May 11, 2011

Mr. Russell J. Bell
Director, New Plant Licensing
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, D.C. 20006-3708

SUBJECT: COMMENTS ON NUCLEAR ENERGY INSTITUTE 96-07, APPENDIX C: GUIDELINE FOR IMPLEMENTATION OF CHANGE CONTROL PROCESSES FOR NEW NUCLEAR POWER PLANTS LICENSED UNDER TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*, PART 52

Dear Mr. Bell:

My staff is continuing its review of Nuclear Energy Institute (NEI) 96-07, Appendix C*, Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR 52*, which you submitted to the U.S. Nuclear Regulatory Commission (NRC) on October 5, 2010 (Agencywide Documents Access and Management System Accession No. ML102980298), and amended *Section 4.6* on February 24, 2011 (ADAMS Accession No. ML110700132). This document provides guidance for implementing the licensing basis change process requirements of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 52. Overall, we have found that *Appendix C* to NEI 96-07 is comprehensive and provides an appropriate level of detail for future users. However, we have identified a number of suggestions for changes and some areas that need further clarification to meet the objectives of the change processes of 10 CFR Part 52, and have listed them in the enclosure.

We will discuss the staff comments on the guidance document at a future meeting. We look forward to resolving these comments at the meeting and working to finalize this important guidance document. We appreciate your extensive effort in developing this document and anticipate you are issuing it in final form later this year. Subsequently, the staff will develop and issue its interim staff guidance endorsing Appendix C to NEI 96-07 during 2011.

If you have any questions regarding the staff comments, please contact Mr. Earl R. Libby at (301) 415-0522.

Sincerely,

/RA/

William F. Burton, Chief
Rulemaking and Guidance Development Branch
Division of New Reactor Licensing
Office of New Reactors

Project No.: 689

Enclosure:
NRC Comments on
NEI 96-07, Appendix C

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NRC Comments on
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DATE	04/21/2011	04/21/2011	05/09/2011	05/11/2011

U.S. Nuclear Regulatory Commission
Comments on NEI 96-07, Appendix C

General Comments

1. Include sections to deal with plant changes and modifications to the ex-vessel severe accident mitigation features. Page C-85, Section 4.1.2.2.2, *Evaluation of Tier 2 Departures that Affect Ex-Vessel Severe Accident Design Features* and Page C-93, Section 4.3, *Changes to Chapter 19*. Currently scheduled for May 2011.

2. The document would benefit from the deletion of references to *applicant* as the change processes are applicable for a Part 52 licensee during both construction and operation.

Detailed Comments/Questions (Note: Red type identifies suggested text additions)

Page C-1, Section 1.1 {Open for Discussion}

Delete text: "~~... and a description of the approach to be used to establish a site-specific change process for limited work authorization (LWAs).~~" LWAs do not have a change or change control process, except as part of an early site permit (ESP) (52.12, 52.39(e))

Page C-8, Section 1.2.3 {Open for Discussion}

Rearrange text for clarity: "~~Additional regulatory change control process requirements are identified in Section 4.1.1 of NEI 96-07, which may take precedence over 50.59 for control of specific changes.~~" Additional regulatory change control process requirements, which may take precedence over 50.59 for control of specific changes, are identified in Section 4.1.1 of NEI 96-07.

Page C-12, Section 1.2.5

Delete section: "~~Future LWAs are anticipated to include a change process. An LWA holder may make a change to the LWA using the screening/change process that is included in the issued LWA. Those changes that require NRC approval are processed as license amendment requests in accordance with 10 CFR 50.90 and 50.92. The LWA change process is outlined in Section 4.5.~~" There is no change process associated with a Part 50.10 LWA.

Page C-13, Section 1.3.1

Incorrect Regulation Reference: "Where changes to the facility or procedures are controlled by more specific regulation (e.g., quality assurance, security and emergency preparedness program changes control under 10 CFR 50.54(a), (p) and (q), respectively; Off-Site Dose Calculation Manual changes controlled by technical specification), ~~10 CFR 50.59(d)~~ 10 CFR 50.59(c)(4) and 10 CFR 52.98(c)(2) state that the more specific regulation applies."

Pages C-28-29, Section 3.9

Remove editing strikeouts.

Page C-37, Section 3.20

Consistency within Section 3.0: Add the term Definition: under Section 3.20 *Site Safety Analysis Report (SSAR) for Early Site Permits*.

Page C-41, Section 4.1.1

Sentence fragment: "Therefore, a COL applicant or holder may make changes in the operation as discussed or depicted in Tier 1 without taking a departure from Tier 1."

Page C-42, Section 4.1.1

Correct Spelling: "The licensee decides to delete a valve shown on a Tier 2 diagram but no shown in a Tier 1 diagram. Such a change would not constitute a departure from Tier 1 (but would constitute a departure ~~form~~ from Tier 2)."

Page C-46, Section 4.1.2.1.1

Correct Spelling: "In general, changes that have none of these effects, or have positive effects, may be screened out because only adverse changes have the potential to increase the likelihood of malfunctions, increase consequences, create new accidents, or otherwise meet the Section VIII.B5 departure evaluation criteria."

Page C-51, Section 4.1.2.1.3

Remove editing strikeouts.

Page C-59, Section 4.1.2.2.1.1 {Open for Discussion}

"Example 3

The change in frequency of occurrence of an accident is calculated to support the evaluation of the proposed departure, and one of the following criteria are met:

- The increase in the pre-change accident or transient frequency does not exceed 10 percent or

- The resultant frequency of occurrence remains below 1E-6 per year or applicable plant-specific threshold.

If the proposed departure would not meet either of the above criteria, the change is considered to involve more than a minimal increase in the frequency of occurrence of an accident, and prior NRC approval is required."

Also see SECY-10-0121 on new reactor risk metrics, and SRM-10-0121
This example reflects the increase in risk associated with the current operating fleet and does not take into account the lower frequency of occurrence calculated for the new plants.

Page C-62, Section 4.1.2.2.1.2 {Open for Discussion}

"Example 8

The change in likelihood of occurrence of a malfunction is calculated in the support of the evaluation and increases by more than a factor of two. Note: The factor of two should be applied at the component level. Certain changes that satisfy the factor of two limit on increasing likelihood of occurrence of malfunction may meet one of the other criteria for requiring prior NRC approval (e.g., exceed the minimal increase standard for accident/transient frequency under criterion VIII.B.5.b(1)). For example, a change that increases the likelihood of malfunction of an emergency diesel generator by a factor of two may cause more than a 10% increase in the frequency of station blackout."

Also see SECY-10-0121 on new reactor risk metrics, and SRM-10-0121
This example also reflects the allowable increase risk with the current operating fleet and does not take into account the characteristics of the new plants.

Page C-64, Section 4.1.2.2.1.3 {Open for Discussion}

Note: The following highlighted paragraphs been updated to be consistent with the current regulations for new plants.

Therefore, for a given accident, calculated or bounding dose values for that accident would be identified in the plant-specific DCD. These dose values should be within the GDC 19 or 10 CFR 50.34 limits, as applicable, as modified by SRP guidelines, as applicable. An increase in consequences from a proposed departure is defined to be no more than minimal if: (1) the increase is less than or equal to 10 percent of the difference between the current calculated dose value and the regulatory guideline vale (10 CFR 50.34 or GDC 19, as applicable); and (2) the increased dose does not exceed the current SRP guideline value for the particular design basis event. The current calculated dose values are those documented in the most up-to-date analyses of record. This approach establishes the current SRP guideline values as a basis for

minimal increases for all facilities, not just those that were specifically licensed against those guidelines.

Also see SECY-10-0121 on new reactor risk metrics, and SRM-10-0121
This example also reflects the allowable increase risk with the current operating fleet and does not take into account the characteristics of the new plants.

Page C-65, Section 4.1.2.2.1.3

Remove editing strikeouts.

Pages C-66-67, Section 4.1.2.2.1.3

"Note: The following highlighted examples need to be updated to be consistent with the current requirements in 10 CFR 50.34 and GDC 19."

Examples 1 through 5, inclusive need additional review.

Page C-85, Section 4.1.2.2.2 {Awaiting Development for Review}

4.1.2.2.2 *Evaluation of Tier 2 Departures that Affect Ex-Vessel Severe Accident Design Features*

Still under development – OPEN ITEM

Page C-93, Section 4.3 {Awaiting Development for Review}

4.3 *Changes to Chapter 19* (*Probabilistic Risk Assessment and Severe Accident Evaluation)*

Still under development – OPEN ITEM

Page C-94, Section 4.4.2

Incorrect Regulation Reference: "After issuance of a COL, the ESP and SSAR no longer have any effect with respect to the plant that is the subject of the COL. Instead, as provided in ~~10 CFR 27(d)~~ 10 CFR 26(d), …."

Page C-99, Section 5.2

"In such ~~mixed-scope~~ dual-scope cases, the applicable provisions of Section 52.98 and the design certification rule apply."

Section 4.6 Disposition of Departures and Changes, dated February 24, 2011

Page 1

Recommend reordering these two sections in chronological order.
4.6 Disposition of Departures and Changes
4.6.1 Evaluations performed after the Section 52.103(g) ITAAC finding
4.6.2 Evaluations performed before the Section 52.103(g) ITAAC finding

Page 3, Section 4.6.2

"Licensees should discuss planned changes with the NRC staff prior to submittal of LARs/exemption requests. The purposes of pre-LAR submittal interactions are to:

- Ensure that NRC is informed and can plan for submittal of LARs and changes to fabrication/construction activities or schedule
- Facilitate preparation of LARs that are complete in terms of administrative requirements and technical basis
- Identify potential challenges to timely NRC approval of LARs
- Determine if the licensee needs to request a Preliminary Acceptability Review (PAR). ~~(as discussed in the following section) to allow work to proceed while the LAR is under NRC review~~"

Page 4, Section 4.6.3

"To maintain schedule, licensees may need to proceed with installation and testing of changes pending a final NRC decision on a required LAR/exemption request. Before proceeding with installation and testing of a change during construction that requires NRC approval of an LAR, Part 52 licensees should notify the NRC and request a Preliminary Acceptability Review (PAR). ~~for the change.~~"

Relocate second paragraph beginning with "Design, procurement, fabrication, …." in its entirety to the end of this Section 4.6.3, Page 7.

"The primary purpose of the PAR is to enable the NRC to assess and ensure the ~~impact~~ inspectability of the proposed change and adjust its inspection activities as necessary. Based on the information provided in the licensee's PAR request, the NRC ~~will~~ may issue the licensee a PAR Notification stating that the NRC has no objection to the licensee proceeding at its own risk with …."

"Following licensee receipt of the NRC's PAR Notification of No Objection, the licensee may perform installation and testing activities, …."

Page 4, Foot Note

Delete text: ~~The NRC is considering establishing a license condition on the PAR process to be included in each COL.~~

The COL must contain a Preliminary Acceptability Review (PAR) License Condition enabling the licensee to request the PAR for the license amendment request/exemption.