



**COMBINED LICENSE
COL-ISG-025**

on Changes During Construction Under 10 CFR Part 52

Interim Staff Guidance

July 2015

(Final)

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

Issuance Status:

Final

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) 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, an exemption, or both, 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, an exemption, or both, prior to constructing the plant change or modification. The licensee’s evaluation process comprises several successive steps, including the safety-security interface evaluation, the construction impacts evaluation and the 10 CFR 50.59 and 10 CFR 50.59-like³ evaluation (including applicability determination, screening and evaluation, as applicable).

If the licensee’s screening/evaluation process determines that NRC approval via a license amendment, an exemption, or both, is required for the desired departure from the CLB, the licensee may elect to use the PAR process. The PAR process preserves the design configuration control mechanisms while avoiding unnecessary construction delays by creating a process whereby a licensee can opt to submit a request to the NRC seeking a determination on whether the NRC objects to the licensee proceeding with construction changes, subject to strict conditions, before the NRC’s review of the LAR is complete. If the NRC determines it has no objection to the licensee’s request, the licensee may proceed with the construction change, but

¹ In this ISG, the staff uses the term “current licensing basis” in the sense that the term is used in 50.54(f).

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 10 CFR Part 52 Appendices for each certified design. Changes not within the scope of the certified design are governed by 10 CFR 50.59.

the licensee is required to return the facility to its CLB should the related LAR be withdrawn or denied.

The PAR and related LAR requests may describe proposed plant changes or modifications that require a license amendment (and possibly an exemption) because they describe a change to Tier 1⁴ or Tier 2*⁵ information and, as part of the certification of the referenced design, such changes were determined to require prior NRC approval. This is analogous to Technical Specification changes under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," which always require a license amendment.

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 construction and testing of a proposed plant change or proposed modification requiring a license amendment or exemption while the NRC is conducting the detailed technical review of the related LAR. A licensee may proceed with construction 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 updated final safety analysis report (UFSAR). 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 structure, system or component (SSC) prior to the completion of its inspections, tests, analyses and acceptance criteria (ITAAC) and the related ITAAC Closure Notification⁶ 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 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 Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by a design certification rule appendix (Tier 1 information) to Part 52. The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes: (1) Definitions and general provisions; (2) Design descriptions; (3) Inspections, tests, analyses, and acceptance criteria (ITAAC); (4) Significant site parameters; and (5) Significant interface requirements.

⁵ Tier 2* means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of a design certification rule appendix to Part 52. This designation expires for some Tier 2* information under paragraph VIII.B.6.

⁶ 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 submission 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 this ISG. Nuclear Energy Institute (NEI) 96-07, Appendix C provides guidance on the preparation and submittal of PAR submissions.

The NRC will not issue a determination on the PAR until: (1) the licensee submits the related LAR; and (2) the NRC has accepted the related LAR for detailed technical review⁷. The NRC's PAR determination letter will state whether the licensee may proceed in accordance with the PAR, LAR and COL-ISG-025. The 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 withdrawn or 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 (DNRL) or designee is responsible for the recommendation contained in the PAR determination letter.

The Branch Chief, Licensing Branch (LB) 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.

⁷ The NRC's acceptance review of the LAR includes confirmation that the LAR contains a proposed no significant hazards consideration (NSHC) determination and a basis for asserting that, with respect to the NRC's review pursuant to the National Environmental Policy Act, the LAR qualifies for a categorical exclusion under 10 CFR 51.22.

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 (RII) as necessary.

Review of a Preliminary Amendment Request

Review PAR for Completeness

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

- Oath or affirmation⁸
- Date by which a PAR determination is requested
- Description of the proposed change
- 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 13 working days or a mutually agreed upon time⁹. 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 (with the identified discrepancies corrected) in the future.

The licensee's submittal may include 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 Office of Nuclear Reactor Regulation, Office Instruction (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, Office of 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, compelling a more rapid

⁸ RIS 2001-018, "NRC Regulatory Issue Summary 2001-018: Requirements for Oath or Affirmation," August 22, 2001, ADAMS Accession No. ML010990211.

⁹ NRR OI LIC-109, "Acceptance Review Procedures."

review, are coordinated by the PM and do not require the additional development of scheduling information.

Review of the Description of the Impact on Associated ITAAC

The Construction Operations Engineer, with the assistance of the respective technical divisions, 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 as appropriate during the review.

Related License Amendment or Exemption Request Review

The NRC will not issue a determination on the PAR until: (1) the licensee submits the related LAR; and (2) the NRC has accepted the related LAR for detailed technical review.

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 constructed 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

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

PAR Determination Communications to Licensee

When the Construction Operations Engineer completes the review of the 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. The respective technical divisions that were consulted in the PAR review shall be included on concurrence.

Close Out of the PAR Review

The PAR submissions, requests for additional information, responses, licensee communications, supporting documentation, research, evaluations and determinations shall be closed-out and retained with the related license amendment and/or exemption request project/Agencywide Documents Access and Management System (ADAMS) package.

Attachments

Attachment 1 - Preliminary Amendment Request Determination Letter, No Objection
Attachment 2 - 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 either in a new Regulatory Guide (RG) or in the next revision to RG 1.187, "Guidance for Implementation for 10 CFR 50.59, Changes, Tests, and Experiments" (ADAMS Accession Number ML003759710).

Congressional Review Act:

The draft ISG 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 ISG will be \$0.00.

Applicability:

This ISG is applicable to 10 CFR Part 52, COL licensees with a "Changes during Construction" license condition.

Backfitting and Issue Finality:

The ISG addresses the staff's consideration of preliminary amendment requests submitted by both current and future holders of COLs under 10 CFR Part 52 with a "Changes during Construction" license condition. The staff's position is based upon the following considerations.

1. *The ISG positions do not constitute backfitting or an inconsistency with issue finality provisions, inasmuch as the ISG is internal guidance to NRC staff*

The ISG provides internal guidance to the staff on how to review an application for NRC regulatory approval in the form of licensing. In particular, it describes the NRC's internal processes for processing preliminary amendment requests, including scheduling, assignment of review responsibilities within the technical staff, and the necessary prerequisites for NRC

issuance of the preliminary amendment. Staff guidance on internal processes are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of 10 CFR Part 52.

2. *Backfitting and issue finality do not – with limited exceptions not applicable here – protect current or future applicants and licensees*

Applicants and potential applicants, and licensees are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR Part 52. This is because neither the Backfit Rule nor the issue finality provisions under 10 CFR Part 52 – with certain exclusions discussed below – were intended to apply to every NRC action which substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR Part 52 license (e.g., an early site permit) and/or NRC regulatory approval (e.g., a design certification rule) with specified issue finality provisions. However, the matters covered in this ISG are not subject matters or issues for which issue finality protection is provided, as the ISG addresses matters of internal NRC staff procedures.

References:

1. Nuclear Energy Institute, NEI 96-07, Appendix C Revision 0 - Corrected "Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52," March 2014 ADAMS Accession No. ML14091A739
2. U.S. Nuclear Regulatory Commission, "Finalizing Licensing-basis Information," DC/COL-ISG-011, November 2009, ADAMS Accession No. ML092890623.
3. U.S. Nuclear Regulatory Commission, "Control of Licensing Bases for Operating Reactors," Revision 1, NRR OI LIC-100, January 7, 2004, ADAMS Accession No. ML033530249.
4. U.S. Nuclear Regulatory Commission, "License Amendment Review Procedures," Revision 3, NRR OI LIC-101, February 2004, ADAMS Accession No. ML040060258.
5. U.S. Nuclear Regulatory Commission, Table of Contents, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007, NUREG-0800, ADAMS Accession No. ML070810350.
6. U.S. Nuclear Regulatory Commission, "NRC Regulatory Issue Summary 2001-018: Requirements for Oath or Affirmation," RIS 2001-018, August 22, 2001, ADAMS Accession No. ML010990211.
7. U.S. Nuclear Regulatory Commission, "NRC Regulatory Issue Summary 2001-022 Attributes of a Proposed No Significant Hazards Consideration Determination," RIS 2001-022, November 20, 2001, ADAMS Accession No. ML011860215.

8. U.S. Nuclear Regulatory Commission, "Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," RG 1.181, September 1999, ADAMS Accession No. ML003740112.
9. U.S. Nuclear Regulatory Commission, RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," November 2000, ADAMS Accession No. ML003759710.
10. U.S. Nuclear Regulatory Commission, RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007, ADAMS Accession No. ML070720184 (Package).
11. U.S. Nuclear Regulatory Commission, 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.
12. U.S. Nuclear Regulatory Commission, SRM-SECY-00-0092, "Staff Requirements - SECY-00-0092 - Combined License Review Process," September 5, 2000, ADAMS Accession No. ML003747332.
13. U.S. Nuclear Regulatory Commission, SRM-SECY-09-0190, "Staff Requirements - SECY-09-0190 - Major Revision to NRC Enforcement Policy," August 27, 2010, ADAMS Accession No. ML102390327.
14. U.S. Nuclear Regulatory Commission, 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.

Preliminary Amendment Request Determination Letter, No Objection

(Date)

Addressee

SUBJECT: NOTICE OF NO OBJECTION FOR PRELIMINARY AMENDMENT REQUEST
(PAR No: xx-xxxx), □TITLE□ FOR THE (enter licensee facility).

Dear Mr./Ms. xxxxx:

By letter dated (date of PAR), (enter licensee) submitted a Preliminary Amendment Request (PAR) xx-xxxx (Agencywide Document Access and Management System Accession Number MLxxxxxxxx) notifying the U. S. Nuclear Regulatory Commission (NRC) that, absent NRC objection, pending the outcome of the NRC's detailed technical review of License Amendment Request (LAR) xx-xxxx, (enter licensee) will proceed with the installation of proposed plant changes related to xxxx presented in Updated Final Safety Analysis Report (UFSAR) Subsection xxxx.

As required by License Condition 2.D(1), the NRC has received the license amendment request (LAR xx-xxxx) referenced in PAR xx-xxxx. The staff has evaluated the license amendment documentation supporting LAR xx-xxxx and has determined that there is sufficient information to accept LAR xx-xxxx for detailed technical review (ADAMS Accession Number MLxxxxxxxx).

The NRC staff has determined that PAR xx-xxxx contained sufficient information on the impact of the proposed plant change on associated Inspections, Tests, Analyses and Acceptance Criteria (ITAAC). In addition, the NRC staff has reviewed the scope of PAR xx-xxxx and found that it is consistent with the changes from the current licensing basis as requested in LAR xx-xxxx. Therefore, the NRC has no objection to (enter licensee) proceeding with the construction of the proposed plant change identified in PAR xx-xxxx pending the outcome of the NRC's detailed technical review of LAR xx-xxxx. (enter Licensee) acknowledges that if LAR xx-xxxx is denied (enter licensee) will return the plant to its current licensing basis as required by License Condition 2.D.(1)(b).

If you have any questions or comments concerning this matter, please contact the (Senior) Project Manager, (enter PM), at 301-415-xxxx or via e-mail at (enter PM email address).

Sincerely,

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

Docket No: 52-xxx

cc: See next page

Concurrence:

OFFICE	PM: NRO/DNRL	LA NRO/DNRL	PM: NRO/DCIP
NAME			
DATE			
OFFICE	BC: NRO/DNRL/LB	OGC	DD: NRO/DNRL
NAME			
DATE			

Preliminary Amendment Request Determination Letter, Objection

(Date)

Addressee

SUBJECT: NOTICE OF OBJECTION FOR PRELIMINARY AMENDMENT REQUEST
(PAR No: xx-xxxx), □TITLE□ FOR THE (enter licensee facility)

Dear Mr./Ms. xxxxx:

By letter dated (date of PAR), (enter licensee) submitted a Preliminary Amendment Request (PAR) xx-xxxx (Agencywide Document Access and Management System Accession Number MLxxxxxxxx) notifying the U. S. Nuclear Regulatory Commission (NRC) that, absent NRC objection, pending the outcome of the NRC's detailed technical review of License Amendment Request (LAR) xx-xxxx, (enter licensee) will proceed with the installation of proposed plant changes related to xxxx presented in Updated Final Safety Analysis Report (UFSAR) Subsection xxxx.

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 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.

If you have any questions or comments concerning this matter, please contact the (Senior) Project Manager, (enter PM), at 301-415-xxxx or via e-mail at (enter PM email address).

Sincerely,

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

Docket No: 52-xxx

cc: See next page

Concurrence:

OFFICE	PM: NRO/DNRL	LA NRO/DNRL	PM: NRO/DCIP
NAME			
DATE			
OFFICE	BC: NRO/DNRL/LB	OGC	DD: NRO/DNRL
NAME			
DATE			