

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
OFFICE OF NEW REACTORS  
WASHINGTON, DC 20555-0001

Month XX, Year

**NRC 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**

**ADDRESSEES**

All holders of an operating license or construction permit for a nuclear power reactor under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

All holders of and applicants for a power reactor combined license, standard design approval, or manufacturing license under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Reactors." All applicants for a standard design certification, including such applicants after initial issuance of a design certification rule.

**INTENT**

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to clarify the reporting requirements under 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors." Specifically, 10 CFR 50.46(a)(3) requires licensees to report to the NRC each change to, or error discovered in an acceptable emergency core cooling system (ECCS) evaluation model, or in its application, and its estimated effect on the limiting ECCS analysis. This RIS requires no action or written response on the part of an addressee.

**BACKGROUND INFORMATION**

During recent inspection and review activities, the NRC staff noted that certain licensees had made facility changes under 10 CFR 50.59, "Changes, tests and experiments," which directly affected inputs to the respective ECCS evaluation models. These licensees did not submit timely reports to the NRC under 10 CFR 50.46(a) with respect to these facility changes, and their effect on the respective ECCS evaluation models. In one instance, inspectors identified<sup>1</sup> a non-cited violation of 10 CFR 50.46 where changes to the high pressure safety injection system flow rate, caused by the installation of a flow orifice, caused a 300 degree Fahrenheit (°F)

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<sup>1</sup> Hay, Michael, "Fort Calhoun – NRC Integrated Inspection Report Number 05000285/2014002 and Notices of Violations," dated March 19, 2014; available in the Agencywide Documents Access and Management System (ADAMS) at Accession No. [ML14078A666](#).

increase in the small-break loss-of-coolant accident (LOCA) peak cladding temperature (PCT) that was not reported within 30 days.

Section 50.46(a)(3) of 10 CFR, which establishes reporting requirements with respect to ECCS models, states that each licensee or applicant must:

...estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, 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.

For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the... [licensee/applicant] shall 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. If the change or error is significant, the applicant or licensee shall provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements...

The “evaluation model” as used in 10 CFR 50.46 is defined in 10 CFR 50.46(c)(2) as:

...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 reporting requirements in 10 CFR 50.46(a)(3) were adopted on September 16, 1988,<sup>2</sup> and will be referenced as the 1988 ECCS Rule for the purposes of this RIS. In the statement of considerations (SOC) for the 1988 ECCS Rule, the NRC responded to comments regarding the establishment of a 50 °F change in either direction as the threshold for “significant”<sup>3</sup>:

The NRC considers a major error or change in any direction a cause for concern because it raises potential questions about the adequacy of the evaluation model as a whole. Therefore the NRC requires the reporting of significant errors or changes, in either direction, on a timely basis so that the Commission may make a determination of the safety significance.

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<sup>2</sup> 53 FR 35996; September 16, 1988

<sup>3</sup> 53 FR 35998; September 16, 1988

Several commenters questioned the necessity to report “minor or inconsequential” changes or errors, (i.e., those changes or errors that are not significant) on an annual basis. In the 1988 ECCS Rule SOC, the NRC responded<sup>4</sup>:

While errors or changes which result in changes in calculated peak clad temperatures of less than 50 °F are not considered to be of immediate concern, the NRC requires cognizance of such changes or corrections since they constitute a deviation from what previously has been reviewed and accepted.

These comment responses from the 1988 ECCS Rule provide a clarification regarding the NRC’s intent when establishing reporting requirements. The 1988 ECCS Rule SOC documented the NRC staff position that both “minor or inconsequential” and significant changes need to be reported to the Commission.

During recent inspection and review activities, the NRC staff observed that some licensees relied on third-party guidance documents to determine that certain changes to, and errors in, ECCS evaluation models, or the applications of such models, were not reportable under 10 CFR 50.46(a)(3). One such document, authored by the Nuclear Energy Institute (NEI), NEI 07-05, “10 CFR 50.46 Reporting Guidelines,”<sup>5</sup> was identified by NRC staff and is discussed in detail in this RIS. The NRC has not approved for use or endorsed the positions taken in NEI 07-05 or any third-party document providing guidance for compliance with 10 CFR 50.46(a)(3) reporting requirements.

## **SUMMARY OF ISSUE**

### *NRC Staff Position*

The requirement in 10 CFR 50.46(a)(3) states that each change to, or error in, an acceptable ECCS evaluation model, or in the application thereof, that affects the temperature calculation is reportable. Changes to, or errors in ECCS evaluation models, or applications thereof, which result in significant (i.e., 50 degree Fahrenheit) changes in the PCT must be reported within 30 days, while those that result in non-significant changes must be reported at least annually.

As discussed above, 10 CFR 50.46(c)(2) defines an “evaluation model” as the “calculational framework for evaluating the behavior of the reactor coolant system during a [LOCA].” In addition, 10 CFR 50.46(c)(2) states that the evaluation model includes “all other information necessary for application of the calculational framework to a specific LOCA.” Therefore, the NRC staff considers changes to, and errors in, an ECCS evaluation model, or an application thereof, to include not only changes to, and errors in, to the physical models and model parameters that partially comprise the “calculational framework” (e.g., heat transfer correlations, etc.) but also changes to, and errors in, to plant-specific inputs and design parameters (e.g., setpoints, initial conditions, etc.). All of these parameters and inputs are necessary for the analysis of a plant-specific LOCA, as described in 10 CFR 50.46(c)(2).

This NRC staff position has been applied consistently. One example is the NRC response to the public comment from the NEI related to the proposed revision to 10 CFR Part 50, Appendix K. The NRC stated, in part<sup>6</sup>:

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<sup>4</sup> 53 FR 35998; September 16, 1988

<sup>5</sup> Available in ADAMS under Accession No. [ML15140A631](#).

<sup>6</sup> 65 FR 34919; June 1, 2000

...10 CFR 50.46(a)[(3)](ii) contains an unambiguous requirement that changes to the ECCS evaluation model must be reported at least annually... [O]n the basis of the definition of an evaluation model in § 50.46, the Commission does not accept the distinction made by NEI between “model parameters” and “design parameters.”

In the SOC for the 1988 ECCS Rule, the NRC addressed a comment discussing the relationship between 10 CFR 50.46(a)(3) and 10 CFR 50.59 requirements with the following explanation<sup>7</sup>:

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.

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. The Commission does not believe that further clarification of this requirement is necessary and has not done so in the final rule.

The NRC declined to change the rule language regarding the requirement to report changes “in the application of [an ECCS evaluation] model” under 10 CFR 50.46(a)(3), even in consideration of the reporting requirements contained in 10 CFR 50.59. 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). The NRC staff maintains that each change to, or error in, an ECCS evaluation model, or the application thereof, is reportable under 10 CFR 50.46(a)(3).

#### *Issues Identified Regarding NEI 07-05*

The NRC staff identified three specific issues with NEI 07-05 that may cause licensees to determine, incorrectly, that certain changes to, and errors in, ECCS evaluation models, or in applications thereof, are not reportable under 10 CFR 50.46(a)(3).<sup>8</sup> These issues included:

- A. The definition of “application” is both incorrect and inconsistent with the 1988 ECCS Rule SOC.
- B. The definition of the phrase “input information” incorrectly suggests that changes to, and errors in, certain types of inputs to ECCS evaluation models, and applications thereof, are not reportable under 10 CFR 50.46.
- C. The interpretation of the relationship between requirements associated with 10 CFR 50.46 and 10 CFR 50.59 is incorrect.

Each of these issues is addressed in further detail below.

#### A. The Definition of “Application”

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<sup>7</sup> 53 FR 35998; September 16, 1988

<sup>8</sup> As noted in the abstract for NEI 07-05, the document was not submitted to the NRC for review. Therefore, the discussion in this RIS is not intended to provide a comprehensive discussion of all potential issues associated with the NEI guidance document.

Section 2.2.2, "Application," of NEI 07-05 provided the following definition of the term "application":

The term "application" denotes the range of applicability of an evaluation model, i.e., the conditions under which it is appropriate to apply the evaluation model. This definition is consistent with the explanation of application provided in item 6 of the "Summary of Public Comments" section in the statements of consideration that accompanied the final rule language published in the Federal Register in 1988.

Title 10 of the CFR does not define the word "application." 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. The NEI 07-05 definition of "application" may lead licensees to exclude certain changes to, and errors in, applications of ECCS evaluation models from reporting under 10 CFR 50.46(a)(3). In addition, NEI 07-05 incorrectly stated that this definition is consistent with the 1988 ECCS Rule SOC. The 1988 ECCS Rule SOC stated that "the NRC requires cognizance" of both significant and non-significant changes, "since they constitute a deviation from what has previously been reviewed and accepted;" therefore, the above NEI 07-05 definition is inappropriately limiting. The purpose of the 1988 ECCS Rule SOC statement regarding the application of the evaluation model, discussed in the *NRC Staff Position* section, was to respond to a public comment suggesting that the language, "or in the application of an evaluation model," was duplicative and unnecessary. The intent of the statement was not to provide a definition of the word "application;" the NRC chose to retain the phrase in the rule language and indicated in the 1988 ECCS Rule SOC that further clarification was unnecessary. Based on these considerations, the definition of "application" contained in NEI 07-05 is incorrect and inconsistent with the SOC for the 1988 ECCS Rule.

#### B. The Definition of "Input Information"

Section 2.2.11, "Input Information," of NEI 07-05 defines "input information," in part:

The first category of input information is the basic engineering information that describes a specific plant, (for example, component lengths and volumes, initial temperatures and pressures, safety injection flows, set points, cycle specific physics parameters, fuel design parameters, and other quantities that may be modified and evaluated under 10 CFR 50.59). A change to input information of this type is not considered a change to the evaluation model. Changes and error corrections in this category are not reportable under 10 CFR 50.46.

The above definition suggests that some types of facility changes that may affect the temperature calculation for the limiting ECCS analysis are not reportable to the NRC under the requirements of 10 CFR 50.46(a)(3).

As discussed in the *NRC Staff Position*, each change to, or error in, an acceptable ECCS evaluation model, or in the application thereof, that affects the temperature calculation is reportable, including changes to, and errors in, plant-specific inputs that may have resulted from facility changes. Furthermore, an "evaluation model," as defined in 10 CFR 50.46(c)(2), includes, "all other information necessary for application of the calculational framework to a specific LOCA." The position taken in NEI 07-05 that a change to "input information" is not considered a change to the evaluation model is inconsistent with this 10 CFR 50.46(c)(2)

definition. Specifically, 10 CFR 50.46(c)(2) defines the information necessary for the application of the calculational framework to include such information 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 NEI 07-05 definition of “input information” included, “component lengths and volumes, initial temperatures and pressures, safety injection flows, set points, cycle specific physics parameters, and fuel design parameters.” Although NEI 07-05 indicated that changes to and errors in these quantities would not be reportable under 10 CFR 50.46(a)(3), they fall within two categories specifically included in the definition of “evaluation model” provided in 10 CFR 50.46(c)(2). For example, component lengths and volumes constitute information necessary to specify portions of the analysis not included in computer codes. While components are included in computer codes, their specific dimensions, which vary from plant to plant, must be specified in the analysis. In addition, cycle specific physics parameters and fuel design parameters are both values of parameters, as are initial temperatures and pressures, safety injection flows and set points. Since this information is included in the 10 CFR 50.46(c)(2) definition of “evaluation model,” changes to, and errors in, this information that affect the temperature calculation must be reported in accordance with 10 CFR 50.46(a)(3). In consideration of the definition of “evaluation model” provided in 10 CFR 50.46(c)(2), the NEI 07-05 definition of “input information,” along with the related guidance that changes to and errors in certain types of input information are not reportable, is incorrect.

The NRC staff position that plant input changes are considered changes to the evaluation model is a long-standing position and has been previously published. NEI offered a definition of “input information” in the context of 10 CFR 50.46(a)(3), similar to the passage from NEI 07-05, in a letter to the NRC.<sup>9</sup> NEI suggested that the NRC add language in the *Federal Register* stating that, “[c]hanges resulting from plant specific design parameter changes, including cycle-to-cycle reload fuel parameters, are not reportable under 10 CFR 50.46(a)(3).” The NRC responded to the letter and disagreed with the NEI interpretation, stating, in part<sup>10</sup>:

...NEI contended that plant parameters change from cycle to cycle and that changes in PCT caused by plant specific input parameter changes to design information fall outside the scope of reportability under 10 CFR 50.46(a)(3).

...the Commission does not agree with NEI on this point. In their comment, NEI drew a distinction between design inputs and model inputs to ECCS evaluations...

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<sup>9</sup> Modeen, David J., Nuclear Energy Institute, letter to U.S. Nuclear Regulatory Commission, “Transmittal of Comments on Proposed Change to 10 CFR 50, *Emergency Core Cooling System Evaluation Models* (64 *Fed. Reg.* 53270) Request for Comments,” Project Number 689, December 15, 1999. Available in ADAMS at Accession No. [ML003671779](#).

<sup>10</sup> 65 FR 34918; June 1, 2000

...10 CFR 50.46(a)[(3)](ii) contains an unambiguous requirement that changes to the ECCS evaluation model must be reported at least annually... [O]n the basis of the definition of an evaluation model in § 50.46, the Commission does not accept the distinction made by NEI between “model parameters” and “design parameters.”

The NRC staff position discussed in this RIS is consistent with the above NRC discussion (from 2000) in the *Federal Register*. Therefore, the NEI 07-05 interpretation regarding which changes to and errors in inputs to ECCS evaluation models and applications thereof are reportable is both incorrect and inconsistent with previously published NRC staff positions.

### C. The Interpretation of the Relationship Between 10 CFR 50.46 and 10 CFR 50.59

Section 3.0, “Relationship Between 10 CFR 50.46 & 10 CFR 50.59,” of NEI 07-05 cited the public comment related to 10 CFR 50.59, contained in the 1988 ECCS Rule SOC, stating, “10 CFR 50.46 does not apply to a change in plant configuration or operating conditions, even if such change results in a change in the PCT for the limiting transient.” The NRC staff identified two issues with Section 3.0 of NEI 07-05, and they are described below.

First, Section 3.0 of NEI 07-05 is inconsistent with the 1988 ECCS Rule SOC. The NRC stated, in the 1988 ECCS Rule SOC, that the NRC requires cognizance of all changes and errors. The NRC did not distinguish between changes to, and errors in, an evaluation model, or the application of such a model, when discussing the necessity to remain cognizant of both significant and minor changes or errors. In the 1988 ECCS Rule SOC, the NRC also declined to revise the reporting requirements in response to the comment regarding 10 CFR 50.59. This comment response, and the NRC staff’s chosen action, affirm the NRC staff position that 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). Additionally, the NRC stated in the 1988 ECCS Rule SOC that by not providing timely reporting of all changes and errors to evaluation models, or applications thereof, which result in changes to the PCT of more than 50 °F, licensees impact the ability of the NRC to determine the safety significance of each error or change. Changes or error corrections to the input of an ECCS evaluation model or its application made to reflect facility changes may cause models within the calculational framework to be applied in ways that would be inconsistent with the NRC’s prior safety review and approval. This requirement also applies to a cumulation of changes that exceeds 50 °F.

Second, the interpretation within NEI 07-05 regarding the regulatory treatment of changes in the ECCS evaluation model “input information” is inconsistent with 10 CFR 50.59(c)(4). NEI 07-05 indicates that such changes should be evaluated in accordance with 10 CFR 50.59 and are not reportable under 10 CFR 50.46. However, 10 CFR 50.59(c)(4) states, “The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.” Since 10 CFR 50.46 establishes more specific criteria for estimating the effects of and reporting changes to, and errors in, ECCS evaluation models, or in the applications thereof, 10 CFR 50.59 reporting requirements do not apply to changes made to ECCS evaluation models.<sup>11</sup>

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<sup>11</sup> Note that facility changes must be screened and evaluated according to 10 CFR 50.59 criteria, while associated changes to, and errors in, the ECCS evaluation model, or in the application thereof, that affect the temperature calculation are subject to 10 CFR 50.46 reporting requirements.

Section 3.0 of NEI 07-05 is therefore inconsistent with both the SOC for the 1988 ECCS Rule and the requirements contained in 10 CFR 50.59(c)(4), and leads to an incorrect interpretation of the relationship between 10 CFR 50.46 and 10 CFR 50.59.

## **CONCLUSION**

The process by which any changes may be made to an ECCS evaluation model, or in the application thereof, (e.g., under 10 CFR 50.59) is independent from the necessity for reporting of changes under the requirements in 10 CFR 50.46(a)(3). If a change is made to an ECCS evaluation model, or in the application thereof, 10 CFR 50.46(a)(3)(i) requires licensees to estimate the effect of the change on the PCT for the limiting transient. If the predicted change to the PCT is significant (different by more than 50 °F), then the licensee is required to submit a report to the NRC describing the nature of the change, and its estimated effect on the limiting ECCS analysis within 30 days. If the predicted change to the PCT is not significant, then the licensee is required to include such change in an annual report to the NRC under 10 CFR 50.46.

As discussed in the “Background Information” section, the NRC has not reviewed and formally approved for use, or endorsed, NEI 07-05. Licensees that rely on third-party guidance documents, such as NEI 07-05, which have not been approved for use, or endorsed<sup>12</sup>, by the NRC, do so at their own risk.

## **BACKFITTING AND ISSUE FINALITY DISCUSSION**

This RIS discusses reporting requirements under 10 CFR 50.46 applicable to operating license holders (including combined license holders) with respect to ECCS analyses and modeling.

This RIS does not set forth any new or changed NRC requirement, or new or changed guidance or position on compliance with any existing NRC regulatory requirement. The RIS does not require any action by any addressee, nor does this RIS request or suggest that any addressee submit information to the NRC, which is not already required to be submitted by existing NRC requirements under 10 CFR 50.46 or any other NRC regulation (e.g., 10 CFR Part 21). For these reasons, this RIS does not represent backfitting as defined in 10 CFR 50.109(a)(1) and is not otherwise inconsistent with any issue finality provision in 10 CFR Part 52. Therefore, the NRC did not prepare a backfit analysis for this RIS or further address the issue finality criteria in Part 52.

## **FEDERAL REGISTER NOTIFICATION**

[Discussion to be provided in final RIS]

## **CONGRESSIONAL REVIEW ACT**

[Discussion to be provided in final RIS]

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<sup>12</sup> With respect to third-party documents, “approved for use” means that the NRC has determined that the matters addressed in the document are technically acceptable and consistent with NRC regulatory requirements, guidance and policy, but the NRC neither supports nor discourages entities from using the positions set forth in the document. “Endorse,” by contrast means that in addition to the NRC determination above, the NRC encourages entities to follow the positions in the document. As a general matter, the NRC rarely “endorses” third-party documents as NRC guidance.



## PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011.

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