August 31, 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 amended sections, *Section 4.1.1, Construction Change Applicability* (ADAMS Accession No. ML12213A318, dated July 17, 2012) 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, dated November 30, 2011). 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, and are in addition to comments previously communicated to you by letter dated March 20, 2012 (ADAMS Accession No. ML120800072).

We will discuss the staff comments on NEI 96-07, Appendix C, Revision 0C at a meeting to be held on September 6, 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.

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

Sincerely,

/RA/

Amy E. Cubbage, 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

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

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ADAMS Accession No.: ML12200A375 ***via email** **NRO-001**

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

Section 1.2.3 Relationship to the UFSAR

Page C-6 last sentence
~~Guidance for updating FSARs is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1. After the COL is issued, licensees may also apply this guidance to the plant-specific DCD information.~~

NRC Comment:
NEI 98-03, Revision 1 does not recognize the unique role the plant-specific design certification documentation plays in the Part 52 COL final safety analysis report, as updated. 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

NOTE: Comments in addition to the Comments provided to NEI on May 20th

Page C-7 first paragraph

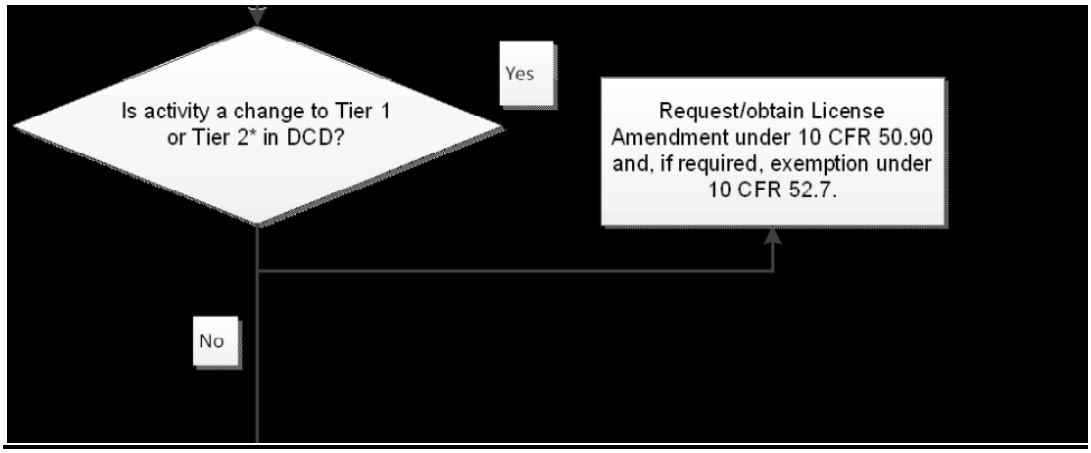
After determining that a proposed activity is safe and effective through appropriate engineering and technical evaluations, the 10 CFR Part 52 change processes are applied to determine if a license amendment and/or exemption is required prior to ~~implementation~~ changing the current licensing basis (CLB). This process involves the following basic steps as depicted in Figure 1:

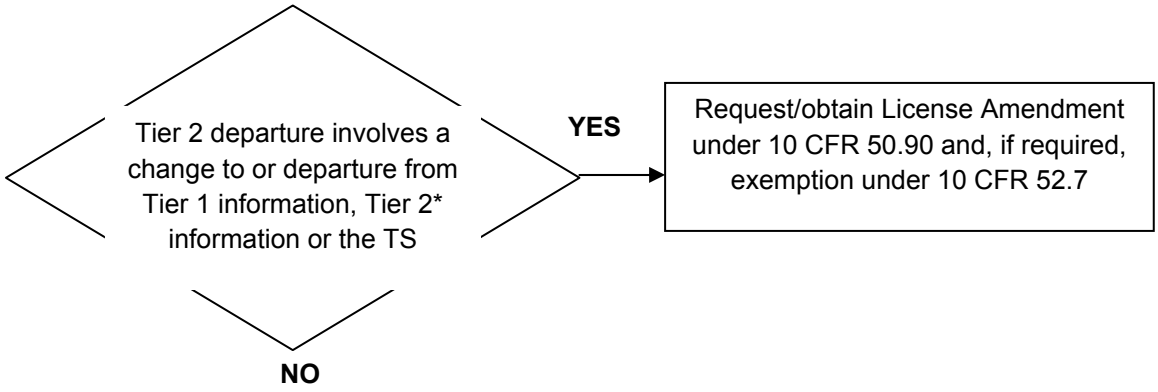
- **Applicability and Screening:** Determine which change process applies and if an evaluation is required.
- **Evaluation:** Apply the applicable change process evaluation criteria to determine if a license amendment or exemption must be obtained from the NRC.
- **Documentation and reporting:** Document and report to the NRC changes and departures implemented under change processes in accordance with NRC requirements.

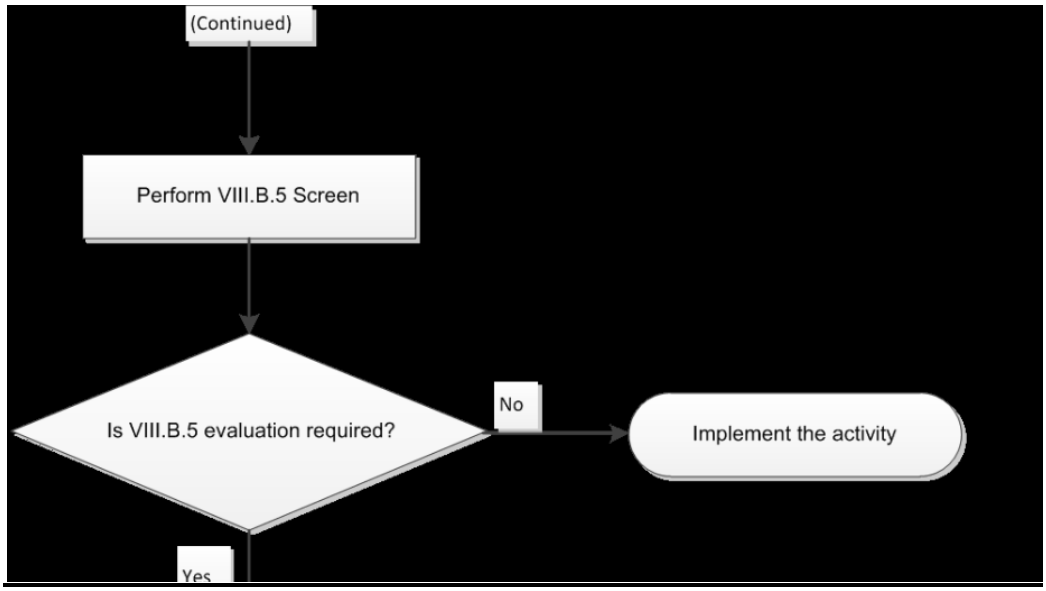
NRC Comment:
Tier 1 changes require both a license amendment and an exemption from the design certification rule.
Additional discussion is required on the definition of the term “implemented” as used in Section 1.3 and Section 4.7.1. The term “implemented” has different connotations during the construction and the operational phases when constructing or placing a plant change or modification into service.

Figure 1 10 CFR Part 52 Change Process

Page C-8 and C-9







NRC Comment:
Add logic decision bi-stable diamond for evaluation of Tier 2 departure impact on Tier 1 and/or Tier 2* information. A Tier 2 departure that involves a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications requires a license amendment and the Tier 1 departure also requires an exemption from the design certification rule. (Section VIII.A.4, Section VIII.B.5.a, and Section VIII.B.6)

Figure 1 10 CFR Part 52 Change Process

Page C-8 third decision block text

Is the activity related to site-specific FSAR information not within the scope of the ~~referenced~~ plant-specific DCD?

NRC Comment:
Following issuance of the COL, the FSAR contains the plant-specific design certification documentation. This plant-specific DCD information was derived from the referenced DCD. 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 1.4.1.1 Generic Technical Specifications and Other Operational Requirements

Page C-11
Changes requested by a COL applicant to generic Technical specifications and other operational requirements fall under the requirements of Section VIII.C of the referenced design certification rule.

NRC Comment:
An applicant cannot make changes to the generic T/Ss or operational requirements. Only the NRC can make changes to the generic T/Ss or operational requirements.

Section 1.4.2.1 COL UFSAR Changes Subject to 10 CFR 50.59

Page C-13 second paragraph
Rather than having two separate change processes (one applicable to site-specific UFSAR information and one applicable to the plant specific DCD), the licensees may elect to utilize an integrated change control process. Licensees electing to utilize an integrated change control process will apply the change control processes in Section VIII of the design certification rule to the entire UFSAR (rather than just the plant-specific DCD), recognizing the differences in the scope between the 50.59 evaluation and the Section VIII evaluation. The results of such an integrated approach should be equivalent to the results of implementing two separate change processes. 10 CFR 50.59 criteria governing changes to the site-specific information in the UFSAR are equivalent to the Tier 2 VIII.B.5.b criteria of Section VIII. As a result, application of the Section VIII.B.5.b change control process to the site-specific information in the UFSAR is substantively equivalent to application of 10 CFR 50.59.

NRC Comment:
While the eight criteria are essentially the same, the scope of information to which the criteria apply is different between 50.59 and Section VIII.

Section 3.1 VIII.B.5 Evaluation

Page C-17-18 Discussion, Add new paragraphs before the current third paragraph

Unique aspects of the VIII.B.5 screening and evaluation criteria are described in Section 4.4.2 of this appendix.

Tier 2 departures that involve a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications require a license amendment under Section VIII.B.5.a. Tier 1 departures also require an exemption from the design certification rule.

For Tier 2* departures from the plant-specific design certification information, a license amendment is required under Section VIII.B.6.

For Tier 2 design certification information, Section VIII.B.5.b contains criteria that are similar to 10 CFR 50.59. Thus, the Section VIII.B.5.b process also includes screening, evaluation, documentation, and reporting with unique aspects of the VIII.B.5.b process described in Section 5 of this appendix.

NRC Comment:
A Tier 2 departure that involves a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications requires require a license amendment and the Tier 1 departure also requires an exemption from the design certification rule. (Section VIII.A.4, Section VIII.B.5.a, and Section VIII.B.6
A Tier 2* departure requires a license amendment request by a COL licensee, for (1) the design parameters in Section VIII.B.6.b, and (2) the parameters in Section VIII.B.6.c until the plant first achieves full power, after which the Section VIII.B.6.c parameters revert to Tier 2 information.

Section 3.2 Accident Previously Evaluation in the FSAR

Page C-18 discussion second paragraph
NOTE: Prior submission to NEI contained requested changes up to the phrase design basis accidents.
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~~ in which substantial damage is done to the reactor core, whether or not there are serious offsite consequences, as defined in the "Commission Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138, dated August 8, 1985).

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-19 Discussion
Section VIII.B.5.a of a design certification rule specifies that an applicant or licensee who references the appendix to Part 52 that contains the rule may depart from Tier 2 information without prior NRC approval, unless the proposed departure involves ~~certain conditions requiring an exemption and /or a license amendment~~ a change to, or departure from Tier 1 information, Tier 2* information, or the Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII. The second sentence of this section specifies that, when evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

NRC Comment:
A Tier 2 departure that involves a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications or triggers one of the criteria in either the paragraphs B.5.b or B.5.c evaluation, requires a license amendment and the Tier 1 departure also requires an exemption from the design certification rule. (Section VIII.A.4, Section VIII.B.5.a, and Section VIII.B.6)

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

Page C-27 Discussion:

The discussion 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) with the clarification that the focus in the information presented in the FSAR to satisfy the requirements of 10 CFR 52.79 for Part 52 licensees rather than 10 CFR 50.34(b) for Part 50 licensees~~.

Construction and pre-operational procedures are not “procedures” as defined in Section 3.11 of the main body of NEI 96-07, Revision 1, and thus are not subject to control under the 10 CFR 52.98 change processes.

NRC Comment:
The definition of “procedures” is only relevant to 50.59 evaluations and not to the Section VIII departure process in the DCRs.

Section 4.1 Applicability

Page C-33 Existing Applicability Guidance in NEI 96-07, Revision 1, bulleted list, fourth bullet

- changes to technical specifications
- precedence of other more specific change processes
- maintenance activities
- ~~UFSAR modifications~~
- Changes to procedures governing the conduct of operations

NRC Comment:
NEI 96-07 Revision 1 Section 4.1 states, "modifications to the UFSAR that are not the result of activities performed under 10 CFR 50.59 are not subject to control under 10 CFR 50.59. Such modifications include reformatting and simplification of UFSAR information and removal of obsolete or redundant information and excessive detail."
That statement that is not justified for the plant-specific DCD information. The NRC comment regarding use of NEI 98-03 on Section 5.3, page C-81, provides more information on the NRC staff's concerns.

Section 4.1.1 Construction Change Applicability
[INSERT AT PAGE C-33/34 (ML12213A318)]

Page 1 (continues to Page 2) of 4, Last Paragraph

Construction changes/departures that ~~directly~~ affect the CLB
If the change/departure is determined to ~~directly~~ affect the CLB, the licensee should apply the 10 CFR 50.59, Section VIII.~~B.5~~, or other applicable change process in accordance with this appendix to determine if an LAR is required. If the change/departure does not require an LAR, the licensee shall document the screening/evaluation results, ~~may~~ implement the change/departure (i.e., construction may proceed/continue) and ~~should~~ update the UFSAR or other affected CLB documents in accordance with applicable requirements and licensee procedures.

NRC Comment:
More correctly reflect the plant-specific DCD change processes contained within Section VIII.

Page 2 of 4, Third full paragraph

Licensees or the responsible design authority should track individual construction changes via their design configuration control processes to monitor the effect of cumulative impacts and to supplement CLB information when necessary ~~to support NRC inspection activities~~.

NRC Comment:

The accumulation of changes during construction impacts on plant analyses/calculations is necessary to support continued safe construction and subsequent safe operations considerations, as well as NRC inspection activities.

Page 3 of 4, Fourth full paragraph

4.1.1.1 Nonconforming Conditions during Construction

~~During construction, licensees may implement the engineering disposition of nonconformances (repair or use-as-is), provided no irreversible/unrecoverable work is performed, in parallel with a review to determine CLB impact and the need for an LAR. Examples of irreversible/unrecoverable work include covering or blocking SSCs such that they cannot be accessed or inspected, or any activity that would preclude returning the facility to its CLB.~~

During construction, licensees need to determine if the engineering disposition of nonconformances (repair or use-as-is) directly affect the CLB before proceeding with construction on the nonconforming SSC. After the determination is reached and documented through the licensee's screening/evaluation process that no LAR is required, construction may continue on the nonconforming SSC in parallel with the licensee's processes to update the UFSAR or other affected CLB documents in accordance with applicable requirements and licensee procedures.

NRC Comment:

Continued construction is dependent upon the as-built plant correctly reflecting the CLB. Corrections of as-built, emergent, non-conformances with the CLB that are not reworked to reflect the CLB must be evaluated by the licensee's processes and procedures to update the CLB, and obtain prior NRC approval, if required, prior to the construction of the correction (repair or use-as-is).

Page 3 (continues to Page 4) of 4, Last paragraph

There may be circumstances where a correction to the CLB is required due to a discrepancy or administrative error within the CLB. In such cases, ~~construction can continue on the applicable SSC consistent with the pending licensee correction of the CLB~~ the licensee shall apply the 10 CFR 50.59, Section VIII, or other applicable change process to determine if an LAR is required to correct the CLB. If the licensee determines after applying the applicable change process that no LAR is required, then the licensee may proceed with construction according to the corrected

CLB. ~~For CLB corrections that require an LAR, it is not necessary, due to the administrative nature of the LAR, to~~ If an LAR is required, the licensees may request ~~and receive~~ a PAR Notification of No Objection from the NRC ~~before~~ to continue ~~continuing~~ construction consistent with the pending ~~licensee~~ correction of the CLB. The correction of the CLB (e.g.; UFSAR update) should proceed in a timely manner and can include any of the applicable processes for CLB change in accordance with licensee processes and procedures.

NRC Comment:
Before commencing construction in accordance with a change to the CLB, including changes intended to correct the CLB, the appropriate change process must be completed as required.

Section 4.2 Applicability of Other More Specific Change Process

Page C-33
In addition to the change control requirements listed in Section 4.1.1 of the main body of NEI 96-07, Revision 1, the following more recently codified change control requirements also meet the intent of 10 CFR 50.59(c)(4) and may take precedence over 10 CFR 50.59 ~~/VIII.B.5~~ for control of changes to the UFSAR~~ including the plant-specific DCD~~. 10 CFR 50.59(c)(4) does not apply to departures under Section VIII of the design certification rule.

NRC Comment:
There is no provision in Section VIII comparable to 50.59(c)(4); therefore, a change to Tier 2 information is evaluated specifically under the Section VIII criteria, even if another change process might also apply.

Section 4.3.1 Screening of Changes to Plant-Specific Facilities or Procedures Described in the UFSAR

Page C-36
The 10 CFR 50.59 screening process and guidance contained in the main body of NEI 96-07, Revision 1, is applicable to changes to plant-specific facilities or procedures described in the UFSAR. The Section VIII evaluation process is applicable to changes to the plant-specific DCD information.

NRC Comment:
The 50.59 change process is applicable to the changes to the current licensing basis outside of the information contained in the plant-specific DCD.

4.3.2 Evaluation of Changes to Plant-Specific Facilities or Procedures Described in the UFSAR

Page C-36
The 10 CFR 50.59 screening process and guidance contained in the main body of NEI 96-07, Revision 1, is applicable to changes to plant-specific facilities or procedures described in the UFSAR, except as updated as identified in Section 4.4.2.2 of this appendix. The Section VIII evaluation process is applicable to changes to the plant-specific DCD information.

NRC Comment:
The 50.59 change process is applicable to the changes to the current licensing basis outside of the information contained in the plant-specific DCD.

4.3.3 Changes to Plant-Specific ITAAC

Page C-36
In accordance with 10 CFR 52.103(h), after the Commission has made the finding in 52.103(g) that the ~~licensee may operate the facility~~ acceptance criteria in the combined license are met, the completed ITAAC attached to the license do not constitute regulatory requirements either for licensees or for the renewal of the license.

NRC Comment:
The Commission finding in 52.103(g) is that the ITAAC acceptance criteria are met, after which, the licensee may operate the facility, including initial fuel load.

Section 4.4.1 Departures from Tier 1 Information

Page 40-41, discussion on Tier 1 simplified diagrams of systems and structures
Tier 1 includes simplified diagrams of systems and structures whose interpretations are based upon the provisions in Tier 1 of the DCR. These diagrams are intended to represent function arrangements of the systems and structures. Therefore, a COL ~~applicant or~~ holder may make changes from the configuration as depicted on the Tier 1 diagrams, provided that the functions of the systems and structures are not affected, but only in accordance with the provisions in Tier 1 of the DCR that specify the interpretations of the simplified diagrams. In such cases, the Tier 1 diagram would not, itself, be changed – any departure from Tier 1 requires NRC approval. Rather, the configuration could differ from the Tier 1 diagram as provided in the Tier 1 provisions describing the interpretation of simplified diagrams.

NRC Comment:
The physical as-built plant may differ from the simplified diagrams of systems and structures contained in the Tier 1 information in accordance with the provisions for the simplified diagrams as stated in Tier 1 of the DCR. Reconciling the Tier 1 simplified diagrams contained within the UFSAR to conform to the physical as-built plant requires a license amendment and an exemption.

Page 40 second bullet

- ~~A Tier 1 figure depicts a stairwell in the southeast corner of a hallway. In the as-built plant, the stairwell can be located in the northeast corner of the same hallway without the need for a Tier 1 departure, because the change in location does not affect any safety function.~~

NRC Comment:
The stairwell example is not representative of Tier 1 functional drawing change a licensee may make without prior NRC approval. Stairwell location information was relied upon by NRC when making the safety evaluation determination, for example, as an input to determinations on the fire programs and security programs.

Section 4.4.2 Departures from Tier 2 Information

Page C-42, fourth paragraph
Section VIII.B.5 describes the process used to evaluate a proposed departure from Tier 2 information and determine if prior NRC approval is or is not required. Section VIII.B.5.a of a design certification rule specifies that an applicant or licensee who references the appendix to Part 52 that contains the rule may depart from Tier 2 information without prior NRC approval, unless the departure involves a change to, or departure from Tier 1 information, Tier 2* information, or the Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII. The criteria VIII.B.5.b are essentially identical to the criteria in 10 CFR 50.59(c), with two specific differences:

1. Reference is to a "departure from Tier 2 information" rather than "changes to the facility as described in the FSAR (as updated)."
2. Reference is to the "plant-specific DCD" rather than to the "FSAR (as updated)."

NRC Comment:
Departures from Tier 2 information must be evaluated under Section VIII.B.5.a. A Tier 2 departure that involves a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications requires a license amendment and the Tier 1 departure also requires an exemption from the design certification rule. (Section VIII.A.4, Section VIII.B.5.a and Section VIII.B.4)

Section 4.4.2.1 Screening and Simplified Evaluations of Departures from Tier 2 Information

Page C-43, new opening paragraph
Section VIII.B.5.a of a design certification rule specifies that an applicant or licensee who references the appendix to Part 52 that contains the rule may depart from Tier 2 information without prior NRC approval, unless the departure involves a change to, or departure from Tier 1 information, Tier 2* information, or the Technical Specifications, or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII.

NRC Comment:
Departures from Tier 2 information must be evaluated under Section VIII.B.5.a. A Tier 2 departure that involves a change to or departure from Tier 1 information, Tier 2* information or the Technical Specifications or requires a license amendment under paragraphs B.5.b or B.5.c of Section VIII, requires require a license amendment and a Tier 1 departure also requires an exemption from the design certification rule. (Section VIII.A.4, Section VIII.B.5.a and Section VIII.B.6)

Page C-43
The discussion in Section 4.2 of the main body of NEI 96-07, Revision 1, also applies, in modified form, to departures from Tier 2 information, i.e., a licensee may perform a simplified VIII.B.5 evaluation for departures from the plant-specific DCD that is analogous to 10 CFR 50.59 screening for changes to UFSAR information outside the scope of the plant-specific DCD. There are some differences in the structure of DCR Section VIII.B.5 and 10 CFR 50.59. All Tier

2 departures require an evaluation under Section VIII.B.5.b, including departures that would not constitute a change requiring an evaluation under 10 CFR 50.59(c). However, because of the close similarity between the eight evaluation criteria in 10 CFR 50.59(c) and Section VIII.B.5.b, the 10 CFR 50.59 screening process can be used as a simplified evaluation to demonstrate that the eight criteria in Section VIII.B.5.b are not triggered. However, Section VIII.B.5.b evaluations, including simplified evaluations, are subject to the record-keeping and reporting requirements in Section X of the DCRs. Screening under Section VIII.B.5 only applies for matters not constituting a "departure" from Tier 2.

NRC Comment:
The DCRs Section VIII specifically requires an "evaluation" for all departures.

Section 4.4.2.2 Evaluation of Departures from Tier 2 Information That Do not Affect Ex-Vessel Severe Accident Criteria

Page C-43
The discussion in Section 4.3.3 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for evaluation of changes under Section ~~VIII.B.5.b.iii~~ VIII.B.5.b.3 of the design certification rule(s).

NRC Comment:
Correct invalid regulatory reference.

Page C-44 and C-45, example 1 through example 5 inclusive
All of the examples are calculated incorrectly. A way to set up these calculations is as follows:

((limiting value – current calculated value)*0.1) + current calculated value > proposed value

Ex. 1: ((25 – 3)*0.1) + 3 = 5.2, which is greater than 4, therefore, no LAR required
Ex. 2: ((25 – 2.6)*0.1) + 2.6 = 4.84, which is greater than 4.0, therefore, no LAR required
Ex. 3: ((25 – 2.5)*0.1) + 2.5 = 4.75, which is greater than 4.7, therefore, no LAR required
Ex. 4: ((5 – 4)*0.1) + 4 = 4.1, which is less than 4.2, therefore, LAR required
Ex. 5: ((25 – 4)*0.1) + 4 = 6.1, which is less than 5.8, therefore, no LAR required

***NOTE**: this gives a different resultant for example 3*

From Section 4.4.2.2 prior paragraph: An increase in consequence from a proposed activity 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 (10 CFR 52.47 or GDC 19, as applicable); and (2) the dose increase 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.

Section 4.4.2.3 Evaluation of Departures from Tier 2 Information That Do not Affect Ex-Vessel Severe Accident Criteria

Page C-46, footnote 3
Design features that prevent or mitigate containment bypass events are important from an overall severe accident safety perspective. However, these features are not in and of themselves EVSA features and as such may not fall under Section VIII.B.5.c criteria. Depending on the nature of the change, proposed changes to containment bypass features need to be evaluated to other criteria in either Section VIII.B.5.a or Section VIII.B.5.b ~~Section 4.4.3.2~~.

NRC Comment:
In SECY-12-0081, staff identified a potential 'gap' in the Tier 2 change process regarding severe accident features that are not related to ex-vessel severe accident prevention and mitigation features. In the paper, staff made a recommendation to the Commission to address the potential gap. Depending on the outcome of the Commission vote and associated staff requirements memorandum, Section 4.4.2.3 may need to be revised.

Page C-53, last paragraph, second sentence
An applicant or licensee who adds or changes supplemental information in the UFSAR should consider the effect of the changed design feature or functional capability on the original Aircraft Impact Assessment required by 10 CFR 50.150(a). Such additions or changes ~~are~~ may not be specifically governed by either change control requirements in the applicable design certification rule or 10 CFR 50.150 since supplemental information ~~is~~ may not be ~~defined as~~ a departure. However, ~~the regulatory intent is that the same criteria should apply~~"supplemental information" affecting the design or functional capabilities of SSCs as described in Tier 2 would be a departure that is governed by Section VIII.

NRC Comment:
When "supplemental information" affects the design or functional capabilities of SSCs as described in Tier 2, this would be a departure that is governed by Section VIII.

Page C-54, Example Screening Question, first sentence
Does the proposed change affect the design features or functional capabilities that are identified in or referenced by the summary description of the Aircraft Impact Assessment in FSAR Chapter 19 (10 CFR 50.150(a)(1))?

NRC Comment:
AIA design features and functional capabilities may also be referenced within Chapter 19 of the UFSAR.

Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information

Page C-55, Sixth paragraph
[As discussed in more detail below, the PRA information in the UFSAR is not subject to the change processes in Section VIII of the design certification rule or 10 CFR 50.59.]

Page C-55, (continues to next page) last paragraph
[As discussed by the NRC in meeting with the industry on July 19 and August 8-9, 2007, changes to the description and results of the PRA as provided in Chapter 19 of Tier 2 of the DCD are not subject to the change control processes contained in Section VIII of the design certification rule. Similarly, changes to the description and results of the PRA as provided in Chapter 19 of the UFSAR that do not involve changes to other Tier 2 information are not subject to the change control process contained in 10 CFR 50.59. Instead, changes to the PRA information are governed by the processes discussed below:]

NRC Comment:
These statements require further discussion.
While the Section VIII change process does not apply to the PRA itself, the Section VIII change process does apply to the summary of the PRA and its results that was included in the DCD. This is established as follows: (1) Tier 2 is defined in Section II of the DCRs to include, among other things, the information required by 10 CFR 52.47(a); and (2) the PRA summary is required by 10 CFR 52.47(a). Therefore, any departure from this PRA summary is subject to the Tier 2 change process. However, 10 CFR 50.71(h) contains updating and maintenance requirements for PRAs and the initial 50.71(h) PRA must be developed prior to the initial fuel load. Changes in accordance with 10 CFR 50.71(h) are not considered departures as these activities are specifically directed by rule. Therefore, the development of the PRA under 10 CFR 50.71(h)(1) and the maintenance and upgrade of this PRA throughout the life of the plant are not subject to the Section VIII change process.

Page C-56, Changes to the PRA Information in Chapter 19 of Tier 2 of the DCD by a COL Applicant, third bullet

~~Interim Staff guidance DC/COL-ISG-03, "Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications"~~

NRC Comment:
This information will be incorporated into SRP 19.0 and does not need to be identified separately. (See additional comment below)

Page C-56, Changes to the PRA Information in Chapter 19 of Tier 2 of the DCD by a COL Applicant, last bullet
~~Slide presentations at NRC meeting on August 8, 2007 (ADAMS # ML072840296), "Refined Guidance on PRA Information to Support Design Certification and Combined License Applications"~~

NRC Comment:
Slide presentations at public meetings are not guidance documents.

Page C-56, Changes to the PRA Information in Chapter 19 of Tier 2 of the DCD by a COL Applicant, last full paragraph

Suffice it to state, a COL applicant does not need to update the PRA information in the DCD to account for relatively minor changes per staff review guidance. ~~Instead, COL applicants should provide the following information as described in ISG-03.~~

NRC Comment:
This information will be incorporated into SRP 19.0 and does not need to be identified separately.

Page C-57, Changes to the PRA Information in Chapter 19 of the FSAR by a COL Holder, last sentence on the page (continuing onto page C-58)
During construction, a licensee is not required to maintain the PRA provided in the COL application, except as necessary to support other programs (e.g., reliability assurance program) due to significant design changes during construction and provide updates to the FSAR in accordance with 10 CFR 50.71(e). ~~due to the large number of changes to the PRA that are expected during construction as the detailed design is finalized and equipment is procured.~~
NRC Comment:
Design changes during construction may impact the PRA information in Chapter 19 that is used for other programs as noted above. Therefore, these design changes should be reviewed to determine their impact on the PRA information or other programs and resulting updates to the FSAR should be considered.

Page C-59, Changes to the PRA Information in Chapter 19 of the FSAR by a COL Holder, first full paragraph following bulleted list
A licensee is not required to seek NRC approval for changes to the PRA information in Chapter 19. As a result, a licensee does not need to perform screening or prepare an evaluation per 10 CFR 50.59 or Section VIII.B.5 of the design certification rules for changes in the PRA information in Chapter 19. COL holders may find value in using the PRA information in assessing the risk impact of plant changes and performing 10 CFR 50.59 or Section VIII.B.5 evaluations. For example, PRA information may be used to quantitatively address increase in the frequency of occurrence of an accident previously evaluated or the likelihood of a malfunction of a structure, system, or component important to safety.

NRC Comment:
NRC believes that the potential use of PRA information as a tool in evaluating plant changes in general could be highlighted more. As discussed in NEI 96-07 Appendix C, plants licensed under Part 52 need to maintain and upgrade the PRA, and periodically update the FSAR to account for the latest PRA information. Such information can be useful in addressing some 50.59 and Section VIII evaluation questions for plant changes. This philosophy may require revisions to other sections of NEI 96-07.

Note that the statements in the first two sentences regarding evaluation of changes to the PRA summary in the UFSAR are subject to further discussion per the comment above on page C-55.

Page 59, Changes to the PRA Information in Chapter 19 of the FSAR by a COL Holder
Second paragraph following bulleted list, second to last sentence
Similarly, changes to Tier 2 of the plant specific DCD that result in ~~significant~~ substantial increases in the probability or consequences of design basis accidents or ex-vessel severe accidents would require NRC approval per Section VIII.B.5 of the design certification rules.

NRC Comment:
"Significant" should be replaced by "substantial" to agree with rule language for ex-vessel severe accidents.

Page C-59, Examples 1) Changes during Construction
1) Changes during Construction - - Early during construction, the licensee decides to make a number of plant modifications to enable it eventually to request a power uprate. The modifications affect a number of chapters of the FSAR, including the PRA information in Chapter 19. The licensee:

- may defer any changes to the PRA information in Chapter 19 pending the PRA upgrade required by 10 CFR 50.71(h)~~(1)~~, unless they are significant; and

must review the modification in accordance with the change processes described in Sections 4.1 and 4.2 and update the FSAR, as necessary, ~~(except for the PRA information)~~ at the next regulatory scheduled interval

NRC Comment:
Design changes during construction may impact the PRA information in Chapter 19 that is used for other programs (e.g., reliability assurance program). Therefore, these design changes should be reviewed to determine their impact on the PRA information or other programs and resulting updates to the FSAR should be considered.

Section 4.4.3.2 Changes to Other Severe Accident Information

Page C-62, Example, first bullet
~~Does not need~~ Needs to assess the change against the criteria in Section VIII.B.5.c of the design certification rule, because the ADS is ~~not used to mitigate ex-vessel severe accidents~~ used to eliminate (i.e., make not credible) a particular ex-vessel severe accident (direct containment heating (DCH));

NRC Comment:
The assessment in the example is partially true, however, additional discussion can be found in Section 19K.4 of the ABWR DCD:

> "The ADS depressurizes the RPV so that the low pressure systems can inject water. Even if no water injection is available, the depressurization via one safety/relief valve (SRV) eliminates the potential for direct containment heating in event of RPV failure."

The ADS thus contributes to DCH being an ex-vessel severe accident previously reviewed and determined to be not credible.
This aspect of the location of information on ex-vessel is forewarned on page C-22 of NEI 96-07 Appendix C that states:

> "Thus, the location of the ex-vessel severe accident design information in the DCD is not important and all ex-vessel severe accident design information in the DCD is subject to the application of this special departure process in Section VIII.B.5.c of the design certification rule. (74 FR 49394)"

Hence, one would need to evaluate the change in the example per VIII.B.5.c for the impact on probability of ex-vessel severe accident previously reviewed and determined not credible.

Section 4.6 Changes to Early Site Permits

Page C-64, entire section
As described in 10 CFR 52.39(e), the holder of an early site permit may not make changes to the ESP, including the Site Safety Analysis Report (SSAR), without prior Commission approval. ~~To determine whether a proposed activity is considered a "change" to the ESP or SSAR, the activity is screened based on the criteria in Section 4.6.1.~~

NRC Comment:
There is no change process or change screening process for ESP and SSAR. The ESP itself is a license and any change of any kind to it requires a license amendment. The Commission explicitly disapproved of a change process for ESPs or SSARs, requiring that a license amendment be submitted for any change, 2007 Part 52 Rule, 72 FR at 49360-61. The only exception the Commission made is for "typographical and administrative corrections."

72 FR 49360. A typographic or administrative correction cannot be used to make substantive changes, but only corrections where it is clear what the intended meaning is and the correction is consistent with the original intent. Also see, LWA Rule SOC, 72 FR at 57422

Section 4.6.1 Screening of Proposed ESP Changes

Page C-65, entire section
Delete entire section 4.6.1 Screening of Proposed ESP Changes

NRC Comment:
There is no change process or change screening process for ESP and SSAR, Section 4.6.1 should be deleted in its entirety. A reference to the typographical and administrative correction language in the 2007 Part 52 rule SOC could be added.

Section 4.6.2 Changes Related to an ESP after Issuance of a COL

Page C-66 Section Title
Renumber to Section 4.6.1

Page C-66, first paragraph, second to last sentence
Thus, after issuance of the COL, the change process in 10 CFR 52.39 no longer applies, and instead changes are controlled by 10 CFR ~~50.59~~ 52.98.

NRC Comment:
10 CFR 50.59 only pertains to the site-specific portion of the UFSAR, but 10 CFR 52.98 covers all the changes to the UFSAR, both to the plant-specific DCD and site-specific information.

Section 4.7.1 Evaluations performed during construction (before the 10 CFR 52.103(g) finding)

Page C-66

Because SSCs are not considered "in service" during construction, and technical specifications are not in effect until after the 10 CFR 52.103(g) ITAAC finding, additional criteria are needed for determining when a change is "implemented" during the construction phase. During the construction phase, a change is considered "implemented" when ~~an ITAAC closure letter for the affected SSC is submitted under 10 CFR 52.99 (e.g., after the change is installed and tested), or otherwise credited in the licensing basis of the plant (e.g., described in an update to the FSAR).~~ the change is credited in the current licensing basis of the plant. The change is credited in the current licensing basis of the plant when (1) the licensee determines that no prior NRC approval is required or (2) the LAR/exemption is approved by the NRC.

~~This means that~~ NRC approval of ITAAC-related LARs/exemption requests is required before the ITAAC closure ~~letters~~ notifications (ICNs) for affected ITAAC are submitted ~~and before changes are reflected in required annual updates to the FSAR~~.

~~Changes to technical specifications and certain other LARs might not involve ITAAC. LARs that do not involve ITAAC would need to be approved before associated technical specifications (if any) become applicable.~~

LARs required for changes to operational programs ~~not subject to ITAAC or technical specifications~~ must be approved before the affected program element is required to be implemented. Implementation requirements for required operational programs are specified in NRC regulations, the FSAR and/or ~~the FSAR~~ license conditions.

~~Some SSCs are required to be placed in service prior to the 10 CFR 52.103(g) finding to comply with requirements other than Technical Specifications such as; security, fire protection, radiation protection and emergency planning requirements. NRC approval of LARs/exemption requests associated with such SSCs is required prior to when the SSC is needed to perform its intended function to comply with the applicable requirement.~~

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

- Ensure the NRC is informed and can plan for submittal of PARs/LARs/Exemption requests and changes to fabrication/construction activities or schedules
- Facilitate preparation of PARs/LARs/Exemption requests that are complete in terms of administrative requirements and technical basis
- Identify potential challenges to timely NRC ~~approval~~ consideration of PARs/LARs/Exemption requests
- ~~Determine if the licensee needs to request a Preliminary Acceptability Review (PAR)~~

Frequent and early communication between the licensee and NRC staff can help avoid

unnecessary delays in NRC's processing of license-related requests.

When an LAR is accompanied by an exemption request, the LAR and exemption request ~~are~~ can be reviewed and dispositioned by the NRC ~~in~~ simultaneously. ~~Licensee LARs should identify impacts of the change on installation and testing schedules for affected SSCs and the date by which an NRC decision is needed to support construction, ITAAC closure, or other actions.~~

~~Many LARs for changes during construction are expected to stem from changes to the standard designs for first-of-kind units. Approved LARs applicable to follow-on units of the same design may be referenced in subsequent COL applications. To facilitate NRC review and approval, subsequent applicants should address the applicability of the prior LAR approval to their plant specific circumstances. If timing does not permit reference in subsequent COLAs, approved LARs may be referenced in corresponding LARs during construction for subsequent units, and those licensees may use the Preliminary Acceptability Review process described in the following section as needed.~~

NRC Comment:
This discussion of the evaluations of changes performed during the construction phase of the COL is controlled by the regulations at Section VIII of the DCRs.
Additional discussion is required on the definition of the term "implemented" as used in Section 1.3 and Section 4.7.1. The term "implemented" has different connotations during the construction and the operational phases when constructing or placing a plant change or modification into service.

Page C-68, last sentence
~~These license conditions will expire upon the NRC's 10 CFR 52.103(g) finding.~~

NRC Comment:
Each license condition has its own characteristics as stated in the license.

Section 4.7.1.1 Preliminary ~~Acceptability Review for Inspectability~~ Amendment Request ~~for "At Risk" Construction~~

Page C-68, first paragraph
To maintain schedules, licensees may ~~need~~ elect to use the Preliminary Amendment Request (PAR) process, ISG-025. ~~proceed with installation and testing of changes pending a final NRC decision on a required LAR/exemption request.~~ If a Licensee elects to submit a PAR, it must be submitted prior to ~~Before~~ proceeding with installation and/or testing of any change ~~during construction~~ that requires NRC approval ~~of an LAR, Part 52 licensees should notify the NRC and request a Preliminary Acceptability Review (PAR)~~.

Page C-69, second bullet
~~2. Briefly identify applicable precedents, in any, discussed in the associated LAR to maximize staff efficiency, minimize requests for additional information and promote consistency of licensing actions. Guidance for identifying applicable precedents is provided in NEI 06-02, *License Amendment Requests Guidelines,* Revision 2.~~

Renumber remaining numbered list items 3 through 7

NRC Comment:
This discussion on precedents was removed from the Draft for Use ISG-025.

Page C-69, third bullet
2. Evaluation of the impact of the change on installation and testing schedules for affected SSCs. PAR requests should identify the following types of ~~inspectability~~ impacts resulting from the proposed change:
   - Acceleration or delay in planned installation or test activities
   - Inaccessibility of certain SSCs for NRC inspection following the change

NRC Comment:
Scope of PAR review changed within the Draft for Use ISG-025.

Page C-70, bullet 7 and following paragraph
7. Preliminary assessment of whether or not the proposed change qualifies for exclusion from environmental review under 10 CFR 51.22. The complete technical bases for the licensee's determination regarding environmental exclusion should be provided in the LAR.

In the event the licensee's preliminary assessment is that the proposed change does not qualify for categorical exclusion from environmental review, the NRC's response to such a PAR request may limit the licensee's work under a PAR, pending completion of the environmental review, to that which does not involve environment impact, or work that does not result in irreversible

environmental impact. In order to respond to such PAR requests, the licensee should provide additional information regarding the extent of work that may be performed without irreversible environmental impact. A PAR request is subject to the National Environmental Policy Act (NEPA) and the NRC implementing regulations at 10 CFR Part 51. Before submitting a PAR, the licensee shall review the change versus the requirements at 10 CFR 51.22, 10 CFR 50.54(aa) and the conditions in the environmental protection plan. The NRC staff must determine whether the PAR qualifies for a categorical exclusion in accordance with 10 CFR 51.22 before any action is taken. If the change does not qualify for a categorical exclusion, then the NRC staff must perform an environmental assessment or an environmental impact statement prior to approving the PAR, and prior to the work involving environmental impacts being performed. Most proposed changes during construction are expected to qualify for categorical exclusion such that changes that do not qualify are expected to be rare.

NRC Comment:
A PAR request is subject to the National Environmental Policy Act (NEPA) and the NRC implementing regulations at 10 CFR 51. Therefore, the NRC staff must determine if the PAR qualifies for a categorical exclusion in accordance with 10 CFR 51.22, or if it does not qualify for a categorical exclusion then perform an environmental assessment (EA) or an environmental impact statement (EIS) prior to approving the PAR.

The licensee should evaluate the PAR against the license condition specified in 10 CFR 50.54(aa) “The license shall be subject to all conditions deemed imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A 1341 (a)(2) and (d).)”

Page C-74 Preliminary ~~Acceptability Review~~ Amendment Request (PAR) ~~Request~~ Template

NRC Comment:
Revise template to reflect the current Draft for Use ISG-025

Section 4.7.2 Evaluations performed after the 10 CFR 52.103(g) ITAAC finding
Page C-77, first paragraph, last sentence
For a Tier 1 departure or change, the license amendment request must demonstrate that there is no significant decrease in the level of safety provided by the certified design and must be accompanied by a request for an exemption from the referenced design certification, as discussed in Section 4.4.1.

NRC Comment:
Recognition of the requirements of Section VIII.A.4 that 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.

Section 4.7.3 LARs for Conforming Changes – Conforming LARs

Page C-77-78, entire section
Delete entire section

NRC Comment:
Part 52 change process Section VIII contains the available change processes for the plant-specific design certification information.

Section 5.3 Records and Reporting for Changes subject to a Design Certification Rule

Page C-80, Documenting Change Process Evaluations, second paragraph
Additionally, the written evaluation should address the ex-vessel change process criteria in Section VIII.B.5.c and the aircraft impact assessment change process criteria in 10 CFR 50.150(c) and Section VIII.B.5.d when applicable

NRC Comment:
Inclusion of the aircraft impact assessment change control process criteria for the records and reporting guidance

Page C-81, Reporting to NRC, last paragraph
~~As discussed in Section 1.2.3 of this appendix, licensees may apply the UFSAR update guidance in NEI 98-03, Revision 1 to the plant-specific DCD. Such modifications should be reported to NRC in accordance with NEI 98-03, Revision 1~~.

NRC Comment:
NEI 98-03, is not an acceptable guidance for 10 CFR Part 52 licensees.
Reference to NEI 98-03 contained in Sections 1.2.3 and 5.3
NEI 98-03 is "stale" with respect to applicability to COLs. NEI 98-03 is "stale' in the sense that there is no recognition of the unique or distinct composition of FSARs for facilities licensed under Part 52 vs. those licensed under Part 50. FSARs for Part 52 licensees include both plant-specific DCD information and site-specific information. NEI 98-03 was written for Part 50 plants and addressed several needs for licensees, for example: the need to establish a mechanism for removing unnecessary information from the FSAR (i.e., obsolete, redundant, historical, construction information, etc.); the need to remove excessive detail from the FSAR, and; the need to replace detailed drawings with simplified schematics. FSARs had grown in complexity and level of detail from the late 1960's through the 1990's where, for example, plants like Turkey Point, licensed in the 1960's have a 5-volume FSAR whereas plants like Palo Verde, licensed in the late 1980's, has about 25 volumes. The reasons behind these needs arose partly due to the perception that there were an excessive number of 50.59 evaluations being performed because of the amount of information and the level of detail contained within these FSARs. The guidance in NEI 98-03 relative to FSAR updates may be appropriate for the site-specific information in FSARs for Part 52 licensees but the guidance is not appropriate for the plant-specific DCD information in these FSARs. By deliberately including different changes process for Part 52 plants (i.e., Section VIII for COLs referencing DCDs vs. 50.59) the NRC sought to achieve a higher level of control of the design information associated with certified standard designs in order to preserve standardization. This level of control carries forward to the updating of information in the FSAR and the guidance in NEI 98-03 does not reflect this unique

type of design control treatment. In addition, Appendix B of NEI 98-03 appears to be out of date because it appears to reference proposed changes to the 10 CFR 50.71(e) that have already been incorporated but does not reflect any regulatory changes associated with updating FSARs for combined license applications submitted under Part 52 or for plants licensed under Part 52. Appendix B of NEI 98-03 could be deleted at this time.