

Interim Staff Guidance Finalizing Licensing-basis Information

Purpose

The purpose of this interim staff guidance (ISG) is to clarify the U.S. Nuclear Regulatory Commission (NRC) staff position regarding applicants finalizing licensing-basis information at a point during the licensing review, a so-called freeze-point, and the control of licensing-basis information during and following the initial review of applications for design certifications (DCs) or combined licenses (COLs).

Background

The 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 point is sometimes referred to as the licensing-basis freeze point. Having the applicant define a licensing-basis freeze point for NRC reviews that take many months to complete (e.g., for DC and COL application reviews) is needed in order for the staff to establish a predictable schedule for completion of the later phases of the reviews and to support a licensing or certification decision schedule. 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.

The applicant 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 decisions on whether immediate notification of the NRC is warranted 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 staff anticipates that the licensee and DC proponent would use established change control processes to manage the majority of changes identified after the licensing-basis freeze point.

This issue was discussed during a public meeting held on November 6, 2008. A discussion paper was provided at that meeting and is available in the NRC Agencywide Documents Access and Management System (ADAMS) at Accession no. ML090480461. Following that meeting, the NRC staff received preliminary comments from the Nuclear Energy Institute in an email dated November 25, 2008 (ADAMS Accession no. ML090480453).

Issue Discussion

The NRC staff, DC applicants and COL applicants will need to closely coordinate their activities related to the reviews of each proposed design and the COL applications referencing each design. It is important that each COL applicant ensure the information contained in the COL application is synchronized with the information contained in the DC and early site permit (ESP) applications as they are revised and supplemented during the review process. As discussed in various public meetings, each COL applicant should submit a revision to its application, including the final safety analysis report (FSAR) and other affected documents, upon the

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completion of the NRC's review of the referenced DC application. 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 design certification rule or license.

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:

- 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 information 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).

For DC applicants, proposed changes (other than those of a type described immediately above) 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. As such (assuming no subsequent DC amendment), changes affecting the design control documents 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 chose, 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 in order to facilitate NRC review for subsequent 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. 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. Under no circumstances, however, will the NRC grant an application that does not satisfy the requirements of the Atomic Energy Act and the Commission's regulations.

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.

Final Resolution Method

Following the resolution of public comments, the staff intends to issue this ISG in final form and subsequently incorporate its contents into the appropriate sections of Regulatory Guide (RG) 1.206.

Applicability

This ISG is applicable to all DC, ESP, and COL applications submitted under 10 CFR Part 52. It shall remain in effect until it has been superseded, withdrawn, or incorporated into a revision of RG 1.206.