

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

Issuance Status:

Draft - Proposed – Revision 01

Background:

New nuclear power plant construction must be conducted in accordance with the combined license (current licensing basis)¹, the Atomic Energy Act, and the applicable regulations. The change process for the combined license (COL) is set forth in 10 CFR 52.98. Certain changes to the facility 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 implementation of the plant change or modification. For the purpose of maintaining licensing basis configuration control and in order to avoid potential construction delays related to changes during construction arising after the issuance of the COL through the 10 CFR 52.103(g) finding, there shall be a 10 CFR 50.90 license amendment request acceptability review process, as described below.

Issue Discussion:

The holder of a COL that desires to depart from the current licensing basis must evaluate and determine if the desired plant change or modification requires NRC approval, via a license amendment or exemption, prior to implementing the plant change or modification (“Changes during Construction” hereafter referred to as “CdC”). The CdC evaluation process is comprised of several successive steps, including an applicability determination evaluation, the safety-security interface evaluation, the construction impacts evaluation and the 10 CFR 50.59 like² screening evaluation.

When the evaluation process determines that NRC approval, via license amendment or exemption, is required prior to implementation of the plant change or modification, attention is then directed to what does the term implemented describe. When a licensee is performing

¹ 10 CFR 54.3 – Current licensing basis (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 (FSAR) 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 The “10 CFR 50.59 like” criteria are defined in Section VIII B.5.b of the Part 52 Appendices for each certified design (A, B, C and D)

construction activities³, implemented shall mean when the SSC is relied upon to perform its intended function, or when the Inspection, Test, Analysis and Acceptance Criteria (ITAAC) for the SSC is completed and the ITAAC Closure Letter⁴ is submitted to the NRC. The construction phase of a COL is that period of time between the issuance of the COL license and the 10 CFR 52.103(g) finding. In all cases, implementation of changed or modified SSCs requiring a license amendment request or exemption shall precede the 10 CFR 52.103(g) finding.

To make certain the NRC staff has sufficient information to effectively perform inspection and verification of construction activities associated with CdCs requiring NRC approval, the License Amendment Request (LAR) Preliminary Acceptability Review (PAR) was developed and made effective via a condition of license in the Part 52 COL. The result of the PAR evaluation is a determination of whether the NRC has any objection to a COL holder 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 that request.

Rationale:

The NRC developed this guidance to identify the actions necessary on the part of the licensee to maintain the current licensing basis of the plant during the construction phase of a COL. In addition, this guidance provides a method for NRC staff to evaluate and respond to a PAR request to ensure effective inspection, verification and evaluation of the licensee's construction activities to maintain the health and safety of the public and the common defense and security.

Staff Guidance:

Through this document, NRC staff provides interim staff guidance (ISG) detailing the process by which a COL holder may proceed with the installation and testing of plant changes or modifications requiring a license amendment or exemption during the review of license amendment request. Specifically, this guidance contains the Preliminary Acceptability Review (PAR) process that the NRC staff employs to evaluate and respond to a licensee request for a PAR related to the license amendment request.

In addition, this guidance is the endorsement of Revision XX of Nuclear Energy Institute (NEI) 96-07 *Appendix C, Guideline for Implementation of Change Control Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52*, dated XXXXX, 2011, available at Agencywide Documents Access and Management System (ADAMS) ML102980302, which provides methods that are acceptable to the NRC staff for complying with the provisions of the change processes contained within 10 CFR Part 52.

Revision XX of NEI 96-07, Appendix C references other documents, but NRC's endorsement of Revision XX should not be considered an endorsement of the referenced documents.

Revision XX of NEI 96-07 Appendix C includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in Revision XX of NEI 96-07, Appendix

³ 10 CFR 50.10 - Construction – in-place assembly, erection, fabrication or testing for specified SSCs

⁴ 10 CFR 52.99 - ITAAC Closure Letter

C, the NRC's endorsement of Revision XX should not be considered a determination that the examples are applicable for all COL licensees. A COL licensee should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

To meet the requirements of the change processes contained within 10 CFR Part 52, COL holders may use methods other than those set forth in Revision XX of NEI 96-07, Appendix C. The NRC will determine the acceptability of other methods on a case-by case basis.

The Office of Nuclear Regulatory Research (NRR) Regulatory Guide (RG) 1.187, *Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments*, (ADAMS ML003759710) contains requirements for the process by which licensees may make changes to their facilities and procedures as described in the safety analysis report, without prior NRC approval, under certain conditions. NRR Office Instruction (OI) OI-LIC-100, *Control of Licensing Bases for Operating Reactors*, is useful when making decisions about creating, revising or deleting licensing basis information for operating reactors, and NRR OI-LIC-101, *License Amendment Review Procedures*, is useful when processing license amendment requests.

Preliminary Acceptability Review (PAR) Decision Process

The approval or denial of PAR requests is part of a continuous process of managing issues related to nuclear power plant construction. The review of PAR requests and their related license amendment or exemption requests is one of the primary mechanisms for regulating changes in the current licensing basis of the facility under construction. **Frequent and early communications between the staff and the licensee can help avoid unnecessary delays in the processing of license-related requests.** Pre-application review meetings or conference calls (discussions regarding future licensing action requests prior to the request being submitted) between the licensee and staff members are encouraged to allow sufficient exchange of information concerning schedule, technical information and/or resource planning.

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

Prior to NRO's issuance of a written PAR notification, the COL holder shall submit the related license amendment request (LAR). Thereafter, NRO will issue a written PAR notification, setting forth whether the COL holder 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 COL holder shall return the facility to its current licensing basis.

The timeframe for issuance of the acceptability decision will be established in consideration of the schedule expectations of the COL holder with the goal of minimizing delays in their construction plans/schedules. An NRO PAR decision is not a pre-approval of the LAR, nor does it imply any NRC approval of the LAR.

Preliminary Acceptability Review (PAR) Responsibilities

The Office Director, Office of New Reactors 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 COL holders PAR request and is responsible for the assignment of a Project Manager (PM) to facilitate the PAR evaluation and associated correspondence with the COL holder.

The Projects PM is responsible for the preparation, concurrence and transmittal of the PAR Determination Letter to the requesting COL holder. The Projects PM for the PAR may not be the responsible PM for the related license amendment or exemption request processing, although this continuity is suggested.

The Division of Construction Inspection and Operational Programs (DCIP) Construction Project Engineer is responsible for formulating the decision regarding the PAR request and providing a recommendation for the PAT Determination Letter. The Construction Project Engineer will

coordinate with Region II Center for Construction Inspection (RII CCI) and the NRO Technical Divisions as necessary to identify technical, process and schedule impacts of the PAR.

The NRO Technical Division and Construction Project Engineer shall assist the PM, as necessary, in the evaluation of ITAAC changes, additions or deletions identified in the PAR request and the identification and evaluation of additional potential impact on related SSCs and their associated ITAAC.

Evaluation of a PAR Request

Review PAR Request for Completeness and Acceptability

After the PM receives the PAR request the task of reviewing the request for completeness should immediately begin. The minimal requirements for preliminary applicability reviews are listed below:

- Oath and affirmation⁵
- PAR determination requested by date
- Related license amendment request identifier
- Description of the proposed change
- Description of the basis for the license amendment request
- Basis for exemption request (if required)
- Preliminary assessment of no significant hazards consideration determination (50.92)
- Preliminary assessment of categorical exclusion from environmental review (51.22(c))
- Assessment of the impact on installation and inspection schedules
- Assessment of impact on ITAAC

If a licensee's preliminary application 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 request (with the identified discrepancies corrected) in the future.

The PM should also perform a preliminary assessment to determine the scope of the request which should provide an initial position regarding the reasonableness of the proposed changes,

⁵ Oath or affirmation may be in the form of a notarized statement or may be within the cover letter for an preliminary acceptability review request in the form of a sentence similar to the following:

"I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on [date]".

Oath or affirmation statements are required on preliminary acceptability review requests, license amendment requests, exemption requests and supplements to such requests, including responses to request for additional information.

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 (SUNSI) (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 (LAs), Technical Branch staff, Nuclear Security and Incident Response (NSIR) staff and the Office of General Council (OGC) staff.

Prior to NRO's issuance of a PAR Notification Letter, the COL holder shall submit the related license amendment request (LAR).

Precedent PAR Reviews and Licensing Actions

Searching for, identifying, and using precedents in the preliminary applicability review process maximizes staff efficiency, minimizes the need to issue requests for additional information and ensures consistency of licensing actions. The search for a precedent should continue until the staff is satisfied that either 1) they have identified one or more appropriate precedents, or 2) that no appropriate precedents exist. PMs have the primary responsibility for conducting a precedent search but can be assisted by technical staff familiar with specific technical areas.

Establish PAR Request Evaluation 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 requests under emergent circumstances are coordinated by the PM and do not require the additional development of scheduling information.

Related License Amendment or Exemption Request

The PM is responsible for ensuring the PAR request 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, rapidly distort the relationship between the physical plant as-built and the current licensing basis of the facility. Historically, this has resulted in stop work orders and on occasion, the complete abandonment of SSCs or entire facilities.

Basis for Immediate 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 overlaps prior PAR without the prior related LAR approved

Identify PARs associated with the same or closely related SSCs
Proposed plant change or modification requested

Identification of the affected Structure, System or Component

Assessment of No Significant Hazards Consideration Determination (50.92)

The PM shall review the adequacy of the PAR's preliminary No Significant Hazards Consideration Determination and enlist the assistance of the Technical Divisions as necessary to establish that the PAR does not result in a significant hazard consideration.

Basis for Immediate Denial under No Significant Hazards Considerations

- PAR will result in a significant hazard consideration

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

The PM shall review the adequacy of the PAR's preliminary Categorical Exclusion from Environmental Review to establish that the PAR is contained within one or more of the exclusion categories.

Basis for Immediate Denial under Categorical Exclusion from Environmental Review

- PAR does not conform to the categorical exclusions of 10 CFR 51

Assessment of PAR Inspectability

The DCIP Project Engineer, with the assistance from RII CCI, will assess the inspectability of the PAR request taking into consideration the following:

- Construction schedule impacts
- Inspection schedule impacts
- Inspectability

The PAR request should contain information similar to a gap analysis between the original installation and inspection schedule and the proposed installation and inspection schedule.

Basis for Immediate Denial of the PAR under PAR Inspectability:

- Critical dimensions no longer accessible for verification
- Critical components no longer accessible for verification
- Non destructive testing parameters no longer accessible for verification
- One time testing scheduled or completed without opportunity for observation

Assessment of the ITAAC

The DCIP Project Engineer should request assistance from the NRO Technical Branch, if necessary, on the rationality of the modifications, additions or deletions to the ITAAC. The ITAAC were established to verify specific design commitments, COL license commitments, security SSCs, and emergency planning program attributes. A rigorous evaluation of resultant ITAAC modifications, additions or deletions is required to ensure the underlying basis for the ITAAC is not negated. Targeted ITAAC computations may also be effected by a plant change or modification and should be thoroughly evaluated by the Construction Inspection Branch to ensure adequate test representation is available for support a reasonable assurance determination of the testing schema.

Within the families of ITAAC, there is a subset identified as Complex ITAAC. Complex ITAAC are dependent on a technical analysis, technical report or equivalent documentation to satisfy the corresponding acceptance criteria. Usually, the inspection of complex ITAAC involves some level of technical review beyond the standard field verifications.

Basis for Immediate Denial of the PAR under ITAAC:

- PAR involves complex ITAAC

Cumulative Effects of PAR Requests

The PMs should verify that PAR request do not unreasonably compound upon one-another or augment or off-set a prior PAR request without the related LAR approval. PARs support the installation and testing of structures, systems and components different from the current licensing basis of the facility, as such, they introduce the possibility of the physical as-built plant rapidly deviating from the current licensing basis, unnecessarily complicating the inspection, verification and validation of the facility during construction. The physical as-built plant differing from the current licensing basis may result in protracted inspections, justifications, evaluations and examinations to support the 52 CFR 103(g).

PAR Determination Communications to Licensee

Prior to NRO's issuance of the written PAR Notification, the COL holder shall submit the related license amendment request.

When the DCIP Project Engineer completes the assessment of PAR inspectability, the recommendation will be provided to the PM. The PM will inform the COL holder and prepare the PAR Determination Letter for review, concurrence and transmittal to the COL holder.

Close Out of the PAR Evaluation

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

Attachments

Attachment 1 - Preliminary Acceptability Review Evaluation Template

Attachment 2 - Preliminary Acceptability Review Determination Letter, No Objection

Attachment 3 - Preliminary Acceptability Review Determination Letter, Objection

Attachment 4 - AP1000 Complex ITAAC List

Information Collection:

The information collections contained in this Interim Staff Guidance are covered by the requirements of 10 CFR Part 52, which were approved by the Office of Management and Budget, approval number XXX-XXXX. 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 RG 1.187. (or perhaps a rule change, Part 52)

Congressional Review Act:

Not applicable – less than \$100M, not a major rule

Applicability:

This ISG is applicable to Part 52 COL holders.

Backfit Determination:

This ISG does not constitute a backfit. This ISG does not contain any new requirements for Part 52 COL holders. Rather, it contains additional guidance, clarification and a process for Part 52 COL license holders and the NRC staff to use as part of the licensing basis change processes under 10 CFR Part 52.

References:

- (1) NRC, NRR OI No. LIC-100, "Control of Licensing Bases for Operating Reactors," Revision 1, January 7, 2004. ML033530249
- (2) NRC, NRR OI No. LIC-101, "License Amendment Review Procedures," Revision 3, February 2009, ML040060258
- (3) DC/COL-ISG-011, "Finalizing Licensing-basis Information", November 2009. ML092890623
- (4) NUREG-0800, "Standard Review Plans for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007. TOC ML070810350
- (5) RG 1.181, "Content of the Updated Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," September 1999. ML003740112
- (6) RG 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments" November 2000. ML0037597101
- (7) RG 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007. ML070720184 PKG
- (8) 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. ML992870043
- (9) SRM-SECY-00-0092, "Staff Requirements - SECY-00-0092 - Combined License Review Process," September 5, 2000. ML003747332
- (10) SRM-SECY-09-0190, "Staff Requirements - SECY-09-0190 - Major Revision to NRC Enforcement Policy," August 27, 2010. ML102390327
- (11) SRM-SECY-10-0121, "Staff Requirements - SECY-10-0121 - Modifying the Risk-Informed Regulatory Guidance for New Reactors." March 2, 2011. ML110610166

Attachment 1

Preliminary Acceptability Review Evaluation Template

Attachment 2

Preliminary Acceptability Review Evaluation Determination, No Objection

Attachment 3

Preliminary Acceptability Review Evaluation Determination, Objection

Attachment 4

AP1000 Complex ITAAC List