

C.3 Application Regulatory Topics

C.3.11 COL Action Items and Post-license Commitments

[Record-keeping: This guidance updates: 1) RG 1.206 Section C.III.4, *Combined License Action or Information Items* (2007) and 2) Final Interim Staff Guidance ESP/DC/COL-ISG-015, *Post-Combined License Commitments* (2010)]

OVERVIEW

A combined license (COL) applicant who references a design certification (DC) shall, in addition to complying with the requirements of 10 CFR 52.77, 52.79, and 52.80, comply with provisions of the referenced design certification rule (DCR) contained in the appendices to 10 CFR Part 52. Each DCR, at Section IV.A.2.e, requires that the COL application include information that addresses the COL action items¹ identified in the DCR. These COL action items are regulatory matters that the DC vendor deferred to the COL applicant to address in the COL application.

Similarly, a COL applicant who references an early site permit (ESP) must address any COL action items pertaining to the ESP terms and conditions that were deferred to be addressed in the COL application. In addition, a COL applicant may, at its discretion, address in the COL application commitments to perform future regulatory actions (e.g., update information, programmatic schedules) that are related to site-specific design features or programs that were not identified in the referenced DC or ESP.

The terms “COL action item” and “COL information item” have been used interchangeably. However, the NRC staff has typically used the term “COL action item” in regulations and safety evaluation reports; and, DC applicants have typically included the term “COL information item” in application design control documents. The term “COL action item” is used throughout this regulatory guide.

Although the COL application must address all COL action items in the referenced DC and/or ESP, the NRC staff recognizes that it may not be feasible for all COL action items to be completed prior to issuance of the COL. However, a COL applicant must provide all information in the COL application that is necessary for the NRC staff to make the findings required to issue the license; and, the information necessary for the NRC staff to issue the license cannot be deferred by a COL action item. This may necessitate, for example, the partial closure of COL action items, with the remaining portions of the items associated with information that is not necessary to issue the license identified as post-licensing commitments.

The NRC staff determined that additional guidance and clarification on COL action items that cannot be resolved prior to issuance of a COL should be provided to ensure consistency and to facilitate common understanding by COL applicants. Further, the guidance should include options and illustrative examples to assist in determining the most appropriate post-licensing commitments for ensuring completion of COL action items following license issuance. The guidance herein identifies options available to the COL applicant for treatment of those COL

¹ As defined in Section II.E.3 of each DCR: *COL action items (COL license information) identify certain matters that must be addressed in the site-specific portion of the FSAR by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.*

action items that can only be completed after license issuance and, additionally, those post-licensing information commitments identified by the COL applicant or by the NRC staff during the application review.

GUIDANCE

COL Action Items

The COL applicant referencing a DC should address all COL action (information) items in its application. COL applicants should review the COL action items to identify those items that can be resolved as part of the COL application and those items that cannot be resolved as part of the COL application. Regardless of the disposition of these items, each COL applicant should provide a cross-reference identifying the section in the COL application that addresses each COL action item from the referenced certified design. The COL applicant should include this cross-reference information in Chapter 1 of the FSAR of the COL application.

In addition, the COL applicant referencing a DC should review the NRC staff's final safety evaluation report (FSER) for the referenced DC. The FSER contains a listing of COL action items, which are cross-referenced with COL action items in the related DCD. In addressing the COL items in the DCD, the COL applicant should ensure that it has also addressed the issues described by the COL items listed in the related FSER. The staff intends to review the FSER list of COL action items during its review of each COL application and may request additional information from the COL applicant to address issues described by the listed action items that the COL application did not adequately consider.

Similarly, the COL applicant referencing an ESP should review each COL action item identified in the ESP and determine those items that can be resolved as part of the COL application and those items that cannot be resolved as part of the COL application. The COL applicant should provide a cross-reference identifying the section in the COL application that addresses each COL action item from the referenced ESP. The COL applicant should include this cross-reference information in Chapter 1 of the FSAR of the COL application.

COL Action Items that Cannot Be Resolved Before Issuance of a License

For each COL action item, whether its source is the referenced certified design or an ESP, the COL applicant should provide the requested information or justify why that item cannot be completed prior to issuance of the license. For example, items that call for plant walkdowns cannot be completed because the plant has not been constructed at the time the application is submitted. The COL applicant must provide sufficient information to support the NRC licensing decision. Therefore, a COL action item cannot be deferred until after a COL is issued if resolution of that item is necessary for the NRC staff findings required to issue the license. If, for example, the COL action item addresses both information necessary for licensing action and information necessary to update the FSAR or other licensing basis documents following license issuance, the COL applicant must provide the information necessary for licensing and should propose a method for ensuring the final closure of the remaining portion of the COL item following issuance of a COL. The COL applicant should identify the COL items that cannot be completely resolved before the COL is issued, as well as any post-licensing information commitments made to the NRC as part of the license application review.

The COL applicant may select among the following options for proposing the completion, after license issuance, of those COL action items that are not necessary for the NRC staff license

determination. These options are also applicable to post-licensing information commitments that were identified during COL application reviews that were not associated with COL action items.

1. Consider the COL item unnecessary if it is found to be completely redundant to an ITAAC from the referenced certified design that will be included or incorporated by reference in the COL application.
2. Identify new site-specific ITAAC to resolve the COL item. COL applicants may also propose, in accordance with the appropriate change process, new or revised ITAAC for items within the scope of a referenced certified design.
3. Identify a new condition to the license or an existing license condition (e.g., Technical Specifications) to govern the matter addressed by the COL item. The license condition should include implementation schedules, where appropriate.
4. Ensure that the COL application describes the proposed approach to addressing a COL item in sufficient detail to support the NRC licensing finding. The COL applicant should also describe how it intends to update any affected licensing basis documents (e.g., the FSAR) or otherwise inform the NRC staff of the final disposition of the COL item. The descriptions provided should include implementation schedules, where appropriate.

The COL applicant may propose the option considered appropriate; however, the NRC staff will make the final determination as to the most appropriate option during the application review. In selecting an option, the COL applicant should consider the following discussion of 1) ITAAC, 2) license conditions, and 3) FSAR commitments.

ITAAC:

The requirement for inclusion of ITAAC in an application for a COL is set forth in 10 CFR 52.80(a). The licensee is required to provide notification along with sufficient documentation to demonstrate successful completion of ITAAC in accordance with 10 CFR 52.99(c). The NRC is required to ensure that the prescribed ITAAC are performed and to publish notices in the *Federal Register* of the NRC staff's determination of the licensee's successful completion of ITAAC per 10 CFR 52.99(e). The licensee may not operate the facility until the Commission finds that the acceptance criteria of the ITAAC are met.

The COL applicant, when considering whether a post-licensing information commitment or a COL action item that cannot be completed until after license issuance should be treated in an ITAAC or not, should use the guidance provided in Section 14.3 of Appendix A to this regulatory guide. ITAAC are post-licensing verification license conditions whose focus is on ensuring that the as-built condition of the plant complies with the license for the facility and the Commission's regulations. Another consideration for ITAAC is that *completion of ITAAC, by definition, must take place prior operation of the facility, including fuel load*. The licensee must successfully complete all ITAAC in order for the Commission to make the findings prerequisite to fuel load as required by 10 CFR 52.103(g).

License Conditions:

The license for a nuclear facility contains terms and conditions for operation. For example, 10 CFR 50.54, "Conditions of Licenses," identifies the standard conditions, with some exceptions, which are applicable to every COL issued. In addition to those standard conditions, additional license conditions may be proposed by the COL applicant to address completion of post-licensing information commitments or COL action items that cannot be completed until after license issuance. For example, a license condition may be necessary to govern those tests that can be

performed only after fuel is loaded into the reactor. However, a license condition is not necessary for those matters already covered by the license, including Technical Specifications, or regulations. The following discussion should be considered by COL applicants for proposing license conditions in the application:

- License conditions remain in effect for the licensee until satisfactorily completed and their removal is approved via the license amendment process per § 52.98(f). Note that there is no requirement for a licensee to remove a condition from its license following satisfactory completion of the condition.
- License conditions are enforceable the same way a regulation or order is enforceable. The terms of the FSAR are not similarly enforceable, but changes to the FSAR must comport with the provisions of 10 CFR 50.71(e), which itself is an enforceable regulation.
- In contrast to completion of an ITAAC, where a licensee is required to make a submission to the NRC staff documenting satisfactory completion of the ITAAC, there need not be submission requirements associated with completion of a license condition that necessitate further NRC reviews. However, there may be some conditions specifically included in the license that require the licensee to notify the NRC of the schedule of availability of information for inspection or implementation schedules of programs or activities to be inspected.
- License conditions may be used to include operational restrictions for the facility, impose restrictions on operating power levels, require performance of special tests, impose operational constraints associated with implementation of specific design features (e.g., containment sump screen sweepers).
- License conditions may be used to include implementation schedules for operational programs.

FSAR Commitments:

COL applicants may address completion of post-licensing information commitments or COL action items that cannot be completed until after license issuance through an FSAR commitment. In this context, an FSAR commitment is a commitment to provide updated information in the FSAR, which contains the design basis portion of the licensing basis, or other licensing basis documents that have been considered appropriate by the NRC staff to ensure that the licensing basis for the facility is up to date. This approach may also be used for other licensee controlled documents such as Quality Assurance plans, emergency plans, and security plans.

The staff has identified two approaches for providing the information necessary to maintain the design basis for the facility: 1) include specific design basis information items in a license condition, and; 2) include design basis information in FSAR updates required by 10 CFR 50.71(e). In the first approach, the focus is on ensuring that FSAR information that is identified during the combined license review process, and is necessary to include in the design basis, is included in an FSAR update. In the second approach, the focus is on ensuring that routine FSAR updates that have traditionally occurred following issuance of an operating license are performed. These routine FSAR updates are typically associated with:

- Changes to the facility in accordance with the requirements of 10 CFR 50.59
- Changes to the facility resulting from approved exemptions and departures from a referenced certified design
- Changes to the facility resulting from approved variances from a referenced early site permit
- Amendments to the license in accordance with the requirements of 10 CFR 50.90 and 10 CFR 52.98

FSAR information commitment included in a license condition

The regulations in 10 CFR 50.71(e) and the appendices to 10 CFR Part 52 that contain the DCRs include requirements for holders of COLs to update their FSARs. Specifically, § 50.71(e)(3)(iii) requires that an update of the FSAR be submitted annually to the NRC during the period from the docketing of a COL application until the Commission makes the finding under § 52.103(g). In addition, § 50.71(e)(4) requires that subsequent FSAR revisions be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months. These revisions must reflect all changes up to a maximum of 6 months prior to the date of the filing. Although these requirements for FSAR updates currently exist, the focus of FSAR information commitment items included in a license condition is to ensure the inclusion of specific information identified during the initial licensing review that should be included in the design bases for the facility. This includes the information that should be reviewed as part of the design bases for the facility when reviews and evaluations such as those performed in accordance with 10 CFR 50.54(f), 10 CFR 50.59, and 10 CFR 50.65 are required. The license condition should also include a milestone schedule for ensuring that the specific FSAR information identified is included in an FSAR update required by 10 CFR 50.71(e).

Examples of the types of information that may be included in this license condition are:

- FSAR level design information from completed digital instrumentation and controls (I&C) DAC
- FSAR level design information from as-built reconciliations of piping
- Design features installed as a result of the completed pipe break hazards analyses
- Update to turbine missile generation analyses, as necessary, based on as-procured material data
- Update to reactor vessel materials data, as necessary, based on as-procured vessel material data
- A specific subset of FSAR information that was identified during the original licensing review (e.g., the licensee could provide a commitment to include information associated with vendors in an FSAR update at least 60 days prior to the initiation of construction).

The NRC staff considers the above types of information to be appropriate to include in a timely FSAR update on a schedule that is more suitable to ensuring an updated design basis for initial operation of new plants than that required by 10 CFR 50.71(e). For example, the updated information would ensure that the design basis for the facility is up to date prior to loading fuel, prior to initial criticality, prior to exceeding 5% of the authorized power level, etc. The COL applicant should specifically identify these FSAR information requirements and consolidate them under a license condition that includes a proposed milestone for implementation.

The NRC staff considers this information to have sufficient relevance and distinction from the types of information typically included in routine FSAR updates to warrant its inclusion in a license condition. Together with the requirements of 10 CFR 50.71(e) and Part 52, this type of license condition furthers the NRC's goal of ensuring that the design basis for the facility (i.e., the FSAR) is up-to-date when operation of the facility begins.

FSAR information commitments included in routine FSAR update:

Updated information that does not warrant inclusion in the above categories or that occurs after the milestone associated with the license condition should be included in the periodic FSAR

updates required by 10 CFR 50.71(e). Guidance on FSAR updates is provided in RG 1.181, "Content of the Update Final Safety Analysis Report in Accordance with 10 CFR 50.71(e)," which endorses Revision 1 of Nuclear Energy Institute (NEI) 98-03, "Guidelines for Updating Final Safety Analysis Reports." The guidance for these routine FSAR updates is contained in RG 1.181 and NEI 98-03 and is typically associated with:

- Changes to the facility in accordance with the requirements of 10 CFR 50.59
- Changes to the facility resulting from approved exemptions and departures from a referenced certified design
- Changes to the facility resulting from approved variances from a referenced early site permit
- Amendments to the license in accordance with the requirements of 10 CFR 50.90

The following additional guidance should be considered by COL applicants when proposing FSAR information commitments in their applications:

- Completion of COL action items or completion of post-licensing information commitments that do not include information necessary for license issuance could be used to ensure that the licensing basis for the facility is updated and maintained current.
- For COLs referencing certified designs that include as-built reconciliation activities in COL action items rather than in ITAAC, a license condition containing specific FSAR information requirements can be made to include the relevant as-built facility information from these activities in the FSAR (e.g., fire hazards analysis, pipe break hazards analysis, site-specific seismic responses and their impacts on design features).