

**Industry Responses to December 5, 2013 NRC Comments on NEI 96-07, Appendix C, Revision 0D – 1/29/2014**

	<b>December 5, 2013 NRC Comments</b>	<b>Staff Comment</b>	<b>Industry Response</b>
1	<p><b><u>Section 1.1 Purpose and Scope</u></b></p> <p><u>Page C-1, second paragraph</u></p> <p>The main body of NEI 96-07, Revision 1, was written to provide guidance for developing effective and consistent processes for implementing 10 CFR 50.59. This appendix was developed by starting with the NEI 96-07, Revision 1, guidance and providing additional guidance / clarification only as needed to ensure that <del>applicant-and</del> licensee-initiated changes and departures are properly controlled, documented, and reported to the NRC in accordance with the Part 52 requirements.</p> <p><del>To encompass all of the change processes that may be needed by a Part 52 COL applicant, this</del> <b>This</b> appendix also provides guidance for changes to early site permits (ESPs), per 10 CFR 52.39(e).</p> <p>In general, this appendix has been written for <del>applicants and</del> holders of combined licenses (COLs).</p>	<p>Delete reference to applicant because all aspects specifically applicable to applicants are not adequately covered.</p>	<p>Comment accepted.</p>
2	<p><b><u>Section 1.2.3 Relationship to the UFSAR</u></b></p> <p><u>Page C-3</u></p> <p><i>New plant change processes identified in 10 CFR 52.98 are the processes that identify when a license amendment is required prior to implementing <del>departures from the plant-specific DCD, other</del> changes to the facility or procedures described in the FSAR (as updated, or UFSAR), or tests 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. Guidance for updating FSARs <b>information outside the scope of the plant-specific DCD</b> is provided by Regulatory Guide 1.181, which endorses NEI 98-03, Revision 1.</i></p>	<p>Replace "FSARs outside" with "FSAR information outside" because the FSAR is not outside the plant-specific DCD. However, there is FSAR information outside the scope of the plant-specific DCD.</p>	<p>Comment accepted.</p>

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3	<p><b><u>Section 1.3 10 CFR Part 52 Change Process Overview</u></b></p> <p><u>Page C-6 Figure 1, 10 CFR Part 52 Change Process, Note at top of page</u></p> <p>Note: For both site-specific FSAR and plant-specific DCD information, other regulations may apply in addition to <del>10 CFR 50.59 and VIII.B.5</del> <b>those discussed here</b>. See Section 4.2</p>	<p>The AIA change process is not discussed here and is also in Section VIII.B.5.</p>	<p>Comment accepted.</p>
4	<p><b><u>Section 1.3 10 CFR Part 52 Change Process Overview</u></b></p> <p><u>Page C-6 Figure 1, 10 CFR Part 52 Change Process</u></p> <p>On the decision diamonds, the YES branch process lines are depicted as emanating from the NO branch</p>	<p>'Yes' branches need to proceed from the YES point of the logical decision diamond.</p>	<p>Comment accepted.</p>
5	<p><b><u>Section 1.3 10 CFR Part 52 Change process Overview, Figure 1 (continued)</u></b></p> <p><u>Page C-7 Figure 1 (Continued) first process block</u></p> <p>Perform VIII.B.5 Screen <b>Simplified Evaluation</b></p>	<p>Consider introducing the concept of the simplified evaluation process within this figure.</p> <p>NOTE: Section 3.19 does equate the VIII.B.5 screen to the VIII.B.5 simplified evaluation.</p>	<p>No change. Sections 3.19 and 4.4.2.1 describe the concept and treatment of VIII.B.5 Screens as VIII.B.5 Simplified Evaluations.</p>
6	<p><b><u>Section 1.3 10 CFR Part 52 Change process Overview, Figure 1 (continued)</u></b></p> <p><u>Page C-6, second decision block, output of the 'No' leg</u></p> <p><b>Document simplified evaluation, implement the activity, and report to the NRC as appropriate.</b></p>	<p>Consistent with the following decision diamond later on the page which, with a negative result, states "Document evaluation, implement activity, and report to NRC as appropriate."</p>	<p>Comment accepted with "screen" in place of "simplified evaluation" per response to Comment 5, above.</p>

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		<p>Section X.A.3 of the design certification rules states that "An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by Section VIII of this appendix. These evaluations must be retained ..."</p> <p>The reporting obligation is governed by Section X.B of the design certification rules.</p>	
7	<p><b><u>Section 3.4 Change/Departure (Plant Specific)</u></b></p> <p><u>Page C-18, Discussion section, third paragraph</u></p> <p><del>Consistent with the treatment of changes to an SSAR by an ESP (72 FR 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.</del></p>	<p>The NRC has given this further consideration, and determined that the policy basis for the ESP exception does not apply to Tier 2 information since there is a change process for Tier 2 information</p> <p>Any change or departure from the plant specific information contained in the UFSAR requires an evaluation. This concept is further described in the following Section 4.4.2.1, second paragraph.</p>	Comment accepted.

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8	<p><b><u>Section 3.14 Methods of Evaluation</u></b></p> <p><u>Page C-24, Discussion section</u></p> <p>The discussion in Section 3.10 of the main body of NEI 96-07, Revision 1, also applies to Part 52 licensees for changes under 10 CFR 50.59 or departures under Section VIII of the design certification rule(s) with the clarification that, with respect to the consequences of accidents, the dose limits for members of the public for Part 52 licensees are found in 10 CFR 52.47(a)(2) and 52.9779(a)(1) rather than 10 CFR 100 for Part 50 licensees.</p>	Correct reference.	Comment accepted.
9	<p><b><u>Section 3.19 Screening</u></b></p> <p><u>Page C-27, Definition</u></p> <p>Screening <del>or simplified evaluation</del> is the process for determining whether a proposed activity requires a 10 CFR 50.59 <del>or Section VIII.B.5</del> evaluation to be performed. <i>Screening may be considered a simplified evaluation for purposes of meeting the requirements of Section VIII.B.5.a.</i></p>	The proposed edit improves the definition because a simplified evaluation is an evaluation under Section VIII.B.5, while the original text implies that it is not.	Comment accepted except that "or Section VIII.B.5" has been retained as indication that the screen/simplified evaluation may result in a need to perform a full VIII.B.5 evaluation.
10	<p><b><u>Section 4.1.1 Construction Change Applicability</u></b></p> <p><u>Page C-33 Construction change activities that do not directly affect the CLB</u></p> <p>This is expected to be the largest category because construction change activities typically affect detailed design information that does not impact the CLB or require an LAR. (Thus, these construction change activities are not changes/departures as defined in Section 3.4.) This includes various emerging unanticipated conditions or conflicts that may require an engineering change, e.g. interferences</p>	The use of the term "directly" may confuse licensees applying the change and departure screening and evaluation processes, by omitting a change or departure that "affects" the CLB.	Comment accepted.

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	(recognized but not yet installed), conflicts with field routing, accumulation of acceptable field tolerances, etc. Licensees should manage these construction changes in accordance with 10 CFR Part 50, Appendix B, and should document the basis for concluding that the construction change does not directly affect the CLB (and thus does not require an LAR). Construction may proceed/continue while this type of change is dispositioned and documented.		
11	<p><b><u>Section 4.1.1 Construction Change Applicability</u></b></p> <p>OK as written Rev 0D</p> <p><u>Page C-33 Construction changes/departures that affect the CLB</u></p> <p>If the change/departure is determined to 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 <del>shall document the screening/evaluation results,</del> may <del>proceed/continue with construction of</del> <b>construct</b> the change/departure <b>(i.e., construction may proceed/continue)</b> and <del>should</del> update the UFSAR or other affected CLB documents in accordance with applicable requirements and licensee procedures.</p>	<p>See NRC Comment #12 August 31, 2012 Page 9</p> <p>A licensee must complete and document the screening or simplified evaluation prior to constructing the change/departure that is determined not to require prior NRC approval.</p>	<p>Comment accepted while maintaining "should" rather than "shall" consistent with NEI practice for guidance documents.</p>
12	<p><b><u>Section 4.1.1 Construction Change Applicability</u></b></p> <p><u>Page C-34, Top of the page first and second paragraph</u> <u>Construction changes/departures that require an LAR</u></p> <p>In particular, <del>construction</del> LARs should provide... ...and other NRC guidance when preparing <del>construction</del> LARs</p> <p>Changes/departures that require a <del>construction</del> LAR may affect...</p>	<p>LAR guidance is not constrained to LARs during the construction phase. LAR guidance is applicable throughout the life of the plant.</p>	<p>Comment accepted.</p>

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	<p align="center">– ALTERNATIVELY –</p> <p>In particular <del>construction</del> LARs <b>during construction</b> should... ...and other NRC guidance when preparing <del>construction</del> LARs <b>during construction</b></p> <p>Changes/departures that require a <del>construction</del> LAR <b>during construction</b> may affect...</p>		
13	<p><b><u>Section 4.1.1 Construction Change Applicability</u></b></p> <p><u>Page C-34</u></p> <p><del>Licensee or the responsible design authority</del> 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</p>	<p>Maintenance of the CLB is the responsibility of the licensee.</p> <p>The licensee may delegate the development and processing of CLB change documents, retaining responsibility for the results of any change to the CLB documents.</p>	<p>Agree in principle. Alternative language provided to clarify as follows:</p> <p>"Licensees <b>ensure</b> individual construction changes <b>are tracked</b> via design configuration..."</p>
14	<p><b><u>Section 4.1.1.1 Nonconforming Conditions during Construction</u></b></p> <p><u>Page C-35</u></p> <p>Nonconforming conditions are placed in the CAP (or other tracking process for nonconformances) and dispositioned by licensees as requiring rework, repair or use-as-is. Licensees will establish and maintain processes for review of corrective actions for nonconformances that are dispositioned as repair or use-as-is to determine the impact, if any, on the CLB and whether an LAR is required. Licensee processes <del>will</del> assure configuration management <b>during construction</b> and transparency of pending licensing basis changes. <del>in support of NRC's continuing inspection activities.</del> If and when the licensee determines that corrective actions for</p>	<p>Maintenance of the current licensing basis assures that the physical plant corresponds with the Updated Final Safety Analysis Report (UFSAR).</p> <p>NRC inspection activities are verifications of a licensee conformance with the AEA, and the Commission's regulations.</p>	<p>Comment accepted. Retained the last paragraph and moved up to the end of the first paragraph discussed here because the option to request a PAR is still accurate and useful guidance.</p>

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	<p>nonconformances require an LAR, the licensee should stop the work that requires prior NRC approval and submit the required LAR without delay.</p> <p>A licensee may continue with construction activities to resolve emergent <del>the nonconforming</del> conditions <del>by repair or a use-as-is determination</del>, based on an approved engineering solution and an assessment of its impact on the licensing basis—provided this assessment does not determine that an LAR is required <del>the determination that prior NRC approval is not required</del>. This work is considered at-risk because it is performed in parallel with any required change to the licensing basis, including completion and documentation of the change/departure review. If at any point it is determined that a proposed change/departure requires prior NRC approval, the licensee must submit an LAR. If a required LAR is ultimately denied by the NRC, the licensee must return the facility to its current licensing basis.</p> <p>Until the change/departure review is completed and documented, licensees should not perform any irreversible/unrecoverable work. 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.</p> <p>If the licensee wishes to proceed with work that is the subject of an LAR, it should first request and receive a Preliminary Amendment Request (PAR) Notification of No Objection from the NRC as discussed Section 4.7.1.1.</p>	<p>Construction activities progress toward constructing the facility as specified in the current licensing basis. When the licensee changes the current licensing basis and determines that prior NRC approval is not required for the change, construction continues towards the, then changed, new current licensing basis. There is no exception for “emergent” conditions.</p>	
15	<p><b><u>Section 4.3.5 Changes to Operational Requirements</u></b></p> <p><u>Page C-40</u></p> <p>In accordance with Section VI.C of the design certification rules, operational requirements in the generic DCD do not have finality.</p>	<p>Clarifying the applicability of Section VIII.C to ISI and IST</p>	<p>Comment accepted.</p> <p>Alternative example organization provided to clearly illustrate the different</p>

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	<p>Section VIII.C of the design certification rules discusses the processes for changes and departures to operational requirements. As specified in Section VIII.C.4 of the design certification rules, if a COL applicant departs from the operational requirements specified in the DCD, the applicant must request an exemption in accordance with 10 CFR 52.7. However, the Section VIII.C processes only apply to specific operational requirements that were completely reviewed and approved in the design certification rulemaking (72 FR at 49365). For example, the Section VIII.C processes do not apply to the NRC's acceptance of portions of the inservice testing (IST) and inservice inspection (ISI) operational programs in the review of a design certification application because these portions of the operational programs were not completely reviewed and approved.</p> <p>The Tier 2 portion of a generic DCD includes information considered as "other operational requirements" which are addressed for COL applicants in Section VIII.C of the design certification rules. The NRC will approve plant-specific operational requirements as part of the COL proceeding. Therefore, after issuance of a COL, the operational requirements in the generic DCD are not applicable to that licensee, except to the extent that the FSAR incorporates by reference those operational requirements. Changes to operational requirements in an FSAR are governed by 10 CFR 50.59 or 10 CFR 50.55a, whether or not the FSAR has incorporated by reference the operational requirements from the generic DCD.</p> <p><u>Examples:</u></p> <ul style="list-style-type: none"> <li>• A change to the plant-specific Technical Specifications requires a license amendment under 10 CFR 50.90.</li> <li>• <del>The DCD states that in-service testing (IST) will be performed in accordance with a specific edition and addendum of the ASME</del></li> </ul>	<p>programs.</p> <p>Use 50.55a for Code and Standards Operational Requirements.</p> <p>10 CFR Part 52 Appendices, Section VIII.C.6. Specifically identify changes to the TS as requiring a license amendment request.</p>	<p>examples. NRC staff's proposed first bullet not incorporated as NEI 96-07, Rev 1 and Appendix C both state upfront that any change to Technical Specifications requires a license amendment under 10 CFR 50.90.</p>



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	<p><del>Code. The COL applicant desires to use a subsequently issued code case for IST that has been endorsed by the NRC. Such a change constitutes a departure from an operational requirement in the DCD. As a result, the COL applicant must request an exemption from the DCD to use the code case.</del></p> <ul style="list-style-type: none"> <li>The DCD <b>Tier 2</b> states that IST will be performed in accordance with a specific edition and addendum <b>addenda</b> of the ASME <b>OM</b> Code. The UFSAR incorporates by reference this particular provision from the DCD. <b>The NRC regulations in 10 CFR 50.55a(f)(4)(i) require that the ISTs that are conducted by a COL holder during the initial 120-month interval to verify the operational readiness of pumps and valves, whose function is required for safety, must comply with the requirements in the latest edition and addenda of the Code incorporated by reference in 10 CFR 50.55a(b) (or the optional ASME Code cases listed in RG 1.192 that is incorporated by reference in 10 CFR 50.55a(b)), on the date 12 months before the date scheduled for initial fuel loading, subject to the limitations and modifications listed in 10 CFR 50.55a(b). Regulatory Guide (RG) 1.192, "Operation and Maintenance of Code Case Acceptability, ASME OM Code," is incorporated by reference in 10 CFR 50.55a identifying the most current set of NRC-approved ASME OM Code Cases with any applicable conditions. The change need not be evaluated in accordance with 10 CFR 50.59.</b></li> <li><del>After issuance of the COL, the</del> <b>If a COL holder desires to use a subsequently issued edition and addenda to the ASME OM Code that is incorporated by reference in 10 CFR 50.55a, the COL holder may submit a letter to the NRC requesting approval to use that later edition or addenda to the OM Code pursuant to 10 CFR 50.55a(f)(4)(iv). In addition, a COL holder may implement an ASME code case for IST that has been endorsed by the NRC in RG 1.192 that has been incorporated by reference in 10 CFR</b></li> </ul>	<p>Remove example pertaining to applicants.</p> <p>Modified examples to identify the application of 10 CFR 50.55a.</p> <p>Second example is an operational requirement change required by the regulations.</p> <p>Third example is an operational requirement change desired by the licensee.</p>	

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	<p>50.55a without submitting an alternative request provided all conditions in RG 1.192 are implemented. Such a change constitutes a change to an operational requirement in the UFSAR, and must be evaluated in accordance with 10 CFR 50.59. The change need not be evaluated in accordance with 10 CFR 50.59. Additional information on the use of later editions and addenda of the ASME Code for preservice and inservice testing programs (as well as ISI programs) is discussed in Revision 1 to RIS 2012-08, "Developing Inservice Testing and Inservice Inspection Programs under 10 CFR Part 52."</p>		
16	<p><b><u>Section 4.3.2 Evaluation of Changes to Plant-Specific Facilities or Procedures Described in the UFSAR</u></b></p> <p><u>Page C-38</u></p> <p>The 10 CFR 50.59 evaluation 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 outside the scope of the plant-specific DCD, except as updated as identified in Section <a href="#">4.4.2.2</a> of this appendix</p>	<p>Delete "as updated" These are extraneous words.</p>	<p>Comment accepted.</p>
17	<p><b><u>Section 4.4.2.2 Evaluation of Departures from Tier 2 Information That Do Not Affect Ex-Vessel Severe Accident Criteria</u></b></p> <p><u>Page C-48 graphic</u></p> <p>Change the symbol between "proposed value" and "SRP guideline value" from "&lt;" (less than) to "≤" (less than or equal to)</p>	<p>The proposed edit is to conform to the NEI 96-07 textual description because the "do not exceed" language in the preceding NEI 96-07 text would imply "less than or equal to" the SRP guideline value.</p>	<p>Comment accepted.</p>

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18	<p><b><u>Section 4.4.2.3 Evaluation of Departures from Tier 2 Information That Affect Ex-Vessel Severe Accident Criteria</u></b></p> <p><u>Page C-50, last paragraph</u></p> <p>Severe accident mitigation features are design specific and are discussed primarily in the Chapter 19 of the DCD. However, EVSA features may be described elsewhere in the DCD, and the location of the EVSA design ...</p>	<p>Delete superfluous "the".</p>	<p>Comment accepted.</p>
19	<p><b><u>Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information</u></b></p> <p><u>Page C-59</u></p> <p>Tier 2 is defined in Section <a href="#">3.23</a> to include, among other things, the PRA summary information required by 10 CFR 52.47(a). A description of the design-specific PRA and its results is Tier 2 information contained in Chapter 19 of the UFSAR as required by 52.47(a)(27) and 52.79(d)(1). A change to either the description of the PRA or its results is a departure from Tier 2 information, requiring a Section VIII.B.5 review <b>to determine if prior NRC approval is required</b>; however, such departures will screen out of further review because they will not meet the eight criteria of Section VIII.B.5.b <b>or the two criteria of Section VIII.B.5.c</b>. Thus, as a general matter, the VIII.B.5 review conclusion for departures from either the description of the PRA or its results will be that no prior NRC approval is required.</p> <p><b>[Include, at this location, a generic evaluation for a departure from either the description of the PRA or its results to substantiate that the eight criteria of Section VIII.B.5.b and the two criteria of Section VIII.B.5.c will not require prior NRC approval. This generic evaluation is necessary to support the conclusion carried throughout the remainder of this section that the simplified evaluation is not required</b></p>	<p>Include the evaluation for changes to ex-vessel severe accident design features.</p> <p>Agree that further evaluation is not required; however a generic evaluation must be included in the guidance document to demonstrate why further 50.59 screenings and Section VIII.B.5 evaluations are not required.</p>	<p>Comment accepted.</p>

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	<p>for the departure from either the description of the PRA or its results. Also explain that the Section VIII.B.5 evaluation shows that no license amendment is required by 10 CFR 50.59.]</p> <p><del>Changes to the description and results of the PRA as provided in Chapter 19 of the UFSAR are not subject to 10 CFR 50.59. This is because 10 CFR 50.59 controls changes within the plant's design basis, while the PRA models beyond design basis events.</del></p> <p>The plant-specific PRA itself is subject to maintenance and upgrade requirements specified in 10 CFR 50.71(h). The initial PRA required by 50.71(h) PRA must be developed prior by the scheduled date of 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 departure process. While guidance on PRA maintenance and upgrade is outside the scope of this appendix, changes to the PRA information are governed by the processes discussed below:</p>	<p>PRA models include both design basis and beyond design basis events. However, a generic evaluation can show that no license amendment is required under 10 CFR 50.59.</p> <p>Clarification of which PRA is being discussed.</p>	
20	<p><b><u>Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information</u></b></p> <p><u>Page 60</u></p> <p>It is beyond the scope of this appendix to provide detailed guidance for PRA changes for a COL application that references a design certification. Suffice it to state, a COL applicant does not need to update the PRA information in the DCD to account for relatively minor changes; SRP 19.0 provides NRC staff reviewer guidance on the content of the PRA summary information in the FSAR.</p>	<p>Not a valid conclusion for an applicant's departures from the DCD.</p>	Comment accepted.

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21	<p><b><u>Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information</u></b></p> <p><u>Page C-61</u></p> <p>As indicated by the structure of <del>required by</del> 10 CFR 50.71(h), the development of a PRA meeting RG 1.200, <del>which endorses consensus standards on PRA</del>, is due <del>by initial</del> prior to fuel load. The requirements for maintenance and periodic upgrades of the PRA apply after the initial RG 1.200 PRA is developed prior to fuel load. During construction, a licensee is not required to maintain <del>or upgrade</del> the PRA provided in the COL application, but it is recommended that licensees maintain the PRA as necessary to support other programs (e.g., reliability assurance program). Licensees may also <del>wish</del> find it beneficial to update the plant-specific PRA to reflect significant design changes during construction. <del>PRA maintenance includes updating the PRA model to reflect plant changes, such as modifications or procedure changes, while PRA upgrade includes incorporating into the PRA model a new methodology or significant changes in scope or capability such as human error analysis methodology or new treatment of common cause failures. However, the licensee must still satisfy the requirements of 10 CFR 50.71(e) to update the FSAR annually. In particular, if</del> If there are changes to the PRA summary or results presented in Chapter 19 of the UFSAR, the licensee <del>is required to</del> should provide updates to <del>update</del> the FSAR, as appropriate, in accordance with 10 CFR 50.71(e). <del>In scenarios where design changes or departures may impact or change the PRA information in FSAR Chapter 19, the licensee needs to update the FSAR accordingly. One way for a licensee to comply with 10 CFR 50.71(e) is to discuss the impact of the design changes or departures on the PRA information in FSAR Chapter 19. For example, if a methodology, SSC attribute, operator action or procedure in Chapter 19 is affected by a design change or departure, the licensee would discuss this in Chapter 19 of the updated FSAR.</del></p>	<p>The UFSAR should reflect the current plant design when updated as required by 10 CFR 50.71(e). The licensee can update the FSAR to reflect current plant information, including discussion about design change impacts on the PRA summary in chapter 19 without performing PRA maintenance or upgrade.</p> <p>While not required by regulation, a method of tracking and compiling plant changes that impact the plant-specific PRA may facilitate the completion of the 10 CFR 50.71(h) PRA that is required by the initial fuel load.</p>	<p>Alternative language provided to accurately reflect the requirements of 10 CFR 50.71(h) as follows, "As indicated <del>by the structure of</del> <del>required by</del> 10 CFR 50.71(h), the development of a PRA <del>that covers those initiating events and modes for which NRC-endorsed consensus standards on PRA exist (one year prior to the scheduled date for initial loading of fuel), meeting RG 1.200,</del> <del>which endorses consensus standards on PRA,</del> is due <del>by initial</del> prior to fuel load."</p> <p>Suggested addition of information on what constitutes PRA maintenance &amp; upgrade and examples of design changes or departures that may</p>

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	<p>As <del>stated</del> <b>discussed</b> in the SOC, the NRC intends that PRA maintenance and upgrades be consistent with the guidance for those processes in <b>PRA standards endorsed by RG 1.200</b> <del>American Society of Mechanical Engineers (ASME) "Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications" (ASME RA-Sb-2005)</del>. In particular, <del>the SOC state:</del></p>		<p>impact or change the PRA information not incorporated as it already exists elsewhere in this section.</p> <p>Alternative revision provided to streamline guidance while capturing intent of comment, e.g., we consider it unnecessary to add the proposed language about "one way to comply with 50.71(e)."</p>
22	<p><b><u>Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information</u></b></p> <p><u>Page C-62 and 63</u></p> <p>In addition, the periodic updates to Chapter 19 of the FSAR should account for the following types of changes related to the PRA updates:</p> <ul style="list-style-type: none"> <li>•Changes to the PRA models and methodologies as described in Chapter 19.</li> <li>•A description of any new PRA models and methodologies needed to comply with 10 CFR 50.71(h), including a <del>description of the results.</del></li> </ul> <p>A licensee is not required to seek NRC approval for changes to the PRA</p>	<p>Change to reflect the language in 10 CFR 52.47(a)(27) and 52.79(a)(46).</p>	<p>Comment accepted with modified wording for second bullet that better reflects the language in Part 52.</p>

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	<p>information in Chapter 19. As a result, a licensee does not need to perform screening or prepare and 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. However, any changes to the PRA information in Chapter 19 should be reported to the NRC in accordance with 10 CFR 50.71(e).</p> <p>To the extent that changes in the PRA information are attributable to changes in design or procedures, described elsewhere within the DCD or FSAR, the applicable change process should be followed for such changes/departures (including, as necessary, requesting NRC approval for the change). As a general matter, it is expected that any change that significantly impacts the results of the PRA (e.g., a significant design change) would be subject to the other change control processes discussed in Section 4.4.2 above. For example, Tier 1 of the <b>plant-specific</b> DCD typically includes information regarding risk-significant systems, structures, and components (SSC). Any departure from such information would require an exemption from Tier 1 and would therefore be subject to NRC review and approval. Similarly, departures from Tier 2 of the plant-specific DCD that result in 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. Consequently, while NRC approval is not directly required for changes to the PRA information in Chapter 19, NRC approval would likely be required for departures from other portions of the plant-specific DCD that have a significant impact on the results of the PRA.</p>	<p>The DCD is the plant-specific DCD and the plant-specific DCD is part of the FSAR.</p> <p>Clarify which DCD.</p>	
23	<p><b><u>Section 4.4.3.2 Changes to Other Severe Accident Information</u></b></p> <p><u>Page C-66 first bullet</u></p> <ul style="list-style-type: none"> <li>Needs to assess the departure against Criterion 1 in Section VIII.B.5.c of the design certification rule, because the ADS is used</li> </ul>	<p>Add necessary parenthesis.</p>	<p>Comment accepted.</p>

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	to eliminate (i.e., make not credible) a particular ex-vessel severe accident (direct containment heating (DCH));		
24	<p><b><u>Section 4.4.3.1 Changes to Probabilistic Risk Assessment (PRA) Information</u></b></p> <p><u>Page C-63 Examples 1)</u></p> <p><u>Changes during Construction</u> – 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:</p> <ul style="list-style-type: none"> <li>o <del>must review the modifications in accordance with the change processes described in Sections 4.1 and 4.4.2 and update the FSAR, as necessary, at the next regulatory scheduled interval; and</del></li> <li>o <del>may defer any changes to the PRA information in Chapter 19 pending development of the PRA upgrade required by 10 CFR 50.71(h)(1). However, the licensee must update its FSAR, including Chapter 19, at the next regularly scheduled interval to reflect the modification. The licensee may describe the results of a PRA screening and/or the impact on the PRA information in Chapter 19; and</del></li> <li>o <del>must review the modifications in accordance with the change processes described in Sections 4.1 and 4.4.2 and update the FSAR, as necessary, at the next regulatory scheduled interval.</del></li> </ul> <p><u>Page C-63 Examples 2)</u></p> <p><u>Use of NRC-Endorsed Consensus Standard</u> – The <del>plant-specific</del> DCD <del>for a plant</del> uses a seismic margins <del>low power and shutdown conditions (LPSC)</del> analysis rather than a seismic LPSC PRA. After issuance of the COL but more than one year prior to fuel load, the NRC endorses a</p>	<p>Reordered bullets to reflect the expected sequence of events. Proposed an acceptable method of updating FSAR Chapter 19 PRA information.</p> <p>Consider modifying example from seismic margin analysis to low power and shutdown conditions analysis as the seismic PRA standard is now available.</p>	<p>Comment intent accepted consistent with Comment/Response #21, with reorganization to improve guidance flow.</p>



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	<p>consensus standard for a seismic LPSD PRA. The licensee:</p> <ul style="list-style-type: none"> <li>o must upgrade its PRA to use the NRC-endorsed consensus standard within the time frames provided in 10 CFR 50.71(h), and should make the PRA available for inspection or review by the NRC staff upon request, but does not need to seek NRC approval for the upgrade; and</li> <li>o following the PRA upgrade, must update its FSAR at the next regularly scheduled interval to replace the discussion of the seismic margins LPSD analysis with a description of the seismic LPSD PRA and the results of the seismic LPSD PRA, including an identification of any risk insights.</li> </ul>		
25	<p><b><u>Section 4.6 Changes to Early Site Permits</u></b></p> <p><u>Page C-68, first paragraph</u></p> <p>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), <del>without prior Commission approval, with the exception of other than</del> typographic and administrative corrections <del>to the SSAR</del> (see 72 FR 49360, Aug. 28, 2007). <del>without prior Commission approval.</del></p>	<p>The exception for “Typographic and administrative corrections” applies to the SSAR but not to the ESP since the ESP is a license and any changes to a license require NRC approval.</p>	<p>Comment accepted.</p>
26	<p><b><u>Section 4.7.1 Evaluations performed during construction (before the 10 CFR 52.103(g) finding)</u></b></p> <p><u>Page C-69</u></p> <p>Licensees must comply with applicable change processes in accordance with Section 52.98 (e.g., 10 CFR 50.59, 50.54, design certification, etc.), including the requirements governing submittal of LARs and exemption requests when necessary. <del>Changes during construction</del> Licensing basis changes that require prior NRC approval may not be implemented <del>constructed</del> until after the required LARs/exemptions are approved by the NRC <del>or a PAR No Objection Letter is received.</del></p>	<p>Clarification of when construction activities may proceed in accordance with proposed changes to the licensing basis.</p>	<p>Comment accepted.</p> <p>Deleted second paragraph except for last sentence which was moved to end of first paragraph. Due to the sum of NRC comments, only the last sentence remained relevant.</p>

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	<p>Because SSCs are not considered in service during construction, and technical specifications are not in effect until after the 10 CFR 52.103(g) finding, additional criteria are needed for determining when a change is "implemented" during the construction phase. <del>During both construction and operation, the emphasis is on when SSCs can provide their intended function.</del> During construction, a change or departure is considered "implemented" when <b>the change is credited in the current licensing basis of the plant.</b> <del>an ITAAC closure notification (ICN) for the affected SSC is submitted under 10 CFR 52.99 (e.g., after the change/departure is installed and tested).</del> NRC approval of ITAAC related LAR/exemption requests is required before the ITAAC closure notification for affected ITAAC are submitted.</p> <p>LARs that do not involve <b>ITAAC construction</b> would need to be approved before associated Technical Specification (if any) become applicable, <b>the implementation date of the program, or the ITAAC ICN is submitted.</b></p>	Clarification of the definition of 'implemented' in the context of the current licensing basis.	In last paragraph discussed: additional clause on "implementation date of the program" not incorporated as it would duplicate the existing sentences that follow within the document; and, specified " <b><u>an associated</u></b> ITAAC ICN..."
27	<p><b><u>Section 4.7.1.1 Preliminary Amendment Request During Construction</u></b></p> <p><u>Page C-71</u></p> <p>The primary purpose of the PAR is to maintain licensing basis configuration control and avoid unnecessary construction delays related to changes during construction arising after the issuance of the COL and before the 10 CFR 52.103(g) finding. This process will enable the NRC to assess and ensure that inspectability of SSCs affected by the proposed change and adjust its inspection activities as necessary. Based on the information provided in the licensee's PAR, the NRC may issue the licensee a PAR <del>Notice</del> <b>No Objection Letter</b> stating that the NRC has no objection to the licensee proceeding at its own risk with installation and testing of the proposed plant change pending the</p>	Clarify document title.	Comment accepted.

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	outcome of the NRC's technical review of the licensee amendment/exemption request.		
28	<p><b><u>Section 4.7.1.1 Preliminary Amendment Request During Construction</u></b></p> <p><u>Page C-76</u></p> <p>PARs should be submitted in writing in accordance with 10 CFR 52.3. Less formal (e.g. verbal) communications may <del>precede</del> <del>proceed</del> <del>and/or supplement</del> the required written submittal; this type of interaction may be especially important for communicating emergent situations.</p>	<p>Early and frequent verbal communications are important, however it cannot replace a written record.</p> <p>Replace "proceed" with "precede".</p>	Comment accepted.
29	<p><b><u>Section 4.7.1.1 Preliminary Amendment Request During Construction</u></b></p> <p><u>Page C-76</u></p> <p>A licensee's PAR should contain the following information: ...</p> <p><del>4 Preliminary assessment of whether or not the proposed change involves no significant hazards consideration...</del></p> <p><del>5 Preliminary assessment of whether or not the proposed change qualifies for exclusion from environmental review...</del></p> <p>6 Renumber to 4</p> <p>7 Renumber to 5</p>	<p>ISG-025 revision 0A relies upon the related License Amendment Request to provide these two pieces of information for NRC review.</p>	Comment accepted.
30	<p><b><u>Section 4.7.1.1 Preliminary Amendment Request During Construction</u></b></p> <p><u>Page C-77</u></p> <p>A template for submittal of PAR requests by licensees is provided at the end of this section. PAR requests should be submitted to the Office of New Reactors in accordance with COL-ISG-025.</p>	<p>Revise template for ISG-025 revision 0A.</p>	Comment accepted.

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31	<p><b><u>Section 5.2 RECORDS AND REPORTING FOR CHANGES</u></b>  <b><u>SUBJECT TO 10 CFR 50.59</u></b></p> <p><u>Page C-81, First paragraph</u></p> <p>Per 10 CFR 50.59(d)(2), for combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 52.103(g). Since 10 CFR 50.59(d)(2) only applies to licensees, the effective application of this requirement is only from issuance of the combined license until the 10 CFR 52.103(g) finding.</p>	<p>Comment to correctly constrain the applicability of 10 CFR 50.59(d)(2). The Part 50 processes are applicable from the issuance of the license until the license is rescinded.</p>	<p>Comment accepted.</p>
32	<p><b><u>Section 5.3 RECORDS AND REPORTING FOR CHANGES</u></b>  <b><u>SUBJECT TO A DESIGN CERTIFICATION RULE</u></b></p> <p><u>Page C-81, Last paragraph</u></p> <p><u>Documenting Change Process Evaluations</u></p> <p>The guidance provided in Section 5.0 of the main body of NEI 96-07, Revision 1, for documenting a 10 CFR 50.59 evaluation of a proposed activity is similarly applicable for plant-specific departures under Section VIII of the design certification rule appendices including Tier 2 changes under Section VIII.B.5.b, ex-vessel severe</p> <p>accident changes under Section VIII.B.5.c and aircraft impact assessment changes under 10 CFR 50.150(c) and Section VIII.B.5.d, when applicable.</p>	<p>Editorial correction.</p>	<p>Comment accepted.</p>

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33	<p><b><u>Section 5.3 RECORDS AND REPORTING FOR CHANGES SUBJECT TO A DESIGN CERTIFICATION RULE</u></b></p> <p><u>Page C-82, lettered list</u></p> <p>a. On the date that an application for a license referencing a design certification rule appendix is submitted, the application must include the VIII.B.5 summary report and any <del>updates to generic changes to, or plant-specific departures from,</del> the generic DCD.</p>	<p>Clarification of change type</p>	<p>Comment accepted.</p>
34	<p><b><u>Section 5.3 RECORDS AND REPORTING FOR CHANGES SUBJECT TO A DESIGN CERTIFICATION RULE</u></b></p> <p><u>Page C-82, last paragraph</u></p> <p>As discussed in Section <a href="#">1.2.3</a> of this appendix, licensees may apply the UFSAR update guidance in NEI 98-03, Revision 1, to information outside the scope of the plant-specific DCD. Such modifications should be reported to NRC in accordance with <del>NEI 98-03, Revision 1</del> <b>10 CFR 50.71(e)(3)(iii) prior to the Part 52.103(g) finding and 10 CFR 50.71(e)(4) thereafter.</b> <del>In addition to Section VIII.B.5 reviews, NEI 98-03, Revision 1, guidance may be considered when a departure from information in the plant specific DCD involves removal, reformatting and simplification of information, as appropriate.</del></p>	<p>Section 1.2.3 of this Appendix provides guidance for updating the UFSAR, however neither Section 1.2.3 of this appendix nor NEI 98-03 provides guidance for reporting requirements for the UFSAR for Part 52 plants.</p> <p>As the NRC staff explained in its August 31, 2012 comments on NEI 96-07, Appendix C, Revision 0C, "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</p>	<p>Comment accepted.</p>

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		<p>(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.”</p> <p>This NRC staff comment applies to NEI 98-03, Revision 1, guidance on removing, reformatting, and simplifying information, and NEI has given no regulatory basis for why a licensee may be permitted to remove, reformat, or simplify Tier 2 information without NRC approval.</p>	