C.2 Application Regulatory Topics

C.2.16 Finalizing Licensing-basis Information

OVERVIEW

In 2008, staff recognized that activities such as engineering, procurement, and program development generally continue throughout and following licensing and certification reviews and that applicants for DCs, COLs, or other licenses or permits issued under Part 52 to Title 10 of the *Code of Federal Regulations* (10 CFR Part 52) may need to define a point during the review process at which the licensing-basis information is considered final. This issue was discussed during public meetings held in September and November of 2008 for which a discussion paper was provided (ML090480461). NRC staff received preliminary comments from the Nuclear Energy Institute in an e-mail dated November 25, 2008 (ML090480479). NRC staff subsequently issued a proposed interim staff guidance (ISG) on May 28, 2009 (ADAMS ML090550772) and final guidance, DC/COL-ISG-011, on November 2, 2009 (ML092890623). This regulatory topic provides updated guidance for current and future applicants and allows retirement of DC/COL-ISG-011.

An applicant for a COL or DC may choose to finalize licensing-basis information at a point during the licensing review and then defer any subsequent licensing-basis information changes or additions until after the licensing or certification process is complete. The licensing-basis specified for final review before licensing and certification has been referred to as a "freeze point" and the process has been used by both COL and DC applicants. When a licensing basis freeze point is defined, the licensing or certification decision will be based on that information which has been provided to the NRC on or before the freeze point established by the applicant. NRC reviews take many months to complete. Having the applicant define a licensing-basis freeze point has supported staff's ability to establish a predictable schedule for completion of the later phases of the reviews thereby increasing efficiency and reliability in the review process.

An applicant for a DC or COL, is not required to define a freeze point and the rationale for defining a freeze point may not be sufficient in future reviews to support this choice. Though this guidance is also applicable to early site permits (ESPs), the concept of a freeze point has primarily been associated with COL and DC applications. For DCs, using a freeze point in the generic design review results in significant challenges because any revisions after the DC involve either additional rulemakings or departures on multiple COL that reference the DC. This regulatory topic preserves key guidance from the retired DC/COL-ISG-011 and focuses on criteria that would identify changes that are inappropriate to defer beyond licensing or certification and would therefore require a change to the licensing basis. Though a freeze point does not directly relate to COL applications that reference a DC with errors identified after certification, the guidance provided regarding safety significance applies and is discussed.

GUIDANCE

General Guidance

The concept of the freeze point reflects an applicant's ability to defer the submission of additional design changes and information for review until after licensing or certification. There is no requirement for a formal declaration or correspondence regarding such a decision and the most recent submission of an application represents a de facto "freeze point" if the applicant does not formally identify a licensing basis freeze point. Sufficient information must be provided, in all cases, to support findings that are necessary in a final safety evaluation report for a COL or DC application.

If an applicant chooses to defer submission of planned design changes, it may only do so if it

does not affect information on which staff relies upon for their safety determination. The NRC staff may require an applicant to supply additional information to support its review under 10 CFR 2.102 and, under 10 CFR 2.108, the NRC may deny an application if the applicant fails to respond to a request for additional information (RAI) within 30 days of the date of the request, or within such other time as may be specified by the NRC staff. Under no circumstances will the NRC grant an application that does not satisfy the requirements of the Atomic Energy Act and the Commission's regulations.

Certain changes should not be considered for deferral, owing to their relevance to the staff conclusions with respect to the requested certification or licensing decision. Categories of those changes which should not be deferred include, but are not limited to the following:

- the correction of significant errors in an application,
- changes needed to ensure compliance with NRC regulations,
- changes needed to support other licensing-basis documents (e.g., conforming changes to formation in the FSAR supporting technical specifications)
- significant technical corrections associated with the design or program described in the licensing document (i.e., if not changed, would preclude operation within the bounds of the licensing basis, as opposed to proposed alternatives to the described design or program), and
- changes needed to address a significant vulnerability identified by probabilistic risk assessments (PRAs) or other studies (e.g., a change in a PRA insight).

A COL or DC applicant that plans a change that falls under the above list should inform NRC immediately. Staff recommends that the applicant provide information, when available and appropriate, to support the applicant determinations on whether addressing the design error can be deferred due to the level of impact on NRC's safety evaluation.

The applicant that defines a freeze point will need to rely on its programs to evaluate, track, and report (as appropriate) those changes identified after the licensing-basis freeze point. These applicant processes will need to support applicant determinations on whether immediate notification of the NRC is warranted due to its potential impact on NRC's safety evaluation so that the information may be considered in the pending licensing or certification decision. If immediate notification is not warranted, inclusion of the information in the application for the applicant's convenience may significantly delay the ultimate NRC decision on the application. Should the NRC grant the requested certification or license, the NRC staff anticipates that the licensee and DC vendor would use established change control processes to manage the majority of changes identified after the licensing-basis freeze point. For potential changes to a DC, ESP, or COL that are identified following the licensing-basis information freeze point, the applicant will need to ensure that reporting requirements are met for those specific changes for which submittals are deferred until after the issuance of the DC rule or license.

The NRC staff, DC and COL applicants will need to closely coordinate their activities related to the reviews of each proposed design and COL application including COL applications that reference a design that is still under review. Discussion of creating or changing a freeze point will facilitate this coordination and is strongly recommended. Though a formal notification referencing a freeze point is not required, the applicant must be clear on the design version that should be reviewed. Requirements under 10 CFR 50.30(a)(1) state that amendments to applications must be submitted in accordance with 10 CFR 52.3 or 10 CFR

50.4. Communicating clearly regarding the design version to be reviewed is also critical to the identification of appropriate review activities by NRC staff to be covered by licensing fees stipulated under 10 CFR 52.45 for DC and 10 CFR 52.75 for COLs.

Finalizing Licensing Basis Information for COL Applications

For COL applicants, proposed changes to licensing-basis information provided in the FSAR or other document that are identified following the freeze point would usually be controlled by the applicant and not submitted to the NRC for review in connection with the COL application (other than those of a type described in the general guidance section of this regulatory topic). Instead, the COL applicant would control the potential changes and if the COL is granted, would treat the change under the appropriate control process and, if required by NRC regulations, submit a license amendment request. If no amendment is necessary, then the licensee would submit updates to the FSAR or other document in accordance with established reporting requirements. Changes to licensing basis that should not be deferred due to their role in supporting staff findings that are necessary in a final safety evaluation report for a COL or DC application must be submitted to the NRC for review during the licensing process.

It is important that each COL applicant ensure the information contained in the COL application is synchronized with the information contained in a DC, if referenced, and early site permit (ESP) applications as they are revised and supplemented during the review process. A COL applicant that indicates an intent to reference a DC that is still under review and not yet certified or approved bears the schedule risk associated with the DC review in addition to those schedule risks that are germane to a COL application. Such a COL applicant should submit a revision to its application, including the final safety analysis report (FSAR) and other affected documents, upon the completion of the NRC's review of the referenced DC application.

Finalizing Licensing Basis Information for Design Certifications

For DC applicants, proposed changes (other than those of a type described in the general guidance section of this regulatory topic) that are identified following the freeze point will not be included in the documents supporting the certification and will therefore not be part of the approved or certified design. Once the DC rule is finalized assuming no subsequent DC amendment, changes affecting the design certification final safety analysis report, that are identified after the freeze point, would not be implemented unless proposed as departures from the certified design. The DC applicant would identify such potential departures to COL applicants or COL licensees, who could, if they so choose, identify them as requested departures or exemptions in a COL application, an update to a COL application, or in a periodic report submitted by a COL licensee, as applicable. The treatment of these proposed changes by the COL applicant could depend on the status of the DC application relative to the freeze point for the COL application. Until such changes are incorporated into an amendment to a DC, they would need to be handled as departures or exemptions, assuming they meet the threshold in the applicable change control process. COL applicants may identify such departures or exemptions as standard content associated with a reference COL under the design centered review approach described in RIS-2006-06 i and discussed in section C.2.7 of this regulatory guide. n order to facilitate NRC review for subsequent COL applications. Changes to licensing basis that should not be deferred due to their role in staff's review of reasonable assurance of adequate safety must be submitted to the NRC for review during the review and certification process.

For DCs, defining a freeze point has more significant and longer-term impacts than that of a COL application. Under 10 CFR 52.63(a), later revisions to reflect additional design changes require rulemaking which is a lengthier and more complex process than licensing departures associated with COLs. under 10 CFR Part 52.98(e) and 10 CFR 50.91. Revision of the DC would ultimately affect all COLs that reference the DC as well as those COL applications referencing the DC or

COL that are still in the pre-application phase. Design changes after the freeze point could alternatively be included in an application for DC renewal under 10 CFR Part 52.57, however, there could be a significant time between DC certification and the time a renewal request would be expected. The entire DCD (i.e., the version of the DCD last approved for incorporation by reference) must be updated under 10 CFR 52.57(a) to include corrections of errors, typographical corrections, and defects (as defined in 10 CFR Part 21), which are known by the DC renewal applicant as well as any additional design changes.

Either revising the DC through rulemaking or incorporating changes via the DC renewal process, will increase schedule risk for COLs and COL applications referencing the DC. COL applicants will additionally be faced with the decision between departures from the original DC vs. incorporation of an amended DC or face a similar decision related to incorporating by reference the current certified design or the DCD for renewal either under review by NRC or pending submission for review.

An example of information that may change frequently during a review relates to the fuel assembly design described in a particular DC application. In this example, a DC application or an amendment to a DC application is being reviewed by the NRC staff and the reactor vendor identifies a proposed enhancement to its fuel assembly design. Supporting documents for the revised fuel assembly design may even have been submitted to the NRC for review and in some cases may already have been reviewed and approved by the NRC. The change in fuel assembly design then becomes a departure recommended by the vendor for future COL applications or COL licensees that reference the certified design. The COL applicant may propose to use the changed fuel design in its COL application or may continue to reference the certified design, including the original fuel assembly design, and submit the appropriate license amendment request and FSAR updates following the issuance of the COL. In either case, the fuel assembly design ultimately used in the reactor will have satisfied all applicable NRC requirements.

Errors in Design Certifications Referenced by Combined License Applications

Once one or more COL applications have been submitted that incorporate the DC by reference, additional design work is required to address COL Action Items (as discussed in C.2.11 of this regulatory guide), demonstrate compliance with interfacing system requirements in the DC, include proposed ITAAC, describe site-specific design features, and demonstrate that actual site characteristics fall within the site parameters specified in the DC. Similarly, initial COL licensees may need to resolve constructability issues encountered during the construction process. In the course of this work, the DC vendor or the COL applicant or licensee may identify errors in the certified design that are of a generic nature.

Regardless of whether an error in the DC is identified before or after a selected freeze point for the COL application, or in the case that no freeze point was specifically declared by the applicant, the general guidance of this regulatory topic applies. Notwithstanding the requirements of 10 CFR 52.63, the Atomic Energy Act of 1954, as amended, requires the NRC to make the final safety finding for both construction and operation when it issues a COL. In making this finding for a COL applicant referencing a design certification, the NRC relies on the safety findings made during the design certification review. This reliance, however, must be reasonable. Thus, if the NRC knows of a significant error in the DC that undermines the statutorily required COL safety findings, the NRC may issue the COL only after the error is adequately addressed such that the required findings can be made. The resolution of a DC design error cannot be deferred until after a COL license is issued if it affects the information on which staff relies upon for their determination. Under no circumstances will the NRC grant an application that does not satisfy the requirements of the Atomic Energy Act and the Commission's regulations.

Under 10 CFR Part 21, requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the AEA of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the AEA of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

Under 10 CFR Part 52.6, information provided to the Commission by an applicant for a license and information required by statute or by the Commission's regulations to be maintained by an applicant for a license shall be complete and accurate in all material respects. A COL applicant that becomes aware of potential design error that falls under the list presented under the general guidance of this section of the regulatory guide, should inform NRC immediately. Staff recommends that the applicant provide information, when available and appropriate, to support the applicant determinations on whether addressing the design error can be deferred due to the level of impact on NRC's safety evaluation.

A COL application that incorporates a DC by reference, bears schedule risk associated with any safety significant design errors in the referenced DC that are identified after certification. Such design errors that affect the NRC's staff's ability to reach conclusions necessary to support findings in the final safety evaluation report as described in the general guidance section of this regulatory topic, will require a change in the licensing basis information. Though a freeze point does not directly relate to post certification errors, similar considerations regarding safety significance apply.

For each DC, safety significant design errors and their resolution may be documented via an NRC RIS. Such a RIS may be supplemented to include additional errors if any are found. Should the vendor decide to file a timely renewal of the certification, it would be expected that these errors would be included in the scope of the review. Such design errors and their resolution could additionally be documented by industry organizations or from design specific design center working groups as described in RIS-2006-06

SUMMARY

This regulatory topic updates earlier interim guidance, now retired, related to an applicant's choice to define a final licensing basis during the application review process beyond which any additional design changes will be deferred until after COL issuance or DC certification. The guidance focuses on the identification of licensing basis changes that are inappropriate to defer due to their impact on information relied upon by staff in making their safety determination. The general guidance applies to all applications for licenses, certifications, or permits under 10 CFR Part 52 though it is unclear how often it will be referenced in the future and whether it is useful for applications other than COL and DC. The general guidance additionally applies to the treatment of DC design errors that have the potential to affect safety findings for COL applications that reference such a DC.