## **NRC Staff Position on Method of Evaluation Approval**

Applicants for (1) ISFSI licenses; (2) spent fuel dry cask certificates of compliance (CoC); and (3) amendments to licenses and CoCs perform analyses to demonstrate that the structures, systems, and components of the ISFSI or cask fulfill their intended functions. Such analyses must show that the ISFSI or cask meets the regulatory requirements for safe storage of spent fuel (and reactor-related greater than Class C waste, as applicable). Applicants' safety analysis reports (SARs) include descriptions, summaries or outlines of the methods used to perform those analyses, referred to hereafter as methods of evaluation (MOEs). The SAR for an approved ISFSI or cask design is referred to as a final safety analysis report (FSAR), which the licensee or cask CoC holder maintains and updates.

Licensees and CoC holders have sought to make changes to MOEs in their FSARs in accordance with 10 CFR 72.48. The applicable criterion in this regard is 10 CFR 72.48(c)(2)(viii). The criterion states that a licensee or CoC holder must obtain a license or CoC amendment prior to implementing a proposed change that would result in a departure from a MOE described in the FSAR (as updated) that is used in establishing the design bases or in the safety analyses. A departure from a MOE (as this phrase is used in the 10 CFR 72.48(c)(2)(viii) criterion) is defined in 10 CFR 72.48(a)(2) to mean: (i) changes to any of the elements of the MOE described in the FSAR, unless the analysis results are "conservative or essentially the same;" or (ii) any change from a MOE described in the FSAR to another MOE unless the new MOE "has been approved by NRC for the intended application."

Licensees and CoC holders have construed 10 CFR 72.48(a)(2)(ii) to mean that MOEs in FSARs for approved ISFSI and cask designs are approved MOEs. Under this view, such MOEs are "approved by NRC for the intended application," and can be used to make changes without having to obtain prior NRC approval under 10 CFR 72.48(c)(2)(viii). The staff does not agree with this view, and it is contrary to the discussion in the *Federal Register* notice which accompanied the final 10 CFR 72.48 rule (64 FR 53582).

To ensure that spent nuclear fuel will be safely stored, the NRC staff reviews a cask or ISFSI design, as described in an applicant's, licensee's, or CoC holder's SAR, to confirm whether or not the design meets the regulatory requirements in Part 72. In examining a cask or ISFSI design, the staff reviews the MOEs described, summarized, or outlined in the SAR that are used to demonstrate that the cask's or ISFSI's structures, systems, and components accomplish their intended functions (see 10 CFR 72.48(a)(4)(iii)). However, the staff reviews these MOEs only to the extent needed to confirm that the cask or ISFSI design meets the regulatory requirements for safe storage. This is the case whether the application is for an initial 10 CFR Part 72 CoC or license or is for an amendment to an existing CoC or license.

The SAR for the cask or ISFSI design application under review may identify characteristics (e.g., limitations and assumptions) that are important to the use of a MOE in the SAR. The staff may find that a MOE has additional characteristics, or even flaws, that may further limit the MOE's use. However, the staff may find through its review and confirmatory analyses that the MOE in question is sufficient to demonstrate—for the specific cask or ISFSI design application under review—that the cask or ISFSI design complies with the regulatory requirements in 10 CFR Part 72. In such cases, the staff can approve the design and issue a CoC or license, or an amendment to a CoC or license for that design along with a safety evaluation report describing the basis for that approval.

Thus, a CoC, a license, or an amendment to a CoC or license and any accompanying safety evaluation report do not constitute NRC approval of the MOE beyond its use for that particular design application regardless of whether or not the staff's safety evaluation report explicitly discusses the MOE.

To determine whether a MOE is "approved by the NRC for the intended application" licensees and CoC holders need to consider the following three criteria:

- (1) whether the MOE is approved for the type of analysis being conducted,
- (2) whether the MOE is generically approved for use at this type of facility, and
- (3) whether all terms and conditions for use of the MOE are satisfied.

(64 FR 53582, 53598).

Licensees or CoC holders may request generic approval of one or more MOEs by submitting a topical report for NRC review. If the NRC staff approves the generic use of an MOE, the NRC will issue a regulatory guide to document that approval and may include additional terms and conditions for use of the MOE(s) discussed in the topical report. Approval of a topical report may thus constitute a generic approval of MOEs discussed in the topical report. If the approved topical report is applicable to the facility and use of the MOE would comply with the terms and conditions specified in the regulatory guide approving the MOE, then use of the MOE is not a "departure" and the MOE may be used without obtaining a license or CoC amendment under 10 CFR 72.48. (64 FR 53582, 53599).