

**Interim Staff Guidance
on Changes during Construction Under 10 CFR Part 52
COL-ISG-025**

Issuance Status:

For Use and Comment

Background:

New nuclear power plant construction must be conducted in accordance with the combined license (COL) current licensing basis (CLB)¹, the Atomic Energy Act, and the applicable regulations. The change process for the COL is set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 52.98(f). Certain changes to the facility as described in the Final Safety Analysis Report (FSAR) do not require prior U.S. Nuclear Regulatory Commission (NRC) approval. Other changes require a license amendment or exemption and require NRC approval in advance of the construction² of the plant change or modification. For the purpose of maintaining licensing basis configuration control and in order to avoid unnecessary construction delays related to changes during construction (hereafter referred to as “CdC”) arising after the issuance of the COL and before the 10 CFR 52.103(g) finding, there shall be a 10 CFR 50.90 license amendment request (LAR) preliminary amendment request (PAR) process, as described below.

Issue Discussion:

A licensee that desires to depart from its CLB must evaluate and determine if the desired plant change or modification requires NRC approval, via a license amendment or exemption, prior to constructing the plant change or modification. The licensee's evaluation process comprises several successive steps, including an applicability determination evaluation, the safety-security interface evaluation, the construction impacts evaluation and the 10 CFR 50.59-like³ screening evaluation.

¹ As defined in 10 CFR 54.3 – CLB is the set of NRC requirements applicable to a specific plant and a licensee's written commitments for ensuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 26, 30, 40, 50, 51, 52, 54, 55, 70, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions; and technical specifications. It also includes the plant-specific design-basis information defined in 10 CFR 50.2 as documented in the most recent final safety analysis report as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

² Construction as defined in 10 CFR 50.10 is, in part, the in-place assembly, erection, fabrication or testing for specified SSCs.

³ The “10 CFR 50.59 like” criteria are set forth in Sections VIII B.5.b and VIII.B.5.c of the Part 52 Appendices for each certified design. Changes not within the scope of the certified design are governed by 10 CFR 50.59.

Enclosure

When the licensee's screening evaluation process determines that NRC approval, via license amendment or exemption, is required for the desired departure from the CLB, the licensee may elect to use the PAR process as the precursor to the normal LAR process. The PAR process addresses anticipated plant changes and modifications as well as emergent plant changes.

The PAR process preserves the design configuration control mechanisms while avoiding unnecessary construction schedule delays by creating a process whereby the licensee can request a notification that the NRC has no objection to the licensee installing and testing the proposed changed design feature pending NRC's review of the LAR.

The PAR and related LAR requests may describe proposed plant changes or modifications that require a license amendment (and possible exemption) solely because they describe a change to Tier 1 or Tier 2* information and not because the change represents a potential safety issue. This is analogous to Technical Specification changes under 10 CFR Parts 50 and 52, which always require a license amendment independent of their safety significance.

The PAR process is made effective via a license condition in the initial COLs to ensure the NRC staff has sufficient information to effectively perform inspection and verification of construction activities associated with CdCs requiring NRC approval. The result of the PAR process is a determination of whether the NRC has any objection to a licensee proceeding with the installation and testing of a proposed plant change or proposed modification requiring a license amendment or exemption while the NRC is conducting the technical review of the related LAR. A licensee may proceed with installation and testing only upon receipt of the No Objection PAR determination notification. The NRC "No Objection" determination of the PAR is not a pre-approval of the LAR on its technical merits, nor does it imply any NRC approval of the LAR. If the LAR is subsequently approved, the licensee would change the licensing basis in its Final Safety Analysis Report (FSAR). If the LAR is subsequently denied, the licensee must return the facility to its CLB. In all cases, the licensee must obtain the NRC LAR determination for the changed or modified SSC prior to the completion of its inspections, tests, analyses and acceptance criteria (ITAAC) and the related ITAAC Closure Notification⁴ submittal to the NRC.

Rationale:

The NRC developed this guidance to provide the method for NRC staff to respond to a PAR by performing a review of the PAR's no significant hazards consideration determination, categorical exclusion from environmental review, and impact on ITAAC and verifying the PAR is accurately reflected in the LAR, to ensure the health and safety of the public and the common defense and security will be maintained.

Staff Guidance:

Through this document, NRC staff provides interim staff guidance (ISG) detailing the process by which NRC staff will review a licensee's PAR submission.

⁴ 10 CFR 52.99(c)(1) - ITAAC Closure Notification.

Preliminary Amendment Request Process

The objection or no objection determination of the PAR is part of the continuous process of managing issues related to nuclear power plant construction. The review of PAR submissions and their related license amendment or exemption requests is one of the primary mechanisms for regulating changes to the CLB of the facility under construction. **Frequent and early communications between the staff and the licensee can help avoid unnecessary delays in the processing of licensing actions.** Discussions between the licensee and staff members regarding future licensing action requests prior to submittal are encouraged to allow sufficient exchange of information concerning technical information, schedules and resource planning.

The licensee may use the PAR process for license amendments at any time before the 10 CFR 52.103(g) finding. To use the PAR process, the licensee should submit a written request to the NRC in accordance with COL-ISG-025, *Changes during Construction under 10 CFR Part 52*. NEI 96-07 provides guidance on the preparation and submittal of PAR submissions.

The NRC will not issue a determination on the PAR until the licensee submits the related LAR. The NRC's PAR determination letter will state whether the licensee may proceed in accordance with the PAR, LAR and COL-ISG-025. A PAR determination is not a pre-approval of the LAR, nor does it imply any NRC approval of the LAR. If the licensee elects to proceed with construction after receiving the NRC's PAR determination of "No Objection" and the LAR is subsequently denied, the licensee must return the facility to its CLB.

The timeframe for issuance of the PAR determination notification will be established with consideration of the licensee's construction schedules and NRC resources.

Preliminary Amendment Request Responsibilities

The Director, Office of New Reactors (NRO) or designee is responsible for the final authorization of the PAR Determination Letter.

The Division Director, Division of New Reactor Licensing or designee is responsible for the recommendation contained in the PAR Determination Letter.

The Branch Chief, Projects Branch or designee is the designated recipient of the licensee's PAR and is responsible for the assignment of a project manager (PM) to facilitate the PAR review and associated correspondence with the licensee.

The PM is responsible for the preparation, concurrence and transmittal of the PAR Determination Letter to the requesting licensee. When possible, the PAR and LAR should be managed by the same PM.

The Division of Construction Inspection and Operational Programs (DCIP) Construction Operations Engineer is responsible for determining whether the licensee has provided a sufficient description of the impact of the proposed plant change or modification on associated ITAAC (if any) and providing a recommendation for the PAR Determination Letter to the PM. The Construction Operations Engineer will communicate and coordinate with Region II Center for Construction Inspection (RII/CCI) as necessary.

The Technical Divisions shall assist the Project Manager and the Construction Operations Engineer, upon request, in performing the reviews of no significant hazards, categorical exclusion from environmental review, and ITAAC clarity and understanding.

Review of a Preliminary Amendment Request

Review PAR for Completeness

After the PM receives the PAR submission, the task of reviewing the request for completeness should immediately begin. The minimal requirements for PARs are listed below:

- Oath or affirmation⁵
- Date by which a PAR determination is requested
- Description of the proposed change
- Review of no significant hazards consideration determination (50.92)
- Review of categorical exclusion from environmental review (51.22(c))
- Description of the impact on associated ITAAC (if any)

If a licensee's PAR does not include one or more of the aforementioned items, the PM should contact the licensee and arrange for the information to be submitted. Under these circumstances, the licensee may withdraw the request or may correct the deficiencies within a mutually agreed upon time. If the licensee does not correct the deficiencies within the specified time, the request may be denied. If a request is denied due to a deficiency in the submittal (as opposed to a definitive, negative finding by the staff based upon the merits of the PAR), then a licensee may submit a new PAR submission (with the identified discrepancies corrected) in the future.

The PM should also perform a preliminary review to determine the scope of the request, the adequacy of the licensee's no significant hazards consideration determination, and the reasonableness of the environmental review categorical exclusion.

The PM should determine if the licensee's submittal includes any Sensitive Unclassified Non-Safeguards Information (Controlled Unclassified Information) including proprietary information. The PM is responsible for the review of the material requested to be withheld from the public to ensure that the information satisfies the criteria of 10 CFR 2.390. PMs may find additional guidance pertaining to proprietary information in NRR OI-LIC-201, "Handling Requests to Withhold Proprietary Information from Public Disclosure," and may also obtain assistance in making this determination from licensing assistants, Technical Branch staff, Nuclear Security and Incident Response staff, and the Office of the General Counsel staff.

Establish PAR Review Schedule

The schedule is developed by the PM and communicated to the licensee. The PM should resolve any concerns or issues raised by the licensee with respect to the staff's schedule of the PAR evaluation. PAR submissions under emergent circumstances are coordinated by the PM and do not require the additional development of scheduling information.

⁵ RIS 2001-018, "NRC Regulatory Issue Summary 2001-018: Requirements for Oath or Affirmation," August 22, 2001, ADAMS Accession No. ML010990211

Review of No Significant Hazards Consideration Determination (50.92)

The PM shall review the adequacy of the PAR's preliminary "no significant hazards consideration" determination, enlisting the assistance of the Technical Divisions as necessary to establish that the PAR does not result in the creation of a significant hazards consideration.

Review of Categorical Exclusion from Environmental Review (51.22(c))

The PM shall review the reasonableness of the PAR's preliminary determination of categorical exclusion from environmental review, enlisting the assistance of the Technical Divisions as necessary to establish that the PAR is contained within one or more of the exclusion categories.

Review of the Description of the Impact on Associated ITAAC

The Construction Operations Engineer will review the ITAAC Impact Description provided in the PAR to ensure clarity and understanding of the proposed change on associated ITAAC. The Construction Operations Engineer will communicate with Region II/CCI as appropriate during the review.

Related License Amendment or Exemption Request Review

The NRC will not issue a determination on the PAR until the licensee submits the related LAR.

The PM is responsible for ensuring the PAR submission accurately reflects the plant change or modification addressed in the related license amendment or exemption request. During the construction phase, SSCs installed and tested on the basis of a PAR that do not correspond to the related license amendment or exemption request would distort the relationship between the physical as-built plant and the CLB of the facility, unnecessarily complicating inspection, verification and validation of the facility during construction.

Basis for Denial under Related License Amendment or Exemption Request

- PAR does not correspond accurately or technically with LAR
- PAR technical scope exceeds the LAR technical scope, (inverse is acceptable)

PAR Determination Communications to Licensee

When the Construction Operations Engineer completes the review of PAR ITAAC impact, a recommendation will be provided to the PM. The PM will prepare the PAR Determination Letter for internal concurrence and transmittal to the licensee.

Close Out of the PAR Review

PAR submissions, RAIs, responses, licensee communications, supporting documentation, research, evaluations and determinations shall be closed-out and retained in the related License Amendment or Exemption Request project.

Attachments

Attachment 1 - Preliminary Amendment Request Review Template

Attachment 2 - Preliminary Amendment Request Determination Letter, No Objection

Attachment 3 - Preliminary Amendment Request Determination Letter, Objection

Information Collection:

The information collections contained in this ISG are covered by the requirements of 10 CFR Part 52, which were approved by the Office of Management and Budget (OMB), approval number 3150-0151. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Final Resolution Method:

This issue will be resolved in the next revision to Regulatory Guide 1.187, "Guidance for Implementation for 10 CFR 50.59, Changes, Tests, and Experiments" (ADAMS Accession Number ML003759710).

Congressional Review Act:

The draft interim staff guidance has not resulted in and is not likely to result in –

- (A) an annual effect on the economy of \$100 million or more;
- (B) any increase in costs or prices for consumers, individual industries, or geographical regions; or
- (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

This draft guidance is a NRC staff review process and will not change the burden to licensees and may result in the reduction of burden. Thus, the additional cost as a result of this draft interim staff guidance will be \$0.00.

Applicability:

This ISG is applicable to Part 52 COL licensees.

Backfit Determination:

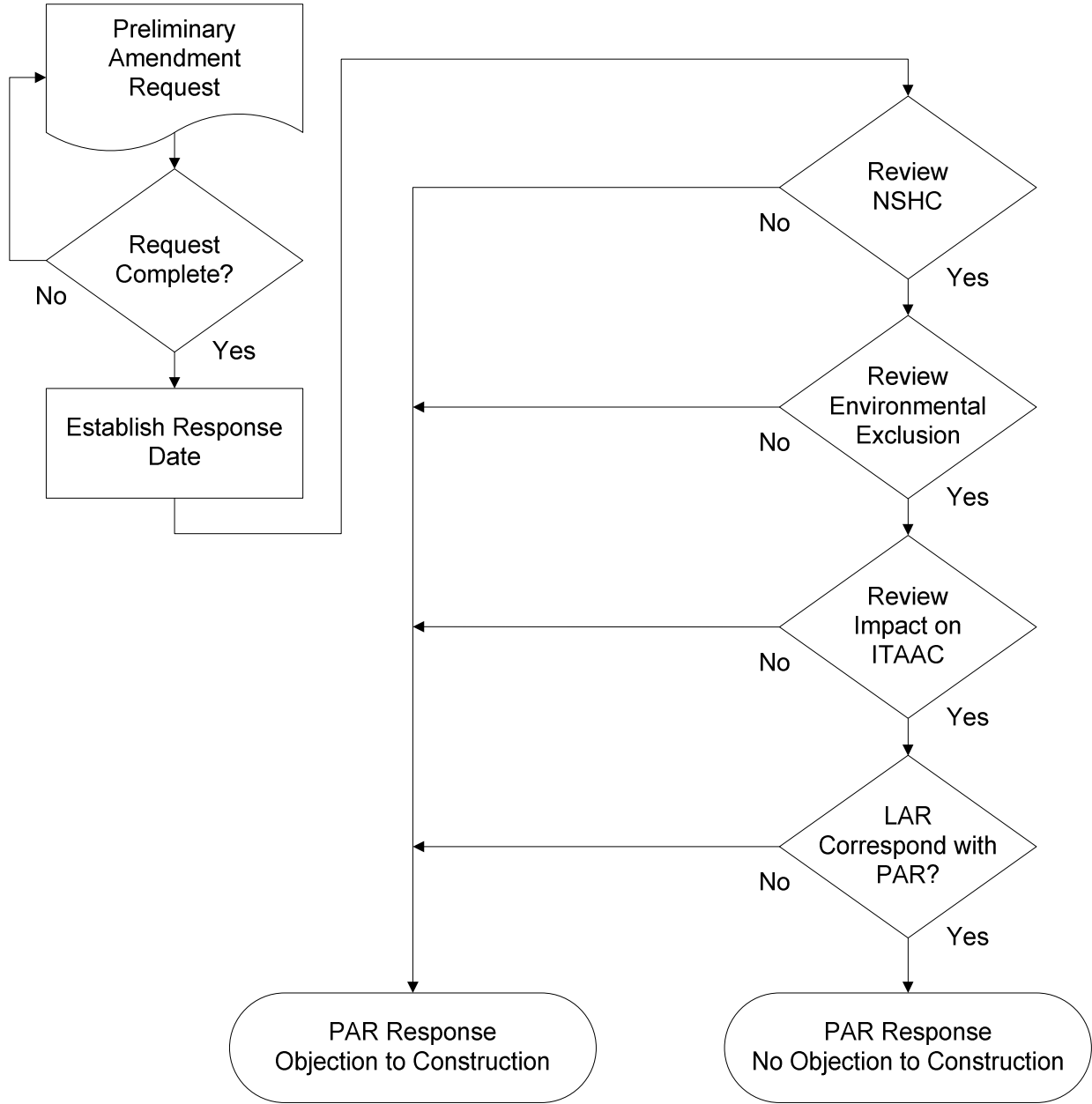
Licensees may voluntarily follow the PAR process described in this draft ISG. Methods that differ from those described in this ISG may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative demonstrates compliance with the appropriate NRC regulations.

The NRC staff does not intend to approve any imposition or backfitting of the guidance in this ISG. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this ISG. The NRC staff does not expect or plan to request licensees to voluntarily adopt this ISG to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action that would require the use of this ISG.

References:

- (1) NRC, NRR OI No. LIC-100, "Control of Licensing Bases for Operating Reactors," Revision 1, January 7, 2004, ADAMS Accession No. ML033530249.
- (2) NRC, NRR OI No. LIC-101, "License Amendment Review Procedures," Revision 3, February 2004, ADAMS Accession No. ML040060258.
- (3) "Final Interim Staff Guidance DC/COL-ISG-011 on Freeze Point on the Design Bases Information," November 2009, ADAMS Accession No. ML092890623.
- (4) NUREG-0800, Table of Contents, "Standard Review Plans for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007, ADAMS Accession No. ML070810350.
- (5) RIS 2001-018, "NRC Regulatory Issue Summary 2001-018: Requirements for Oath or Affirmation," August 22, 2001, ADAMS Accession No. ML010990211.
- (6) RIS 2001-022, "NRC Regulatory Issue Summary 2001-022 Attributes of a Proposed No Significant Hazards Consideration Determination," November 20, 2001, ADAMS Accession No. ML011860215.
- (7) RG 1.181, "Content Of The Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," September 1999, ADAMS Accession No. ML003740112.
- (8) RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," November 2000, ADAMS Accession No. ML003759710.
- (9) RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June, 2007, ADAMS Accession No. ML070720184 (Package).
- (10) SRM-SECY-98-224, "Staff and Industry Activities Pertaining to the Management of Commitments made by Power Reactor Licensees to the NRC," September 28, 1998, ADAMS Accession No. ML992870043.
- (11) SRM-SECY-00-0092, "Staff Requirements - SECY-00-0092 - Combined License Review Process," September 5, 2000, ADAMS Accession No. ML003747332.
- (12) SRM-SECY-09-0190, "Staff Requirements - SECY-09-0190 - Major Revision to NRC Enforcement Policy," August 27, 2010, ADAMS Accession No. ML102390327.
- (13) SRM-SECY-10-0121, "Staff Requirements - SECY-10-0121 - Modifying the Risk-Informed Regulatory Guidance for New Reactors," March 2, 2011, ADAMS Accession No. ML110610166.
- (14) NEI 96-07, Appendix C, "Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52, DRAFT, October 2010 ADAMS Accession No. ML 102980302

Preliminary Amendment Request Review Template



Preliminary Amendment Request Determination Letter, No Objection

(Date)
OFFICE OF NEW REACTORS
NOTICE OF NO OBJECTION FOR
PRELIMINARY AMENDMENT REQUEST

Addressee

SUBJECT: NOTICE OF NO OBJECTION FOR PRELIMINARY AMENDMENT REQUEST
PAR No: xx-xxxx, LAR No: xx-xxxx

Dear :

By Preliminary Amendment Request (PAR) dated (date of PAR), you requested that the U. S. Nuclear Regulatory Commission (NRC) determine if it had any objection to your proceeding with construction activities different from your current licensing basis while the NRC is evaluating the related license amendment request (LAR).

The Office of New Reactors (NRO) has completed its review of the PAR related to the LAR, identified above.

The NRC has no objection to you proceeding with the installation and testing of the proposed plant change or plant modification identified in the PAR/LAR pending the outcome of the NRC's detailed technical review of the LAR. You acknowledge that if the LAR is denied you will return the plant to its current licensing basis.

This evaluation of the PAR is not a pre-approval of the related LAR, nor does it imply any NRC approval of the related LAR.

Sincerely,

(Name), Director
Division of New Reactor Licensing
Office of New Reactors

Docket No: 52-xxx

cc: See next page

Concurrence:

OFFICE	PM:DNRL:NRO	LA:DNRL:NRO	Tech Editor	PM:DCIP:NRO	OGC
NAME					
DATE					
OFFICE	D:DNRL:NRO	D:DCIP:NRO	D:NRO		
NAME					
DATE					

Preliminary Amendment Request Determination Letter, Objection

(Date)
OFFICE OF NEW REACTORS
NOTICE OF OBJECTION FOR
PRELIMINARY AMENDMENT REQUEST

Addressee

SUBJECT: NOTICE OF OBJECTION FOR PRELIMINARY AMENDMENT REQUEST
PAR No: xx-xxxx, LAR No: xx-xxxx

Dear :

By Preliminary Amendment Request (PAR) dated (date of PAR), you requested that the U.S. Nuclear Regulatory Commission (NRC) determine if it had any objection to your proceeding with construction activities different from your current licensing basis while the NRC is evaluating the related license amendment request (LAR).

The Office of New Reactors (NRO) has completed its evaluation of the PAR related to the LAR, identified above.

The PAR submitted does not conform to evaluation criteria XXXXX contained in COL-ISG-025, "Changes during Construction under 10 CFR Part 52," for the following reasons XXXXX. Therefore, this PAR is denied.

This evaluation of the PAR is not a denial of the related LAR.

Sincerely,

(Name), Director
Division of New Reactor Licensing
Office of New Reactors

Docket No: 52-xxx

cc: See next page

Concurrence:

OFFICE	PM:DNRL:NRO	LA:DNRL:NRO	Tech Editor	PM:DCIP:NRO	OGC
NAME					
DATE					
OFFICE	D:DNRL:NRO	D:DCIP:NRO	D:NRO		
NAME					
DATE					