

March 20, 2012

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, REVISION 0C

Dear Mr. Bell:

My staff is continuing its review of Nuclear Energy Institute (NEI) 96-07, Appendix C, Revision 0C, *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 31, 2011 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML113220426), including the two sections amended on November 30, 2011, *Section 4.1.1, Construction Change Applicability* (ADAMS Accession No. ML113390052) and *Section 4.4.2.2, Evaluation of Departures From Tier 2 Information That Do Not Affect Ex-Vessel Severe Accident Criteria* (ADAMS Accession No. ML113390051). NEI 96-07, Appendix C, Revision 0C, provides guidance for implementing the license change process requirements of Title 10 of the *Code of Federal Regulations* (10 CFR), Part 52. Overall, *Appendix C* to NEI 96-07 appears to be comprehensive and to provide an appropriate level of detail for future users. However, we have identified a number of recommendations for changes and some areas that need further clarification to meet the objectives of the change processes of 10 CFR Part 52. These recommendations are set forth in the enclosure.

We will discuss the staff comments on NEI 96-07, Appendix C, Revision 0C at a meeting to be scheduled during 2012. We look forward to receiving stakeholder input on these comments at that meeting. We appreciate your extensive effort in developing this document and anticipate that you will issue it in final form later this year. If you address the staff comments to our satisfaction, we intend to develop and issue an endorsement of NEI 96-07, Appendix C, as revised, as an acceptable method of meeting the change process regulations at 10 CFR Parts 50 and 52.

R. Bell

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

Sincerely,

/RA/

Amy E. Cabbage, Chief
Policy Branch
Division of Advance Reactors and Rulemaking
Office of New Reactors

Project No.: 689

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

R. Bell

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NRC Comments on
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U.S. Nuclear Regulatory Commission
Comments on NEI 96-07, Appendix C, Revision 0C
Dated October 30, 2011

Section 1.1 Purpose and Scope

Page C-4, last paragraph, third sentence

In general, this appendix has been written for applicants and holders of combined licenses (COLs). Additionally, this guidance is applicable to holders of operating licenses that reference a design certification. ~~Furthermore, much of the information in this guidance is applicable to holders of construction permits that reference a design certification.~~

NRC Comment:

Construction Permits (CPs) are beyond the scope of NEI 96-07, Appendix C. All other similar references to CPs should be deleted.

Section 1.2.1 Relationship to Other Processes That Control Licensing Basis Activities

Page C-5, fifth bullet

Changes to the fire protection program for Part 52 licensees are governed by 10 CFR 50.59 as discussed in Section 4.1 of this appendix, and licensee changes to the design of fire protection systems as described in the DCD are governed by Section VIII.B.5 of a referenced design certification rule.

NRC Comment:

Some fire protection system information may be covered by the other Section VIII processes.

Page C-5, sixth bullet

During the construction phase, maintenance activities, including associated temporary changes, are subject to the licensee programs for controlling such changes during construction that will be relied upon to maintain Inspection, Test, Analysis and Acceptance Criteria (ITAAC) closures, and any affected SSCs are ultimately subject to the ITAAC themselves. Accordingly, screening and evaluation under 10 CFR 50.59 and VIII.B.5 are not required.

During the operational phase, maintenance activities, including associated temporary changes, are subject to the technical specifications and are assessed and managed in accordance with the Maintenance Rule, 10 CFR 50.65; screening and evaluation under 10 CFR 50.59 and VIII.B.5 are not required.

NRC Comment:

The scope of NEI 96-07 Appendix C includes both construction and operation under a COL. The Maintenance Rule is applicable only during the operational phase, after the § 52.103(g) finding. As stated in § 50.65(a)(1), "...each holder of a combined license under Part 52 of this chapter after the Commission makes the finding under § 52.103(g), shall monitor the

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performance or condition of structures, systems, or components...” The language change recognizes the licensee control of maintenance activities, including associated temporary changes, during the construction phase. (Reference: NEI 08-01 “Industry Guideline for the ITAAC Closure Process Under 10 CFR Part 52” and RG 1.215 “Guidance for ITAAC Closure Under 10 CFR Part 52”)

Section 1.2.3 Relationship to the UFSAR

Page C-6

New plant change processes identified in 10 CFR 52.98 are the processes that identify when a license amendment is required prior to implementing **departures from the plant specific DCD, other** changes to the facility or procedures described in the FSAR (as updated, or UFSAR) or test and experiments not described in the UFSAR. As such, it is important that the FSAR be properly maintained and updated in accordance with 10 CFR 50.71(e) and Section X of the design certification rules.

NRC Comment:

This section provides guidance on the requirements of both § 52.98 and § 50.59 when addressing the relationship to the UFSAR. It is important to recognize the unique role the plant specific DCD plays in the safety analysis report and the change control regulations for the plant specific DCD information.

Section 1.3 10 CFR Part 52 Change Process Overview

Page C-7 first paragraph

After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR Part 52 change processes are applied to determine if a license amendment **and/or exemption** is required prior to implementation

NRC Comment:

Tier 1 changes require both a license amendment and an exemption from the design certification rule.

Page C-7 second bullet

EVALUATION: Apply the applicable change process evaluation criteria to determine if a license amendment **and/or exemption** must be obtained from the NRC.

NRC Comment:

Tier 1 changes require both a license amendment and an exemption from the design certification rule.

Page C-9 Figure 1

NRC Comment:

Add logic bi-stable diamond for evaluation of aircraft impact features under 10 CFR 50.150.

Section 1.4.1 Departures from Design Certification Information

Page C-10 add new paragraph between second and third paragraph

The NRC has a reasonable expectation that vendors and utilities will cooperate with the NRC in assuring that the level of enhanced safety believed to be achieved with the certified designs will be reasonably maintained for their period of operations including renewal. This expectation that industry will cooperate with NRC in maintaining the safety level of the certified designs applies to design changes under section VIII.B.5. (62 FR 25800; 25810; May 12, 1997)

NRC Comment:

Staff believes there is value in restating upfront Commission's high-level expectations regarding the change process for new reactors in general and VIII.B.5 in particular.

Page C-10 last paragraph, first sentence

10 CFR 52.63 also identifies a process for changing a standard design certification by rulemaking, which includes amending the rule **amendments to the rule sought** by the design certification sponsor.

NRC Comment:

Only the NRC can amend a rule.

Section 1.4.3 Early Site Permits

Page C-14 second paragraph

~~Activities on the proposed site that are not construction activities, as defined under 10 CFR 50.10(a)(2), are not restricted by an ESP. Therefore, a COL applicant may make changes to the description of such activities in the SSAR without prior NRC approval, but must identify such changes as part of its FSAR. Additionally, the environmental impact of such activities or site-related changes will need to be evaluated as potential variances or "new and significant information" in the construction permit or combined license application referencing the ESP.~~

NRC Comment:

Delete paragraph as it is not correct. ESP holders must conduct activities in accordance with the ESP and SSAR, and may not change the ESP or the SSAR without a license amendment. (10 CFR 52.39(e)) If the holder of an ESP believes that the ESP/SSAR governs activities not within the definition of construction, it should seek a license amendment.

Page C-14 last paragraph third sentence

~~In other words~~ **For example**, after issuance of the ~~construction permit or~~ COL, changes to the information in the SSAR, as incorporated in the FSAR, are evaluated pursuant to the change control processes in 10 CFR 50.59 or 10 CFR 52.98, as applicable, rather than 10 CFR 52.39.

NRC Comment:

The change control process of 10 CFR 50.59 or 10 CFR 52.98 does not apply to construction permits.

Section 3.2 Accident Previously Evaluation in the FSAR

Page C-18 discussion second paragraph

The term “accident” is distinguished from the term “severe accident”. Severe accidents are events beyond the plant’s design basis **accidents** as that term is defined in 10 CFR 50.2 and Section 3.7 of this appendix.

NRC Comment:

A severe accident is a beyond design basis accident, but severe accident design features are part of a plant’s design basis, as defined in 10 CFR 50.2. (72 FR 49,352, 49,380)

Section 3.3 All Matters Described in the Plant-Specific DCD

Page C-18 definition

The evaluation of a departure must consider more than just the descriptive information contained in the text of the DCD. Thus, “all matters described in the plant-specific DCD” means **includes:**

NRC Comment:

Specification of a list of items does not define or limit the term “all matters” in this context.

Section 3.4 Change/Departure

Page C-19 definition

The definition in Section 3.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~as well as~~ **but is not the definition of** “departure” from a generic **the plant specific** DCD under Section VIII of the design certification rule(s). ~~with the clarifications in italics below.~~

~~Change or departure means a modification or addition to, or removal from, the facility or procedures that affects: (1) a design function or ex-vessel severe accident function; (2) a method of performing or controlling the function; or (3) an evaluation that demonstrates that intended functions will be accomplished.~~

A departure **is a deviation from the DCD**. Specifically, **a departure** refers to a modification or addition to, or removal from, information contained in a referenced standard design certification rule and reflected in a plant specific DCD. **See RG 1.206, C.III.1.6.**

NRC Comment:

Section VIII has its own terms and definitions separate from section 50.59. Departure is defined in the 2007 Part 52 rule to be a “deviation.” Also see RG 1.206, C.III.1.6.

Page C-19 discussion

The discussion in Section 3.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59. ~~or Section VIII of the design certification rule(s) with one addition to the discussion of design functions:~~

~~Ex vessel severe accident functions are SSC functions or design features for the prevention or mitigation of ex vessel severe accidents. As defined in Section 3.8, ex vessel severe accident refers to a postulated accident when the reactor core has melted and exited the reactor vessel and the containment is challenged. An ex vessel severe accident design feature is a feature that has an intended function to resolve ex vessel severe accidents. (72 FR 49394)~~

Consistent with the treatment of changes to an SSAR by an ESP holder (72 FR at 49360), typographical or administrative corrections that are not substantive deviations from the Tier 2 information are not considered a departure and need not be evaluated through the Section VIII criteria. However, even typographical corrections to Tier 1 and Tier 2* that are sought by a licensee require NRC approval.

NRC Comment:

The 2007 Part 52 Rule and RG 1.206, C.III.1.6 defines a departure as a “deviation.” The NRC did not adopt section 50.59 definitions and limitations wholesale in the 2007 rule revising Part 52. (2007 Part 52 Rule SOC, 72 FR at 49394, Pages 10-11 of Comment Summary Report for the rule).

Section 3.5 Current Licensing Basis

Page C-21 discussion, first paragraph, first full sentence

If the COL application references a certified design, the referenced generic DCD, including any ~~documents specifically incorporated by~~ secondary references in the DCD, will also include design basis information.

NRC Comment:

“Secondary references in the DCD” is more comprehensive than “documents specifically incorporated by reference.” The proper scope of the discussion on external documents assists the accurate retention of important data, upon which the NRC based its licensing decision.

Section 3.9 Facility as Described in the FSAR (as updated)

Page C-23 definition

The definition in Section 3.6 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~or Section VIII of the design certification rule.~~

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NRC Comment:

“The facility as described in the FSAR (as updated)” is terminology relevant to section 50.59 and does not appear in Section VIII of the appendices to Part 52. Therefore, it is not relevant to whether a departure is evaluated under Section VIII, which applies to plant specific DCDs.

Page C-23 discussion

The discussion in Section 3.6 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or ~~Section VIII of the design certification rule(s) with the clarification that~~ **The focus of Section VIII of the design certification rule(s) is the changes or departures from** the information presented in the FSAR to satisfy the requirements of 10 CFR 52.79**47** for Part 52 licensees ~~rather than 10 CFR 50.34(b) for Part 50 licensees.~~

NRC Comment:

Section VIII of the design certification rule(s) addresses changes or departures to the plant-specific DCD. For Part 52, a departure is defined as a “deviation” from the design certification document.

Section 3.10 Final Safety Analysis Report (as updated)

Page C-23 definition, second paragraph

Final Safety Analysis Report (as updated) means the Final Safety Analysis Report (including the plant-specific Design Control Document (DCD)) submitted in accordance with 10 CFR 52.79 , as amended and supplemented, and as updated per requirements of Section ~~X.B~~ **X.A** of the applicable Part 52 design certification appendix, 10 CFR 52.3 and 10 CFR 50.71(e).

NRC Comment:

Section X.B refers to the reporting requirements, but there may be changes in-between the reporting periods of Section X.B.3 that should be considered. Section X.A requires the plant-specific DCD to be updated as the licensee proceeds.

Section 3.17 Procedures as Described in the FSAR (as updated)

Page C-27 definition

The definition in Section 3.11 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or ~~Section VIII of the design certification rule(s).~~

NRC Comment:

“Procedures as described in the FSAR (as updated)” is terminology relevant to section 50.59 and does not appear in Section VIII of the appendices to Part 52. Therefore, it is not relevant to whether a departure is evaluated under Section VIII, which applies to plant specific DCDs.

Section 3.19 Screening

Page C-28 definition

The definition in Section 3.13 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~or Section VIII of the design certification rule(s).~~

NRC Comment:

This does not apply to Section VIII of the design certification rule(s) because it imports the § 50.59 definitions/limitations that were not carried forward into Section VIII of the design certification rule(s).

Page C-28 discussion

The discussion in Section 3.13 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~or Section VIII of the design certification rule(s).~~

Further discussion and guidance on screening are provided in Section 4.2 of the main body of NEI 96-07, Revision 1, (for plant-specific FSAR changes) with any unique aspects of VIII.B.5 screening **evaluation** described in Section 4.4.2.1 of this appendix (for departures from design certification information).

NRC Comment:

Section VIII.B.5.a requires an evaluation. "...When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD..."

Section 3.21 Test or Experiments Not Described in the FSAR (as updated)

Page C-29 definition

The definition in Section 3.14 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~or Section VIII of the design certification rule(s).~~

NRC Comment:

"Tests or experiments not described in the FSAR (as updated)" is terminology relevant to section 50.59 and does not appear in Section VIII of the appendices to Part 52. Therefore, it is not relevant to whether a departure is evaluated under Section VIII, which applies to plant specific DCDs.

Page C-29 discussion

The discussion in Section 3.14 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 ~~or Section VIII of the design certification rule(s).~~

Section 3.22 Tier 1 Information

Page C-30 discussion

Changes to and departures from Tier 1 information are addressed in Section VIII.A of the design certification rule appendices. Generic changes to Tier 1 information are governed by 10 CFR 52.63(a)(1). Plant-specific departures proposed by an applicant or licensee require exemptions, which are governed by the requirement in ~~10 CFR 52.63(b)(1) and 52.98(f)~~ **Section VIII.A.4.**

NRC Comment:

The design certification rule(s) Section VIII.A.4 includes 10 CFR 52.63(b)(1) and 52.98(f) and one additional criterion, ...” the Commission will deny a request for an exemption from Tier 1 if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.” The discussion should include all of the applicable criteria.

Section 4.2.4 Safety Security Interface

Page C-35 **[Move this section to a more appropriate location.]**

NRC Comment:

The Safety Security Interface, 10 CFR 73.58, does not cleanly fall under this topic area covering more specific change processes. The SSI is an assessment and management of potential adverse effects on safety and security, including the site emergency plan, before implementing changes to plant configurations, facility conditions or security. It does not replace required change processes.