example, there has been extensive engagement between the NRC and the industry during the 10 CFR 50.46c rulemaking. This communication has been effective, with the benefit of enhancing the health and safety of the public.

NRC Response

Although this comment falls under Topic 4, above, additional discussion on information specific to this comment is provided below.

The NRC staff agrees that uniform guidance for compliance with 10 CFR 50.46 reporting requirements would be beneficial. It is important to note that NEI 07-05 had not been submitted to the NRC for review and approval for use or endorsement. However, the above comment did not provide any reference information regarding the interactions between the NRC and NEI and Westinghouse regarding the above documents. Therefore, the NRC staff was unable to confirm whether, or for what reasons, the NRC may have previously chosen not to endorse, or approve for use, either document. No revision to the draft RIS was made in response to this comment.

STPNOC 5-01:

The proposed 50.46 rule change published in the Federal Register (79 FR [16105], March 24, 2014) included consideration of a peak clad temperature (PCT) criterion of 800°F for long term core cooling. The proposed RIS does not address if any long-term cooling criterion should be

considered under the 10 CFR 50.46(a)(3) reporting criteria. STPNOC recommends that the RIS be revised to clarify that the 10 CFR 50.46(a)(3) reporting criteria does not apply to PCT for long-term cooling.

NRC Response

The intent of this RIS is to clarify reporting requirements provided in 10 CFR 50.46(a)(3). This comment, by contrast, cites the proposed 10 CFR 50.46 rule change. The proposed rule language may have at one point included considerations of PCT for long-term cooling. However, since the intent of the RIS is to clarify reporting requirements of the existing rule, the NRC staff determined that the comment is out of scope.

WEC 8-01:

Regarding the NRC's position that "plant-specific inputs and design parameters" are a part of the evaluation model: The NRC contends that "this NRC staff position has been applied consistently," yet it appears that the position has changed over time. From the Federal Register, Vol.53, No.180, pages 35996-36005, [53 FR 35996; September 16, 1988] it is stated:

"One commenter interpreted the use of the words 'or in the application of such a model' as requiring reporting when facility changes (already reportable under 50.59), resulting in model changes occur. The regulatory language referred to is intended to assure that applications of models to areas not contemplated during the initial review of the model do not result in errors by extending the model beyond the range that it was intended. The Commission does not believe that further clarification of this requirement is necessary and has not done so in the final rule."

The statement effectively serves to clarify the definition of "application (of such a model)." Specifically, that "application" is intended to mean extending the use of an evaluation model for something other than its intended use or intended range (i.e., using an ECCS model approved for SBLOCA for analyzing events other than a SBLOCA). This interpretation is logically derived from the statement that the regulatory language is "intended to ensure that applications of models to areas not contemplated during the initial review of the model do not result in errors by extending the model beyond the range that it was intended."

Further, this statement also appears to correct the 1988 commenter's misinterpretation about plant changes being reportable (which, as was stated by the NRC), is "already reportable under 50.59." This appears to contradict the NRC's statement within the RIS that "this NRC staff position has been applied consistently."

It is noted that the draft RIS also quotes this same passage, albeit for different reasons. Please elaborate on:

- a. How the interpretations in this comment are incorrect.*
- b. How the NRC came to the conclusion that the statement supports the assertion that "this NRC staff position has been applied consistently," as this interpretation does not appear to follow from the quoted statement.*

NRC Response

The NRC staff disagrees with the comment that “application” in the context of 10 CFR 50.46(a)(3) “is intended to mean extending the use of an evaluation model for something other than its intended use or intended range.” Considering this interpretation, the regulation would specify that an applicant or licensee would merely need to submit a report to the NRC if it used a model intended for small break (SB) LOCA analysis for something other than an SBLOCA analysis, as noted in the comment. Though such a broadening of the use of an evaluation model would not necessarily be reportable to the NRC, it would instead require prior NRC review and approval, either in a plant-specific licensing action request, or via the licensing topical report process as a revision, addendum, or supplement to the original licensing topical report. Otherwise, if a licensee were to apply an evaluation model for other than its intended use or intended range, the licensee would not be using an acceptable evaluation model, which is contrary to 10 CFR 50.46(a)(1)(i). However, once the NRC staff determines that the evaluation model is acceptable for being put to use in a new fashion, then the intended use, or intended range, of the evaluation model would effectively change.

While the interpretation offered by the comment may be logically derived from a single comment response published in the 1988 ECCS Rule SOC, it is inconsistent with the remaining discussion about the 10 CFR 50.46(a)(3) reporting requirements, also published in the 1988 ECCS Rule SOC. Refer to the general response under Topic 2 for further discussion. The consistency of the staff position, by contrast, is already discussed in the draft RIS. It is based on the general discussion in the 1988 ECCS Rule SOC, a plain-language definition of application, and correspondence between the NRC and NEI during the 1999-2000 rulemaking that revised 10 CFR 50.46 and 10 CFR Part 50 Appendix K. However, the comment (and other similar comments) did not offer any justification for its position other than the single comment response in the 1988 ECCS Rule SOC. Additionally, as discussed in the general response to Topic 2, the NRC notes that a different industry guidance document, which was written in 1992, offered an interpretation of application that is similar to the NRC’s definition. Since the draft RIS already explains the derivation and consistency of the NRC definition of “application” in the context of 10 CFR 50.46(a)(3), the NRC did not revise the draft RIS to provide further elaboration on the consistency of the staff position.

WEC 8-02:

This comment is based on the staff's position in the RIS that "plant-specific inputs and design parameters" are elements of an acceptable evaluation model (EM):

There are some changes to "plant-specific inputs and design parameters" that require prior NRC approval in order to implement: When a license amendment request (LAR) for such a change is submitted, it would be expected that the licensee provide adequate justification for the change as part of the amendment request, including any potential impact to the peak cladding temperature (PCT) from the change in plant-specific inputs and design parameters. Assuming that there is a "significant" impact to the PCT and that the LAR [license amendment request] is ultimately approved, there are a few considerations:

- a. The newly approved licensing basis would be required to submit a 30-day 50.46 report.*
- b. Such information had just been submitted, reviewed, and approved by the NRC via the LAR.*

- c. *The same information is therefore being provided to the NRC through two different channels (50.59 and 50.46), which seems to be an undesirable cumulative effect of regulations and the position stated in the RIS.*
- d. *Section 3 of NEI 07-05 describes the relationship between 10 CFR 50.46 and 10 CFR 50.59, and based on the interpretations therein, prevents this type of scenario by taking the position that, contrary to the NRC's position in the draft RIS, "plant-specific inputs and design parameters" are NOT a part of an acceptable EM. It is noted that the NRC identifies this aspect of NEI 07-05 as one of the three explicit "issues" in the draft RIS;*

Please elaborate on the NRC's position on the relationship between 50.59 and 50.46 in the draft RIS, specifically with respect to a licensee's 50.46 reporting obligation for changes to plant specific inputs and design parameters resulting in a "significant" impact before granting the amendment request (prior to incorporation of the change into the licensing basis), as part of the amendment request (in-process change), and after granting the amendment request (subsequent to incorporation of the change).

NRC Response

The comment describes a scenario in which there is a facility change that requires prior NRC approval in order to implement. According to the scenario, the facility change causes changes to the PCT, which are estimated to be significant. The comment provides several considerations, to which the NRC staff responds below:

- a. The newly approved licensing basis would be required to submit a 30-day report.
- b. Such information had just been submitted, reviewed, and approved by the NRC via the LAR.

The NRC staff notes that in the past, licensees have submitted reports pursuant to 10 CFR 50.46(a)(3) following the approval of a license amendment request seeking to implement a new ECCS evaluation model. The implementation required NRC review and approval. However, the licensees submitted reports once the evaluation model was implemented at the facility. Therefore, the considerations above reflect current practice.

- c. The same information is being provided to the NRC through two different channels (10 CFR 50.59 and 10 CFR 50.46), which seems to be an undesirable cumulative effect of regulation.

The NRC disagrees with this consideration. In the scenario described by the comment, a license amendment request is being pursued. This means that an evaluation pursuant to 10 CFR 50.59 has already determined that the facility may not be modified under 10 CFR 50.59 and a license amendment pursuant to 10 CFR 50.90 is required for the facility change.

- d. Section 3 of NEI 07-05 describes the relationship between 10 CFR 50.46 and 10 CFR 50.59, and based on the interpretations therein, prevents this type of scenario by taking the position that, contrary to the NRC's position in the draft RIS, "plant-specific inputs and design parameters" are NOT a part of an acceptable evaluation model. It is

noted that the NRC identifies this aspect of NEI 07-05 as one of the three explicit "issues" in the draft RIS.

In the draft RIS, the NRC clarifies the relationship between 10 CFR 50.59 and the reporting requirements contained in 10 CFR 50.46(a)(3). This clarification is based not only on the regulations contained in 10 CFR 50.59, specifically 10 CFR 50.59(c)(4), but also on NEI 96-07, which unlike NEI 07-05, has been NRC-endorsed. As noted in the general discussion under Topic 1, the NRC did not provide additional discussion in the RIS on the relationship between 10 CFR 50.46 and 10 CFR 50.59, since that discussion is already provided in another, NRC-endorsed guidance document.

Ultimately comment WEC 8-02 sought elaboration on the NRC's position regarding the relationship between 10 CFR 50.59 and 10 CFR 50.46, and more specifically a licensee's reporting obligation, under 10 CFR 50.46(a)(3), for significant changes. Particularly, the comment seeks NRC comment on whether the estimated effects should be reported prior to issuance of the license amendment that is the subject of the scenario, or after.

Appropriate timeliness associated with reporting changes to or errors in ECCS evaluation models, or applications thereof, in regard to planned plant modifications, was addressed in the response to comment NEI 1-08, above.

Table 2. List of All Submitted Comments

Comment Number	Comment	Topic
NEI 1-01.A	<p><i>Regulation 10 CFR 50.46 has two primary functions: 1) to provide reporting requirements in paragraph (a)(3) and 2) provide acceptance criteria in paragraph (b).</i></p> <p><i>10 CFR 50.46 is not a change control rule. 10 CFR 50.59 provides criteria for making changes to methods of evaluation and when NRC approval is required. In comparison, 10 CFR 50.46 does not provide such criteria.</i></p>	N/A
NEI 1-01.B	<p><i>In the guidance for the implementation of 10 CFR 50.59 in Revision 1 of NEI 96-07, as endorsed by Regulatory Guide 1.187, there is a clear distinction between an input parameter and an element of the method of evaluation. 10 CFR 50.46 does not provide such a distinction.</i></p>	N/A
NEI 1-01.C	<p><i>10 CFR 50.46 uses the term "Acceptable Evaluation Model" several times. The rule provides no clear definition of the process for acceptance of an Evaluation Model or acceptance of changes to an Evaluation Model. The only reference to a process may be in paragraph (a)(2) that refers to "...evaluations of ECCS cooling performance submitted..."</i></p>	N/A
NEI 1-01.D	<p><i>While not formally defined in 10 CFR 50.2, "Definitions", paragraph (c)(2) of 10 CFR 50.46 describes or "defines" an Evaluation Model as being the "calculational framework" and the "calculation procedure". This description implies that the Evaluation Model is a process. Paragraph (c)(2) uses the expression "... procedure for treating input and output information..." Again, this describes a process, not values of plant-specific inputs or input parameters.</i></p> <p><i>Paragraph (c)(2) also uses the expression "values of parameters" as being part of the Evaluation Model. This expression has been a source of confusion. It is not clear from the definition of an Evaluation Model in paragraph (c)(2) what is meant by a "parameter". Mathematically, a parameter is a quantity that influences the behavior of a mathematical function. An example would be the coefficients in the Baker-Just equation for calculating the metal-water reaction rate as described in 10 CFR 50, Appendix K. In this case, the parameters (coefficients) would be considered part of the Evaluation Model. This is analogous to an element of a method of evaluation in 10 CFR 50.59 as opposed to an input or input parameter.</i></p> <p><i>The concept of an "Acceptable Evaluation Model" is not clear. Acceptance of models (or methods of evaluation as referred to in 10 CFR 50.59) is typically through the issuance of a Safety Evaluation Report (SER) by the NRC whereby the NRC approves the method for an intended application as in 10 CFR 50.59(a)(2)(ii). Such methods are typically submitted as topical reports by vendors to the NRC for review and acceptance/approval. In the topical reports, as well as in the review and acceptance process, plant-specific inputs or parameters are not typically included. Therefore, plant-</i></p>	N/A

	<i>specific inputs or parameters cannot be considered part of the Evaluation Model.</i>	
NEI 1-01.E	<p><i>In the proposed rulemaking (64 FR 53270, October 1, 1999) related to the revision of 10 CFR 50, Appendix K of NEI submitted comments on the proposed rulemaking in a letter dated December 15, 1999 (ML003671779). NEI Comment 8 addressed the following statement in the Section-by-Section Analysis of the proposed change: "Estimated changes in ECCS performance due to revised analysis inputs are reported under 10 CFR 50.46 (a)(3), at least annually."</i></p> <p><i>NEI sought to clarify the applicability of the reporting requirements in paragraph (a)(3). In particular, NEI argued that paragraph (a)(3) does not apply to changes in the Peak Clad Temperature (PCT) resulting from plant specific analysis input parameter values. NEI proposed revised rule language to clarify this.</i></p> <p><i>In the publication of the final rule, the NRC disagreed with the NEI proposal and took the position that "... the ECCS evaluation model is comprised of the computer code or codes, the input parameters (including plant-specific design parameters), and the calculational results." (65 FR [34913], June 1, 2000).</i></p> <p><i>This position further indicates continued disagreement on what constitutes an Acceptable Evaluation Model. As discussed previously, the definition in paragraph (c)(2) does not include plant-specific information. Further, contrary to the statement above from 65 FR 34918, the definition in paragraph (c)(2) does not include calculational results.</i></p> <p><i>[Proposed Resolution to NEI 1-01.A-E]</i></p> <p><i>Consider clarification within the RIS of the use of an evaluation model to ensure consistency with definitions in 10 CFR 50.46(c)(2).</i></p>	N/A
NEI 1-02	<p><i>The Draft RIS would benefit by better organization of the information. The use of "NRC Staff Position" is unclear whether it was previously stated or is being repeated herein. For example, "NRC Staff Position" is used on page 3 of 9 prior to the section that describes the NRC Staff Position. Even more, the NRC Staff Position is intermingled with the Summary of the Issue. Separation of these would provide better clarity. Finally, the last paragraph in the Background Information would be better placed after the first paragraph in that section.</i></p>	N/A

	<p><i>[Proposed Resolution]</i></p> <p><i>Reorganize the RIS to provide improved clarity and cite specific docketed examples of "NRC Staff Position".</i></p>	
NEI 1-03	<p><i>A statement should be provided relative to potential future changes in reporting under the draft 10 CFR 50.46c and their intent to clarify the language such that the RIS would no longer be needed.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Recommend that a statement be added to clarify what future changes provided by 10 CFR 50.46c would to sunset the RIS.</i></p>	1
NEI 1-04	<p><i>The definition of "application" is both incorrect and inconsistent with the 1988 ECCS Rule SOC.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Revise the definition of "application" to be consistent with the 1988 ECCS Rule SOC.</i></p>	2
NEI 1-05	<p><i>The following items are not addressed in the Draft RIS:</i></p> <ul style="list-style-type: none"> <i>• The wording of the rule (i.e., "acceptable evaluation model," "last acceptable model," "proposed schedule for providing a reanalysis,") is frequently and inappropriately inferred to require regulatory action that is not required by any rule.</i> <i>• Ambiguous characterization of a "change to or error discovered in ... a model that affects the temperature calculation." Is reporting required for changes/errors that have no effect on the PCT calculation result?</i> <i>• Treatment of offsetting changes as compared to the last acceptable analysis (e.g., changes due to installation and removal of lead test assemblies, as discussed in the public meeting).</i> <i>• What constitutes the "last acceptable model," - last NRC SE, last biannual report, last 30-day report or other?</i> <i>• Repeated 30-day reports for inconsequential changes due to the "sum of the absolute</i> 	N/A

	<p><i>magnitudes" exceeding 50 °F.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Recommend clarification on these bullet points be provided within the RIS.</i></p>	
NEI 1-06.A	<p><i>The stated intent of the Draft RIS is to provide clarification with regards to the language in 10 CFR 50.46(a)(3). The Draft RIS was initiated in response to "recent inspection and review activities." Additional clarification [is] needed within the Draft RIS to complete this endeavor.</i></p>	N/A
NEI 1-06.B	<p><i>The proposed language on reporting requirements in 10 CFR 50.46c is different than the current language. It appears that the Staff concludes that the following differences (not inclusive of all differences) are necessary to clarify the intent of the future reporting requirements.</i></p> <ul style="list-style-type: none"> • <i>"estimate" vice "predicted response"</i> • <i>"acceptable" vice "NRC-approved"</i> • <i>"...or in the application of such a model" vice "...or the application of such a model, or any operation inconsistent with the ECCS evaluation model..."</i> • <i>"If the change or error is significant,...a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance..." vice "...but is significant, then a report describing each such change, error, or operation, and a schedule for submitting a reanalysis and implementation of corrective actions must be submitted within 30 days of the change, discovery of the error, or operation."</i> 	1
NEI 1-06.C	<p><i>Within the Draft RIS the arguments for some language are inconsistent. With regards to "application", the discussion on page 4 of 9 of the Draft RIS rebuts the use of application to mean analysis of facility changes and indicates that it is the extension of the (evaluation) model beyond the range intended. Whereas, the discussion on page 5 of 9 of the Draft RIS clearly states that "application" is "...the act of putting an evaluation model to use." (Note: the Draft RIS does not provide a basis for the "broader, plain-language definition.") These are clearly different meanings to the use of application.</i></p>	2

	<p><i>[Proposed Resolution to NEI 1-06.A-C]</i></p> <p><i>Provide clarity to these identified items within the RIS.</i></p>	
NEI 1-07	<p><i>Once issued, this RIS will be in effect until all plants are licensed under the proposed rule 10 CFR 50.46c. A five year time frame for review of the RIS for efficacy is not reasonable if outstanding items that require clarity are identified, affect reporting, and are not resolved.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Consider a review timeframe shorter than five year for the RIS to ensure items requiring clarification are resolved in a timelier manner.</i></p>	1
NEI 1-08	<p><i>[Regarding "Background Information," page 1 of 9, footnote 1]</i></p> <p><i>10 CFR 50.46 and Draft RIS do not provide clear and complete direction with regard to when the 30-day reporting period begins for certain significant changes to Emergency Core Cooling System (ECCS) Evaluation Models, specifically those that arise from discretionary plant design modifications.</i></p> <p><i>In the case referenced in the Draft RIS, the NRC determined that the 30-day reporting period began at discovery, which corresponded with initiation of a documented Condition Report (CR) within the licensee's corrective action process. This determination is analogous to the concept of discovery for 10 CFR Part 21 reporting practices and is not in dispute. However, given the NRC's position in the Draft RIS that certain plant-specific inputs and design parameters are, by definition, part of ECCS Evaluation Models or applications thereof, the implication of this position is that certain significant changes to ECCS Evaluation Models and their applications may also arise from discretionary plant design modifications that are planned, controlled, and executed outside a licensee's corrective action process, and which are in no way corrective actions pursuant to 10 CFR 50, Appendix B, Criterion XVI. In such cases, the concept of discovery as the starting point for a 30-day report is not defined by either 10 CFR 50.46 nor the Draft RIS.</i></p> <p><i>For example, a licensee may decide to implement a design modification that will add heat sinks to a containment building and thereby affect calculated PCT for a postulated Loss of Coolant Accident (LOCA). If that design modification does not otherwise require prior NRC review and approval, then</i></p>	N/A

that licensee would not submit a License Amendment Request (LAR) pursuant to 10 CFR 50.90 and instead would report the change pursuant to 10 CFR 50.59 (if only because of the impact of the new heat sinks on calculated post-accident containment pressures and temperatures or containment subcompartment analyses). If reanalysis with an acceptable ECCS Evaluation Model revealed that the calculated PCT would change by 50°F or more, or that the cumulative sum of absolute magnitudes of Δ PCT estimates would change by 50°F or more once the effects of prior changes/errors were taken into account, then the position in the Draft RIS would require that this discretionary plant design modification be reported within 30 days pursuant to 10 CFR 50.46(a)(3)(ii). If the plant design modification is not itself a corrective action for some other deviation, deficiency, or nonconformance, then implementation of the modification would occur outside the corrective action process. In such a case, neither 10 CFR 50.46 nor the Draft RIS define when the 30-day reporting period would begin.

[Proposed Resolution]

It is recommended to expand the discussion of reporting requirements in the RIS to state the policy with regard to reporting of discretionary plant design changes.

The need for consistent guidance is particularly acute for major modifications that have significant effects on PCT pursuant to 10 CFR 50.46(a)(3)(ii), but are planned, controlled, and executed outside of a licensee's corrective process. In such cases, the traditional concept of "discovery" such as that used for errors and their corrective actions would not necessarily apply to determine the start of a 30-day reporting period. It is recommended that policy and guidance also be provided for minor modifications that have non-significant effects on PCT and which may be reported in annual reports pursuant to 10 CFR 50.46(a)(3)(ii).

It should be recognized that, without such guidance, licensees may interpret 10 CFR 50.46 in a non-consistent manner and may select different start dates for reporting of discretionary plant design modifications, such as upon management approval of funding, approval of a contract with a vendor, completion of design paperwork, 90% design review, beginning or end of physical installation of a modification, turnover to plant operations personnel, etc. For consistency with other licensing requirements, it is recommended that the reporting requirements would start only after both of the following occur: (1) partial or complete physical installation of a modification in the plant; and (2)

	<p><i>when the plant's ECCS is determined to be or declared OPERABLE in accordance with that plant's Technical Specifications.</i></p>	
NEI 1-09	<p><i>[Regarding "Background Information," page 3 of 9]</i></p> <p><i>10 CFR 50.46 and Draft RIS do not provide clear and complete direction with regard to reporting requirements for certain non-significant changes to, and errors discovered in, Emergency Core Cooling System (ECCS) Evaluation Models.</i></p> <p><i>Specifically, if a licensee docketed a 30-day report pursuant to 10 CFR 50.46(a)(3)(ii) for a significant change or error that had a 50°F or greater effect on calculated PCT, along with a proposed schedule for providing a reanalysis, and later discovered another non-significant change or error before that reanalysis was complete, it is not clear what actions the NRC would require of the licensee.</i></p> <p><i>The 1988 Statement of Considerations (SOC), quoted on page 3 of the Draft RIS, suggests that non-significant changes and errors would not normally be of immediate concern to the NRC, and thus could be reported in the licensee's next annual report pursuant to 10 CFR 50.46(a)(3)(ii). However, if a licensee had not yet completed corrective action (reanalysis) in accordance with a 30-day report, another interpretation of the regulation may require the licensee to cumulate the absolute magnitude of the effect on PCT for a newly discovered, non-significant change/error with any previously reported changes/errors, thereby effectively reclassifying the new change/error from non-significant to significant and triggering another 30-day report (or an update to the previous 30-day report). Such an interpretation would have the consequence of requiring certain non-significant changes/errors, with a 0°F effect on calculated PCT, to be treated as significant and reported within a 30-day period of discovery because of how cumulative sums are calculated pursuant to 10 CFR 50.46 and the 1988 Statement of Considerations (SOC).</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>It is recommended to expand the discussion of reporting requirements in the Draft RIS to state its policy with regard to reporting of non-significant changes/errors that are discovered following a 30-day report, but prior to completion of corrective action (reanalysis).</i></p>	N/A

	<p><i>It is further recommended that a statement be added to the RIS that licensees have three options in such a case, as follows: (1) if the reanalysis will not be complete prior to the licensee's next annual report, include the newly discovered non-significant change/error in that next annual report along with its estimated effect on PCT; (2) if the reanalysis will be complete prior to the licensee's next annual report and the newly discovered change/error will not be resolved as part of that reanalysis, then include the newly discovered non-significant change/error in the next annual report along with its estimated effect on PCT; or (3) if the reanalysis will be complete prior to the licensee's next annual report and the newly discovered change/error will be resolved as part of that reanalysis, then describe the newly discovered non-significant change/error in the next annual report but report its estimated effect on calculated PCT as "Not Applicable" because its impact has already been addressed through reanalysis.</i></p> <p><i>It is recommended to state in the RIS that a licensee will not be required to docket a 30-day report pursuant to 10 CFR 50.46(a)(3)(ii) for a change/error that has a 0°F effect on PCT. Such a policy would provide a reasonable balance between the needs of NRC Staff to maintain cognizance with respect to licensee activities and the licensee's burdens associated with reporting requirements.</i></p>	
<p>NEI 1-10</p>	<p><i>[Regarding "NRC Staff Position," page 3 of 9]</i></p> <p><i>The "NRC Staff Position" contained in Draft RIS does not, but should, recognize that there may be differences between a bounding or limiting plant configuration that has been analyzed with an acceptable Emergency Core Cooling System (ECCS) Evaluation Model, and an actual as-built or physical plant configuration. This is important because 10 CFR 50.46 requires reporting of certain changes, but does not explicitly define what a "change" is, unlike 10 CFR 50.59.</i></p> <p><i>A closer examination of how the word "change" is used in 10 CFR 50.46 suggests that licensees do have some latitude to modify their actual plants without necessarily triggering any reporting requirement pursuant to 10 CFR 50.46. Given the positions described in the Draft RIS, it logically follows that only plant modifications that affect the bounding or limiting inputs used in ECCS performance analyses should be of regulatory interest to the NRC pursuant to 10 CFR 50.46, although certain other reporting requirements (e.g., 10 CFR 50.59) may also apply for such modifications.</i></p> <p><i>[Proposed Resolution]</i></p>	<p>N/A</p>

	<p><i>It is recommended to expand the discussion of reporting requirements in the RIS to state the policy with regard to what constitutes a "change" for the purposes of reporting.</i></p> <p><i>This comment is loosely related to the concepts of "margin management" and "margin ownership." Clearly, the acceptance criteria adopted in 10 CFR 50.46 (e.g., 2200°F PCT) represent limits that licensees must not violate, and the NRC is the sole owner of any margin between that acceptance criteria and the ultimate cladding performance limit. Licensees, however, should be the sole owners of any discretionary margins between actual plant configurations and analyzed (bounding or limiting) plant configurations. Thus, a modification of the plant configuration or reload core design practices should not be construed as a "change" for the purposes of 10 CFR 50.46 reporting requirements.</i></p>	
<p>NEI 1-11</p>	<p><i>[Regarding "Summary of Issue," page 4 of 9]</i></p> <p><i>Footnote 8 on page 4 indicates that the RIS has a narrow focus. Use of the phrase "all potential issues associated with the NEI guidance document" indicates that other issues may exist but are not being pursued.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>If the other potential issues exist, they should be in the scope of the RIS. If there are no additional specific issues with NEI 07-05 identified, the footnote should be modified to remove this phrase.</i></p>	<p>N/A</p>
<p>NEI 1-12</p>	<p><i>[Regarding definition of "Application," page 4 and 5 of 9]</i></p> <p><i>The lack of a definition of "application" in 10 CFR 50.46 is a source of confusion. In the Draft RIS, the NRC disagrees with the definition of "application" in Section 2.2.2 of NEI 07-05. It states that the NEI definition is "inappropriately limiting". Further, it states: "In contrast to the NEI 07-05 definition, the Staff has consistently applied a broader, plain-language definition, considering 'application of an evaluation model' to mean the act of putting an evaluation model to use." This is contrary to the position taken by the Staff in their response to a commenter in the 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i></p> <p><i>Specifically, the commenter's interpretation of the words "or in the application of such a model" was a broader interpretation. In response, the NRC stated: "The regulatory language referred to is</i></p>	<p>2</p>

	<p><i>intended to ensure that applications of models to areas not contemplated during initial review of the model do not result in errors by extending a model beyond the range that it was intended." This statement limits the meaning of the word "application". This is the basis for the definition in NEI 07-05 and is consistent with the 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i></p> <p><i>The Draft RIS states: "The intent of the statement was not to provide a definition of the word 'application' ...". In the absence of further guidance, licensees have no other recourse but to treat this statement as at least an interpretation or position, if not a definition. Further, with regard to this NRC statement above containing a "plain-language definition", such a definition does not appear in the regulation or other regulatory guidance document.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Recommend the definition of "application" in NEI 07-05 be incorporated and endorsed within the RIS. This definition is consistent with the interpretation or position in 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i></p>	
NEI 1-13	<p><i>[Regarding definition of "Input Information," page 5 through 7 of 9]</i></p> <p><i>The terms "input", "parameter", "input parameter", "input information", "design input", "model input", have been used in Federal Register Notices, Regulation, and industry guidance. These terms seem to be used interchangeably. Regardless of the term used, if the value of such a quantity is part of the Evaluation Model submitted to the NRC for review and acceptance, and formed the basis for acceptance and documented as a condition for the use of the Evaluation Model in an SER, it would be considered part of the Evaluation Model. However, if the value of such a quantity does not meet this criterion and is plant-specific, it would not be considered part of the Evaluation Model.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Recommend the definition of "input information" in NEI 07-05 be incorporated and endorsed within the RIS. This definition provides a clear distinction between quantities that are and are not part of the Evaluation Model and, therefore, are or are not subject to the reporting requirements of 10 CFR 50.46(a)(3).</i></p>	3

NEI 1-14	<p><i>[Regarding Section C, page 7 of 9]</i></p> <p><i>The interpretation of the relationship between 10 CFR 50.46 and 10 CFR 50.59 provides the NRC's perspective from a 10 CFR 50.46 view point and seems to interject the term "reporting" when the subject is determination of change.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>Clarify if both 10 CFR 50.59 and 10 CFR 50.46 can apply to a change and what that means for the Applicability Determination process used as the pre-screen in 10 CFR 50.59 application.</i></p>	N/A
NEI 1-15	<p><i>[Regarding Section C, page 7 of 9]</i></p> <p><i>The Draft RIS discussion fails to address the distinct differences in the intent of these two rules (10 CFR 50.46 and 10 CFR 50.59). 10 CFR 50.46 does not include requirements for regulatory review of changes to the ECCS analysis. It establishes requirements for the initial calculated cooling performance of the ECCS, and provides guidance for reporting of changes to or errors in that analysis subsequent to "acceptance" by the Staff. The main objective of 10 CFR 50.59 is to allow changes under licensee control if certain criteria are met. The reporting requirements of 10 CFR 50.59 are only ancillary to the main objective, and require only a summary of changes made under the rule. In the last paragraph of the Draft RIS on page 7 of 9, applying the provisions of 10 CFR 50.59(c)(4) to compare the decision making mechanism provided in 10 CFR 50.59 to the reporting requirements of 10 CFR 50.46 is an inappropriate comparison. Both the position attributed to NEI 07-05 and the interpretation provided in the Draft RIS are incorrect for the following reasons:</i></p> <ol style="list-style-type: none"><i>1. As stated in the Draft RIS "changes to, and errors in, ECCS evaluation models, or applications thereof, made as a result of facility changes under 10 CFR 50.59 are reportable under 10 CFR 50.46(a)(3)." Acceptability of the change under licensee control and satisfaction of other reporting requirements (both from 10 CFR 50.59) do not relax this requirement.</i><i>2. Changes to the evaluation model or its application are subject to 10 CFR 50.59 review to the extent that they are described in the UFSAR. That may involve either a change to the evaluation model (method of evaluation, 10 CFR 50.59(c)(2)(viii) or changes to inputs resulting from design modifications or analytical input (10 CFR 50.59(c)(2)(i - vii)). Regardless of 10 CFR 50.46 other requirements, such changes are subject to the two-year summary reporting requirements of 10 CFR</i>	N/A

	<p><i>50.59(d)(2), contrary to the conclusion drawn in the Draft RIS.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>The referenced passages in the RIS should be changed to correctly address the relationship between the two rules, in that they address different aspects of regulatory requirement and that based on the nature and the effect of a particular change to ECCS model, both rules should be independently applied on their own merits.</i></p>	
NEI 1-16	<p><i>[Regarding Section 3, page 7 of 9]</i></p> <p><i>The Draft RIS states, "...that by not providing timely reporting of all changes and errors to evaluation models, or applications thereof, which results in changes to the PCT of more than 50[] [degrees F], licensees impact the ability of the NRC to determine the safety significance of each error or change." Licensees have been cited for inconsistent implementation of other aspects of reporting under 10 CFR 50.46.</i></p> <p><i>10 CFR 50.46(a)3(i) establishes "...a significant change or error is one which results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F."</i></p> <p><i>The Draft RIS does not address what actions allow a re-set of the cumulation of changes and errors. For example:</i></p> <ul style="list-style-type: none"><i>• Does the submittal of an annual report that shows the complete list of changes and errors allow a re-zero of the cumulation?</i><i>• Is a licensee required to maintain the cumulation since the last 30-day report for exceeding 50 F, which could have been 4 years ago?</i> <p><i>The Draft RIS does not address how to evaluate the impact of a temporary EM change when it is no longer applicable and whether it needs to be counted against the cumulation upon the final removal of the change.</i></p>	N/A

	<p><i>For example, consider the assessment of a + 14 [degrees F] PCT for introduction of a new fuel product when in a transition core with the current fuel product. This PCT impact is not applicable for a full core of the new fuel. The PCT penalty is added in cycle N for the first mixed core of the two fuel types. For cycle N+3, a full core of the new fuel is in place and the + 14 [degrees F] is no longer applicable to the Evaluation Model. The PCT cumulation had included +14 F during the transition cores. In this instance, to reflect the full core of the new fuel product, should the plant now have to take a -14 [degrees F] against the cumulation of changes? With this approach, this fuel transition has an absolute change of 28 [degree F] to PCT but no actual change to the Evaluation Model by the end of the fuel transition.</i></p> <p><i>For plants that track the cumulation of changes since the last 30-day report (which could have been before the fuel transition started), this 28 [degrees F] and other changes or errors could trigger an unnecessary 30-day report.</i></p> <p><i>[Proposed Resolution]</i></p> <p><i>The RIS should provide guidance on the cumulation of changes and errors.</i></p>	
<p>AREVA 2-01</p>	<p><i>The phrase "all other information necessary to specify the calculational procedure" in the 10 CFR 50.46(c)(2) definition of Evaluation Model (EM) does not encompass plant specific input values.</i></p> <p><i>An approved topical report for an Evaluation Model describes the equations, methods, and codes utilized for analyzing LOCA events for a variety of plants. It describes how some plant input parameters would be considered and treated, but does not prescribe the values of input parameters for each individual plant. As such, the only "information necessary to specify the calculational procedure" of the EM are those related to the underlying equations and methods. The individual plant inputs are only necessary in order to exercise the EM for a specific plant design's LOCA demonstration. Therefore, relative to the definition of an EM, plant specific input values are not part of the EM.</i></p>	<p>3</p>
<p>AREVA 2-02</p>	<p><i>The consideration of all changes to plant input parameters as reportable is beyond the original intent of the rule.</i></p> <p><i>The Statements of Consideration for the 1988 ECCS Rule change states that the intent of the</i></p>	<p>2,3</p>

	<p><i>regulatory language regarding the application of the model was associated with the concern that a change would result in an extension outside the EM's intended use. Therefore, only plant changes that violated the EM's initial range would be considered reportable. In this situation the potential for reporting under both 10 CFR 50.46 and 10 CFR 50.59 would not be duplicative. Based on that stated intent, plant input changes within the EM's acceptable range would not require 50.46 reporting.</i></p> <p><i>The specific Statements of Consideration text for the 1988 ECCS Rule change is as follows:</i></p> <p><i>"One commenter interpreted the use of the words 'or in the application of such a model' as requiring reporting when facility changes (already reportable under §50.59), resulting in model input changes, occur.</i></p> <p><i>The regulatory language referred to is intended to ensure that applications of models to areas not contemplated during the initial review of the model do not result in errors by extending a model beyond the range that it was intended. The Commission does not believe that further clarification of this requirement is necessary and has not done so in the final rule."</i></p>	
SNC 3-01.A	<p><i>Regulation 10 CFR 50.46 has two primary functions: 1) to provide reporting requirements in paragraph (a)(3) and 2) to provide acceptance criteria in paragraph (b).</i></p> <p><i>10 CFR 50.46 is not a change control rule. 10 CFR 50.59 provides criteria for making changes to methods of evaluation and when NRC approval is required. In comparison, 10 CFR 50.46 does not provide such criteria.</i></p> <p><i>In the guidance for the implementation of 10 CFR 50.59 in Revision 1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation," as endorsed by Regulatory Guide 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, tests, and Experiments," there is a clear distinction between an input parameter and an element of the method of evaluation. 10 CFR 50.46 does not provide such a distinction.</i></p>	N/A
SNC 3-01.B	<p><i>10 CFR 50.46 uses the term "Acceptable Evaluation Model" several times. The rule provides no clear definition of the process for acceptance of an Evaluation Model or acceptance of changes to an Evaluation Model. The only reference to a process may be in paragraph (a)(2), which refers to "...evaluations of ECCS cooling performance submitted [emphasis added]..."</i></p>	N/A

SNC 3-01.C	<p><i>While not formally defined in 10 CFR 50.2, "Definitions", paragraph (c)(2) of 10 CFR 50.46 describes or "defines" an Evaluation Model as being the "calculational framework" and the "calculation procedure." This description implies that the Evaluation Model is a process. Paragraph (c)(2) uses the expression "... procedure for treating input and output information" Again, this describes a process, not values of plant-specific inputs or input parameters.</i></p> <p><i>Paragraph (c)(2) also uses the expression "values of parameters" as being part of the Evaluation Model. This expression has been a source of confusion. It is not clear from the definition of an Evaluation Model in paragraph (c)(2) what is meant by a "parameter." Mathematically, a parameter is a quantity that influences the behavior of a mathematical function. An example would be the coefficients in the Baker-Just equation for calculating the metal-water reaction rate as described in 10 CFR 50, Appendix K. In this case, the parameters (coefficients) would be considered part of the Evaluation Model. This is analogous to an element of a method of evaluation in 10 CFR 50.59 as opposed to an input or input parameter.</i></p> <p><i>The concept of an "Acceptable Evaluation Model" is not clear. Acceptance of models (or methods of evaluation as referred to in 10 CFR 50.59) is typically through the issuance of a Safety Evaluation Report (SER) by the NRC whereby the NRC approves the method for an intended application as in 10 CFR 50.59(a)(2)(ii). Such methods are typically submitted as topical reports by vendors to the NRC for review and acceptance/approval. In the topical reports, as well as in the review and acceptance process, plant-specific inputs or parameters are not typically included. Therefore, plant-specific inputs or parameters cannot be considered part of the Evaluation Model.</i></p>	3
SNC 3-01.D	<p><i>In the proposed rulemaking (64 FR 53270, October 1, 1999) related to the revision of Appendix K of 10 CFR 50, the Nuclear Energy Institute (NEI) submitted comments on the proposed rulemaking in a letter dated December 15, 1999 (ML003671779). NEI Comment 8 addressed the following statement in the Section-by-Section Analysis of the proposed change: "Estimated changes in ECCS performance due to revised analysis inputs are reported under Sec. 50.46 (a)(3), at least annually."</i></p> <p><i>NEI sought to clarify the applicability of the reporting requirements in paragraph (a)(3). In particular, NEI argued that paragraph (a)(3) does not apply to changes in the peak clad temperature resulting from plant-specific analysis input parameter values. NEI proposed revised rule language to clarify this.</i></p>	N/A

	<p><i>In the publication of the final rule, the NRC disagreed with the NEI proposal and took the position that "... the ECCS evaluation model is comprised of the computer code or codes, the input parameters (including plant-specific design parameters), and the calculational results." (65 FR 3491[3], June 1, 2000).</i></p> <p><i>This position further indicates continued disagreement on what constitutes an Acceptable Evaluation Model. As discussed previously, the definition in paragraph (c)(2) does not include plant-specific information. Further, contrary to the statement above from 65 FR 3491[3], the definition in paragraph (c)(2) does not include calculational results.</i></p>	
SNC 3-02	<p><i>[Regarding The Definition of "Application" (Draft RIS page 4-5 of 9)]</i></p> <p><i>The lack of a definition of "application" in 10 CFR 50.46 is a source of confusion. In the draft RIS, the NRC disagrees with the definition of "application" in Section 2.2.2 of NEI 07-05. The NRC states that the NEI definition is "inappropriately limiting." The NRC states: "In contrast to the NEI 07-05 definition, the NRC staff has consistently applied a broader, plain-language definition, considering 'application of an evaluation model' to mean the act of putting an evaluation model to use." This is contrary to the position taken by the staff in their response to a commenter in the 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i></p> <p><i>Specifically, the commenter's interpretation of the words "or in the application of such a model" was a broader interpretation. In response, the NRC stated: "The regulatory language referred to is intended to ensure that applications of models to areas not contemplated during initial review of the model do not result in errors by extending a model beyond the range that it was intended." This statement limits the meaning of the word "application". This is the basis for the definition in NEI 07-05 and is consistent with the 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i></p> <p><i>The draft RIS states: 'The intent of the statement was not to provide a definition of the word 'application' " In the absence of further guidance, licensees have no other recourse but to treat this statement as at least an interpretation or position, if not a definition. Further, in the NRC statement above regarding a "plain-language definition," such a definition does not appear in the regulation or other regulatory guidance document.</i></p>	2

	<i>The definition of "application" in NEI 07-05 is consistent with the interpretation or position in 1988 ECCS Rule Statements of Consideration (53 FR 35996, September 16, 1988).</i>	
SNC 3-03	<p><i>[Regarding The Definition of "Input Information" (Draft RIS page 5-7 of 9)]</i></p> <p><i>Input or input parameters have been discussed extensively in the General Comments section and will not be debated further here. However, some additional comments are provided.</i></p> <p><i>The terms "input," "parameter," "input parameter," "input information," "design input," and "model input," have been used in Federal Register Notices, Regulation, and industry guidance. These terms seem to be used interchangeably. Regardless of the term used, if the value of such a quantity is part of the Evaluation Model submitted to the NRC for review and acceptance, and formed the basis for acceptance and documented as a condition for the use of the Evaluation Model in an SER, it would be considered part of the Evaluation Model. However, if the value of such a quantity does not meet this criterion and is plant-specific, it would not be considered part of the Evaluation Model.</i></p> <p><i>The definition of "input information" in NEI 07-05 provides a clear distinction between quantities that are and are not part of the Evaluation Model and therefore, are or are not subject to the reporting requirements of paragraph (a)(3) of 10 CFR 50.46.</i></p>	3
SNC 3-04	<p><i>[Regarding The Interpretation of the Relationship Between 10 CFR 50.46 and 10 CFR 50.59 (Draft RIS page 7-8 of 9)]</i></p> <p><i>Comparison of attributes of 10 CFR 50.46 and 10 CER 50.59 has been discussed extensively in the General Comments section and will not be debated further here. However, some additional comments are provided.</i></p> <p><i>As discussed previously, the issues regarding the relationship between the two rules go back to the debate over what constitutes an "acceptable evaluation model" and the treatment of plant-specific inputs or parameters. Universal agreement on these is necessary to clarify the relationship between the two rules.</i></p>	N/A
SNC 3-05	<i>The issues identified in the draft RIS are not unique to NEI 07-05. The issues have existed for many years and have been the subject of debate both with respect to the current 10 CFR 50.46 rule as well as the proposed 10 CFR 50.46c rule. It is noted that the proposed 10 CFR 50.46c rule is not the subject of the draft RIS.</i>	4

	<p><i>The issues are centered on the lack of a clear definition of what constitutes an “acceptable evaluation model.”</i></p> <p><i>The industry has attempted on multiple occasions to engage the NRC in discussion on industry-developed reporting guidance for NRC endorsement. Two such guidance documents are WCAP 13451, “Westinghouse Methodology for Implementation of 10 CFR 50.46 reporting,” (October 1992) and NEI 07-05 (July 2008). While discussions with the NRC had taken place during the development of these documents, the NRC chose not to endorse either of these documents.</i></p> <p><i>In light of the issues and remaining ambiguities, it is recommended that the draft RIS be withdrawn. Instead, the NRC is encouraged to engage in discussions with the industry with the goal to establish uniform guidance on the issues discussed above. As an example, there has been extensive engagement between the NRC and the industry during the 10 CFR 50.46c rulemaking. This communication has been effective, with the benefit of enhancing the health and safety of the public.</i></p>	
GEH 4-01	<p><i>In the second paragraph under "Summary of Issue/NRC Staff Position" section, by including the plant-specific inputs and design parameters, the definition of an "evaluation model" as the "calculational framework" is effectively expanded. The extension of this revision of interpretation as to the definition of input as part of the "calculational framework" is to arrive erroneously at the conclusion that each application of the computer program(s) for a plant demonstration of ECCS performance, with all its incorporated input as part of the application, coupled with the need to report changes/errors to every input term, as applied, becomes its own unique evaluation model. The definition of how this input is selected from plant to plant and the margins the licensees may elect to retain or pursue in terms of the "act of putting an evaluation model to use" (NRC staff's plain-language definition of application), makes each one different than that which was originally approved, by definition. Approval of the plant analysis becomes de facto approval of a unique "evaluation model" as directed by that licensee. GEH does not believe that is the intent of the 1988 Rule statement of considerations.</i></p>	3
GEH 4-02	<p><i>The statement of consideration cited within the RIS stipulates the purpose of the "significance test" for changes/errors (greater than 50°F or an accumulation of changes/errors the absolute value of which sums to greater than 50°F) was to establish a standard as to the "adequacy of the evaluation model". In that context, the assertion that changes in a numerical value inserted to a computer program necessarily constitute a change to the computer program requires further justification. The</i></p>	3

	<i>RIS should clarify those changes in input to an evaluation model that would always be considered a change to the evaluation model and those changes that would not be.</i>	
STPNOC 5-01	<i>The proposed 50.46 rule change published in the Federal Register (79 FR [16105], March 24, 2014) included consideration of a peak clad temperature (PCT) criterion of 800°F for long term core cooling. The proposed RIS does not address if any long-term cooling criterion should be considered under the 10 CFR 50.46(a)(3) reporting criteria. STPNOC recommends that the RIS be revised to clarify that the 10 CFR 50.46(a)(3) reporting criteria does not apply to PCT for long-term cooling.</i>	N/A
STPNOC 5-02	<i>STPNOC recommends that the staff work with the industry to develop a position paper similar to NEI 07-15 to address 10 CFR 50.46 reporting requirements that the staff would endorse.</i>	4
VCSNS 6-01	<i>The NRC needs to clearly determine what are inputs and what is methodology. Specifically, give clear examples of what it is the NRC feels licensees should be reporting and what can be changed without notifying the NRC.</i>	3
STARS 7-01	<i>STARS Alliance LLC endorses the comments submitted by the Nuclear Energy Institute (NEI) in their letter written on behalf of the nuclear energy industry, dated September 22, 2015 (Reference 2).</i>	N/A
WEC 8-01	<p><i>Regarding the NRC's position that "plant-specific inputs and design parameters" are a part of the evaluation model: The NRC contends that "this NRC staff position has been applied consistently," yet it appears that the position has changed over time. From the Federal Register, Vol.53, No.180, pages 35996-36005, [53 FR 35996; September 16, 1988] it is stated:</i></p> <p style="padding-left: 40px;"><i>"One commenter interpreted the use of the words 'or in the application of such a model' as requiring reporting when facility changes (already reportable under 50.59), resulting in model changes occur. The regulatory language referred to is intended to assure that applications of models to areas not contemplated during the initial review of the model do not result in errors by extending the model beyond the range that it was intended. The Commission does not believe that further clarification of this requirement is necessary and has not done so in the final rule."</i></p> <p><i>The statement effectively serves to clarify the definition of "application (of such a model)." Specifically, that "application" is intended to mean extending the use of an evaluation model for something other than its intended use or intended range (i.e., using an ECCS model approved for SBLOCA for analyzing events other than a SBLOCA). This interpretation is logically derived from the statement that the regulatory language is "intended to ensure that applications of models to areas not contemplated during the initial review of the model do not result in errors by extending the model</i></p>	N/A

	<p><i>beyond the range that it was intended."</i></p> <p><i>Further, this statement also appears to correct the 1988 commenter's misinterpretation about plant changes being reportable (which, as was stated by the NRC), is "already reportable under 50.59." This appears to contradict the NRC's statement within the RIS that "this NRC staff position has been applied consistently."</i></p> <p><i>It is noted that the draft RIS also quotes this same passage, albeit for different reasons. Please elaborate on:</i></p> <ul style="list-style-type: none"><i>a. How the interpretations in this comment are incorrect.</i><i>b. How the NRC came to the conclusion that the statement supports the assertion that "this NRC staff position has been applied consistently," as this interpretation does not appear to follow from the quoted statement.</i>	
WEC 8-02	<p><i>This comment is based on the staff's position in the RIS that "plant-specific inputs and design parameters" are elements of an acceptable evaluation model (EM):</i></p> <p><i>There are some changes to "plant-specific inputs and design parameters" that require prior NRC approval in order to implement: When a license amendment request (LAR) for such a change is submitted, it would be expected that the licensee provide adequate justification for the change as part of the amendment request, including any potential impact to the peak cladding temperature (PCT) from the change in plant-specific inputs and design parameters. Assuming that there is a "significant" impact to the PCT and that the LAR is ultimately approved, there are a few considerations:</i></p> <ul style="list-style-type: none"><i>a. The newly approved licensing basis would be required to submit a 30-day 50.46 report.</i><i>b. Such information had just been submitted, reviewed, and approved by the NRC via the LAR.</i><i>c. The same information is therefore being provided to the NRC through two different channels (50.59 and 50.46), which seems to be an undesirable cumulative effect of regulations and the position stated in the RIS.</i><i>d. Section 3 of NEI 07-05 describes the relationship between 10 CFR 50.46 and 10 CFR 50.59, and based on the interpretations therein, prevents this type of scenario by taking the position that, contrary to the NRC's position in the draft RIS, "plant-specific inputs and design parameters" are NOT a part of an acceptable EM. It is noted that the NRC identifies this aspect of NEI 07-05 as one of the three explicit "issues" in the draft RIS;</i>	N/A

	<i>Please elaborate on the NRC's position on the relationship between 50.59 and 50.46 in the draft RIS, specifically with respect to a licensee's 50.46 reporting obligation for changes to plant specific inputs and design parameters resulting in a "significant" impact before granting the amendment request (prior to incorporation of the change into the licensing basis), as part of the amendment request (in-process change), and after granting the amendment request (subsequent to incorporation of the change).</i>	
Exelon 9-01	<i>Exelon Generation Company, LLC (Exelon) appreciates the opportunity to comment on the draft RIS. Exelon supports the comments submitted by the Nuclear Energy Institute (NEI) on behalf of the industry related to the subject RIS.</i>	N/A