

NEI Guidance on Changes during Construction – DRAFT 6/24/11

4.6 Disposition of Departures and Changes

4.6.1 Evaluations performed before the 10 CFR 52.103(g) finding

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. As is the case after the Section 52.103(g) ITAAC finding, changes during construction may not be implemented until after required LARs/exemptions are approved by the NRC.

Because SSCs are not considered in service during construction, and technical specifications are not in effect until after the Section 52.103(g) ITAAC finding, additional criteria are needed for determining when a change is “implemented” during the construction phase. During construction, 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). This means that NRC approval of ITAAC-related LARs/exemption requests is required before closure letters 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 and/or the FSAR.

Some SSCs are required to be placed in service prior to the Section 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 LARs/exemption requests. The purposes of pre-LAR submittal interactions are to:

- Ensure the NRC is informed and can plan for submittal of LARs and changes to fabrication/construction activities or schedules

- Facilitate preparation of LARs that are complete in terms of administrative requirements and technical basis
- Identify potential challenges to timely NRC approval of LARs
- Determine if the licensee needs to request a Preliminary Acceptability Review (as discussed in the following section) to allow work to proceed while the LAR is under NRC review

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 reviewed and dispositioned by the NRC in tandem. 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 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.

4.6.2 Preliminary Acceptability Review for Inspectability for "At Risk" Construction

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

For licensees to be able to request a PAR for license amendment/exemption requests, the COL must contain license conditions similar to the following:

License Conditions on Changes during Construction

- (i) The licensee may request use of a preliminary acceptability review (PAR) process, for license amendments, at any time before the finding in Section 2.D(3). To use the PAR process, the licensee shall submit a written request to the Office of New Reactors (NRO) in accordance with COL-ISG-025, "Changes during Construction under Part 52."

(ii) Prior to NRO's issuance of a written PAR notification, the licensee shall submit the license amendment request (LAR). Thereafter, NRO will issue a written PAR notification, setting forth whether the licensee may proceed in accordance with the PAR, LAR, and COL-ISG-025. If the licensee elects to proceed and the LAR is subsequently denied, the licensee shall return the facility to its current licensing basis.

These license conditions will expire upon the NRC's Section 52.103(g) finding.

Design, procurement, fabrication, installation and testing of a proposed change during construction that is performed prior to NRC approval of a required LAR (and exemption request, if applicable) are performed at risk. Such work is considered "at-risk" because the NRC may ultimately decline to approve the change as proposed in the LAR. In that event, the licensee must restore the design to that approved by the NRC or adopt an alternative design that is acceptable to the NRC. Because of the nature of at-risk construction and the potentially high cost for rework and project delay due to NRC denial of an LAR/exemption request, licensees should carefully consider the scope and complexity of changes that require an LAR when determining whether to submit a PAR Request to proceed with the change, and how much work to perform at risk prior to obtaining NRC approval for the change. For example, licensees may choose not to proceed with changes that involve use of unapproved design codes or analysis methodologies, due to the potential that NRC may not approve the proposed change, or because NRC review and approval may not be timely with respect to the project schedule.

The primary purpose of the PAR is to enable the NRC to assess and ensure the 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 Request, the NRC will issue the licensee a PAR Notification 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 outcome of the NRC's technical review of the license amendment/exemption request. The NRC may ask the licensee to supplement or clarify the PAR Request to support a timely response. Following licensee receipt of the NRC's PAR Notification of No Objection, the licensee may perform installation and testing activities, including inspections, tests or analyses specified in the ITAAC, and may document determinations that ITAAC acceptance criteria have been met. However, as discussed in Section 4.6.1, closure letters for affected ITAAC may not be submitted until after NRC approval of the related LAR/exemption request. Activities associated with the proposed change should be performed in accordance with the licensee's approved design engineering processes. The PAR process is depicted in Figure 1.

An NRC PAR Notification is not a pre-approval of the LAR/exemption request, nor does it imply any NRC approval of the proposed change. The PAR has no effect on the NRC's

LAR process; the NRC will perform its normal LAR acceptance review and technical review, request additional information as needed, and make a decision on the LAR in accordance with NRC requirements and processes.

A licensee's PAR Request should contain the following information:

1. Summary description of the proposed change and a summary of the reason for concluding that an LAR (and exemption request, if any) is required (i.e., summary result of the change process evaluation)
2. Briefly identify applicable precedents, if 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 Request Guidelines*, Revision 2.
3. 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
 - new or modified activity with a limited time window for NRC inspection
4. The date by which an NRC PAR Notification is needed to support licensee construction schedules and sequencing. The timeframe for NRC issuance of the PAR Notification will be based on consideration of the licensee's schedule expectations and expressed priorities, and could be as little as 1–2 days, with the goal of minimizing delays in licensee construction plans/schedules.
5. Plans to identify new or modified ITAAC, or removal of any ITAAC; a summary of the reasons for the new, modified or removed ITAAC; and the estimated schedule for installation and testing activities associated with the change(s). The licensee should also identify specific activities for which direct inspection can take place only within a given time frame. For example, licensees should identify when proposed new tests, including one-time type tests, will be performed, and when changes will become inaccessible for inspection due to ongoing construction activities.
6. Preliminary assessment of whether or not the proposed change involves no significant hazards consideration based on the criteria of 10 CFR 50.92(c). The complete technical bases for the no significant hazards consideration determination should be provided in the LAR.

If the licensee's preliminary assessment indicates that the proposed change does

not meet the criteria for a no significant hazards consideration determination, the NRC may decline to issue a PAR Notification allowing construction at risk.

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 environmental 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. Most proposed changes during construction are expected to qualify for categorical exclusion such that changes that do not qualify are expected to be rare.

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.

The PAR process to address inspectability issues is unique to the construction phase and independent of the technical review of the proposed change to the licensing basis. As such, the licensee's PAR Request should be provided and responded to by NRC separately from the LAR. To the extent possible, licensees should provide the PAR Request at the time the LAR is submitted. Even when submitted concurrently with the LAR, the PAR results in a separate earlier response from the NRC and should be submitted separately. When submitted concurrently, the licensee PAR may reference, rather than duplicate, information contained in the LAR.

When necessary, the PAR Request may be submitted before or after the LAR submittal depending on the circumstances. For example, the need for some LARs may arise with little or no warning (e.g., to address an emergent construction issue or in response to the identification of a nonconforming condition that the licensee desires to accept as-is). If the licensee desires to proceed with installation and testing activities for such changes but does not have sufficient time to prepare an LAR, it may first submit a PAR Request that contains the information outlined above. This will enable the NRC to begin its assessment of the inspection impacts in support of a timely NRC PAR Notification upon licensee submittal of the associated LAR. NRC will not issue the no objection PAR Notification until the licensee submits the associated LAR. NRC response to a licensee PAR Request is separate and independent of the status/schedule for the associated LAR acceptance and technical reviews.

For emergent situations when the PAR is submitted prior to the LAR, it is important to ensure that the LAR is consistent with a previously submitted PAR. Thus, before requesting a PAR, licensees should perform sufficient engineering evaluations to ensure there is a firm basis for preparation and submittal of an LAR that is consistent with the summary and preliminary information contained in the PAR.

A PAR Request may also be submitted *during* the NRC technical review of an LAR. At any time during the pendency of an LAR, licensees may notify the NRC of plans to proceed with installation and testing of changes prior to NRC approval of the LAR via submittal of a PAR Request. The PAR Request would include the necessary information concerning inspectability of the change and identify the date that installation and testing is scheduled to proceed. Based on that information, the NRC may issue a PAR Notification as discussed above. The need to install and test changes prior to LAR approval might be identified subsequent to LAR submittal due to changes in the licensee's construction sequence or schedule, or if approval of the LAR takes longer than expected.

PAR Requests should be submitted in writing in accordance with 10 CFR 52.3. Less formal (e.g., verbal) communications may precede and/or supplement the required written submittal; this type of interaction may be especially important for communicating emergent situations.

4.6.3 LARs for Conforming Changes – Conforming LARs

It is expected that some LARs will describe proposed changes to the plant or procedures that require a license amendment solely because they involve a change to Tier 1 information or COL ITAAC and not because the change has a significant impact on safety as determined by applying the applicable change process criteria. Like changes to Technical Specification under 10 CFR Parts 50 and 52, a license amendment is always required for changes to Tier 1/ITAAC information, regardless of their safety significance. LARs required solely because a change impacts Tier 1/ITAAC information that could otherwise be made under the Section 50.59-like process are called conforming LARs because they are necessary to conform Tier 1/ITAAC information to the corresponding information in the FSAR that is being modified.

Licensees should evaluate and document such changes in accordance with 10 CFR 50.59 or other applicable change process criteria. The associated conforming LARs should focus on the impacts on Tier 1/ITAAC information (e.g., the addition of a component to the scope of an ITAAC, or a change to a dimension identified in Tier 1) and may state that the LAR is being requested in order to conform Tier 1/ITAAC to a change made in accordance with the applicable change process. See applicable sections of this appendix, for guidance on performing these evaluations.

Conforming LARs need not contain the detailed design information, evaluations or analyses that support the plant or procedure change, but should otherwise conform to the licensee's format and content guidance for LARs. Detailed design information, evaluations and analyses that support the change should be retained by the licensee in accordance with its plant change and document control processes. Conforming LARs should describe the plant change or modification and include a summary of the 10 CFR 50.59-like evaluation. The summary information should be sufficient to demonstrate that the proposed change may be considered a conforming LAR. The NRC staff is expected to review this summary information to verify that the LAR is a conforming LAR and may request additional information concerning the licensee's evaluation of the change in connection with this verification or its review of the conforming LAR.

If a change requires prior NRC approval for reasons other than an impact on Tier 1/IITAAC, (e.g., a proposed change in safety analysis methodology), the LAR needs to include the technical basis for the change, and the NRC must approve the proposed change, as well as the associated Tier 1/IITAAC impacts.

As discussed above, conforming LARs need not contain evaluations, analyses, or other technical bases for the proposed change. Thus by their nature, conforming LARs should require less time and resources for the licensee to prepare, and less time and resources for the NRC staff to review. To the extent that conforming LARs can be submitted and approved more quickly, the need for licensees to submit PAR Requests in connection with conforming LARs during construction should be reduced. However, licensees may submit a PAR Request in connection with a conforming LAR during construction in the same manner as for any other LAR, as discussed in Section 4.6.2.

4.6.4 Evaluations performed after the Section 52.103(g) ITAAC finding

Once the NRC makes the 10 CFR 52.103(g) finding that all ITAAC are met, plant technical specifications take effect and the guidance on disposition of departures and changes is the same for new plants as it is for any other operating plant. The following guidance is therefore adapted from NEI 96-07, Section 4.5:

There are two possible conclusions to an evaluation conducted under 10 CFR 52.98 and the applicable change control process (e.g., 10 CFR 50.59, 50.54, design certification, etc.):

- (1) The proposed departure or change may be implemented without prior NRC approval.
- (2) The proposed departure or change requires prior NRC approval.

Where a departure requires prior NRC approval, the departure or change must be approved by the NRC via license amendment request (LAR) in accordance with 10 CFR

50.90 prior to implementation. For a Tier 1 departure or change, the license amendment request must be accompanied by a request for an exemption from the referenced design certification, as discussed in Section 4.1.1. A departure or change is considered “implemented” when it provides its intended function, that is, when it is placed in service and declared operable. Thus, a licensee may design, plan, install and test a modification prior to receiving the license amendment/exemption, to the extent that these preliminary activities do not themselves require prior NRC approval.

For example, a modification to a facility involved the replacement of a train of a safety system with one including diverse primary components (diesel-driven pump versus a motor-driven pump). The installation of the replacement train was largely in a new, separate structure. Ultimately the modification would require NRC approval because of impacts on the technical specifications as well as differences in reliability of the replacement pump in some situations. There was insufficient time to seek and gain NRC approval prior to construction. The licensee prepared a change process screening to support construction of the separate structure through preliminary testing. The limited interfaces with the existing facility were assessed and determined to not change the facility or procedures as described in the UFSAR. Upon receipt of the license amendment, the final tie-in, testing and operation were fully authorized. The Section VIII.B.5 change process should be applied to any aspects of the proposed departure or change not adequately addressed in the license amendment request and/or associated safety evaluation report.

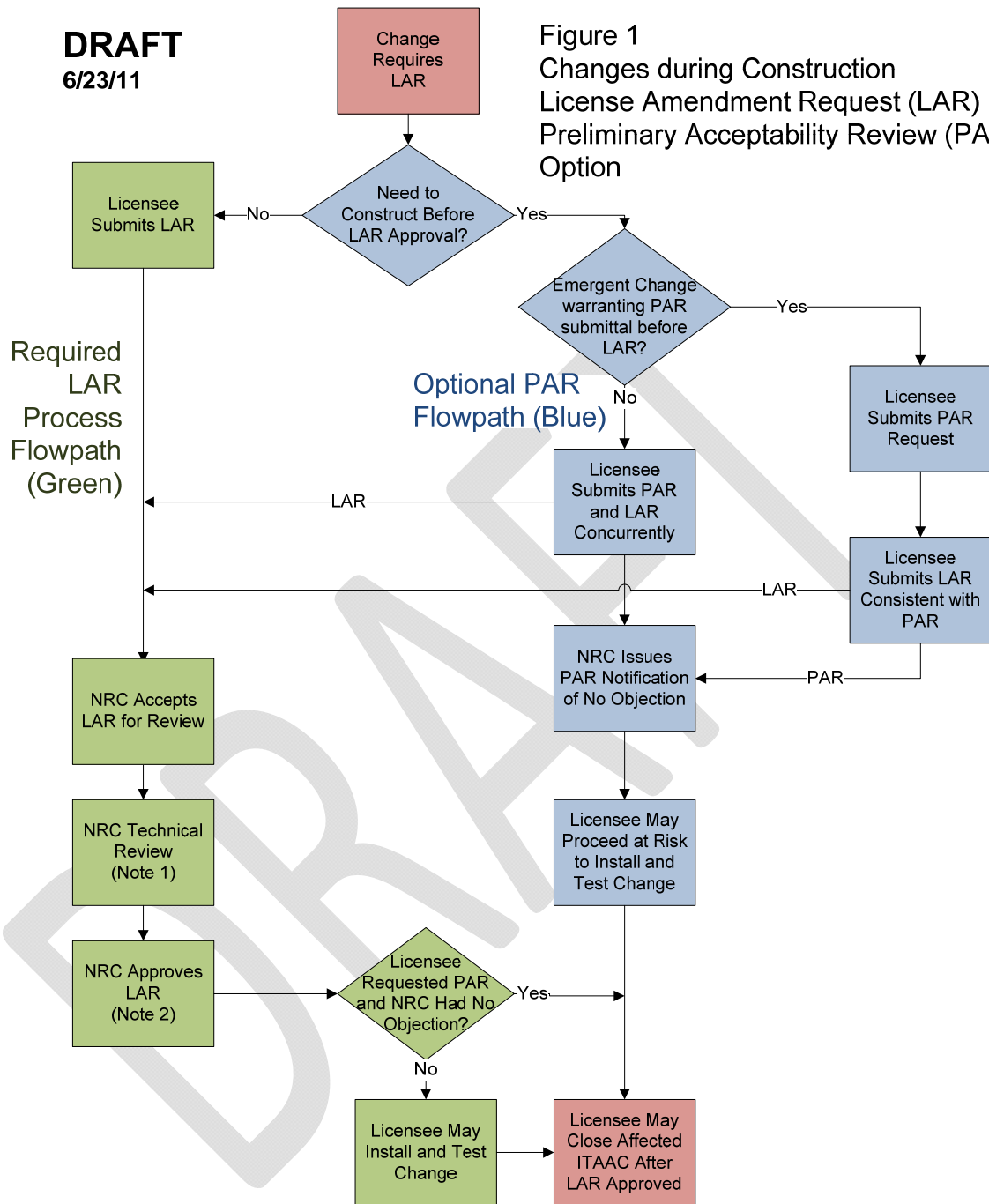
For proposed departures that are determined to require prior NRC approval, there are three possible options:

- (1) Cancel the planned departure or change.
- (2) Redesign the proposed departure or change so that it may proceed without prior NRC approval.
- (3) Apply for and obtain a license amendment under 10 CFR 50.90 prior to implementing the departure or change. Technical and licensing evaluations performed for such departures/changes may be used as part of the basis for license amendment requests.

It is important to remember that determining that a proposed departure or change requires prior NRC approval does not determine whether it is safe. In fact, a proposed departure or change that requires prior NRC approval may significantly enhance overall plant safety at the expense of a small adverse impact in a specific area. It is the responsibility of the licensee to assure that proposed activities are safe, and it is the role of the NRC to confirm the safety of those activities that are determined to require prior NRC review.

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Figure 1
Changes during Construction
License Amendment Request (LAR)
Preliminary Acceptability Review (PAR)
Option



Note 1 – If NRC technical review takes longer than expected or if the construction schedule accelerates, the licensee may request a PAR after the LAR is submitted.

Note 2 – NRC may request additional information and may ultimately deny the LAR. In the event that an NRC PAR Notification was issued and at-risk work was performed, the licensee would need to restore SSCs to the approved design or an alternative configuration acceptable to the NRC.

Preliminary Acceptability Review (PAR) Request Template

PAR Request Number	Station Name	Unit Number	PAR Request Date
1. NRC PAR Notification Requested Date (see Block 8 for basis) _____ Enter the date by which the NRC is requested to issue the PAR notification. Block 9 should provide the basis for the requested date.			
2. License Amendment Request References (as applicable) <input type="checkbox"/> LAR submittal date and letter number _____ <input type="checkbox"/> Expected LAR submittal date _____ If the associated LAR was previously submitted or is being submitted concurrent with the PAR, mark the top box and enter the LAR submittal letter number and date. If the LAR has not been submitted, mark the lower box and enter the expected LAR submittal date.			
3. Brief Description of Proposed Change Enter a summary description of the proposed change. Note: a complete description of the proposed change should be provided in the LAR.			
4. Reason for License Amendment Request Briefly summarize the reason for concluding that an LAR is required (i.e., a summary of the change process evaluation).			
5. Is Exemption Request Required? <input type="checkbox"/> Yes <input type="checkbox"/> If Yes, Briefly Describe Reason for Exemption Mark the Yes or No box to indicate whether or not an exemption request is required. If Yes, enter the reason for concluding that an exemption request is required. The exemption request, including complete technical bases, should be provided with the LAR.			
6. Identify Applicable Precedents <ul style="list-style-type: none"> • Prior applicant experience with similar amendments or licensing actions. • Experience with similar licensing actions at plants with a similar design and licensing basis. Guidance for identifying LAR precedents is provided in NEI 06-02, <i>License Amendment Request Guidelines</i> , Revision 2.			
7. Preliminary Assessment of Significant Hazards Consideration [10 CFR 50.92(c)] Summarize the preliminary assessment of whether or not the proposed change involves a significant hazards consideration based on the criteria of 10 CFR 50.92(c). Note: the complete technical bases for the licensee's no significant hazards consideration determination should be provided in the LAR.			

PAR Request Number	Station Name	Unit Number	PAR Request Date
8. Preliminary Assessment of Categorical Exclusion from Environmental Review [10 CFR 51.22] <p>Summarize the preliminary assessment of whether or not the proposed change qualifies for an exclusion from environmental review under 10 CFR 51.22. Note: the complete technical bases for the licensee's determination regarding environmental review exclusion should be provided in the LAR.</p> <p>For changes that do not qualify for categorical exclusion, provide additional information on the scope of proposed work that may be performed without irreversible environmental impact.</p>			
9. Impact of Change on Installation and Testing Schedules <p>Summarize the results of the evaluation of the impact of the proposed change on the installation and testing schedules for affected SSCs. This block should provide the basis for the date the NRC is requested to issue the PAR notification (Block 1) and should identify the following types of inspectability impacts resulting from the proposed change:</p> <ul style="list-style-type: none"> • acceleration or delay in planned installation or test activities • inaccessibility of certain SSCs for NRC inspection following the change • new or modified activity with a limited window for NRC inspection 			
10. Impact of Change on ITAAC <p>Summarize the results of the evaluation of the impact of the proposed change on ITAAC. The summary should describe plans for any new or modified ITAAC, or the removal of any ITAAC, along with the reason for such changes. An estimated schedule for the installation and testing activities associated with the proposed change(s) should be included. This block should also identify specific activities for which direct inspection can only take place within a given time frame. For example, licensees should identify when proposed new tests, including one-time type tests, will be performed, and when changes will become inaccessible for inspection due to ongoing construction activities.</p>			
11. Additional Information <p>This PAR section is optional and may be used to provide any additional information that may facilitate the NRC's review. Enter "None" if no additional information is provided.</p>			
12. Preparer Name (Print)	13. Preparer Signature	14. Date	
15. Reviewer Name (Print)	16. Reviewer Signature	17. Date	
18. Approver Name (Print)	19. Approver Signature	20. Date	