Proposed Interim Enforcement Policy—Section 9.X, Enforcement Discretion for General Licensee Adoption of CoC Holder-Generated Changes under 10 CFR 72.48

9.X Enforcement Discretion for General Licensee Adoption of Certificate of Compliance Holder-Generated Changes under 10 CFR 72.48

This section sets forth the Interim Enforcement Policy (IEP) that the NRC will use to exercise discretion for the disposition of violations involving a General Licensee's (GL's) adoption of a Certificate of Compliance (CoC) holder-generated change made under the CoC holder's change authority of Section 72.48 of title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, tests, and experiments." The current NRC regulations state:

- 10 CFR 72.212, in a number of regulatory provisions, such as 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), and 72.212(b)(11), requires a GL to ensure it uses casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214.
- 10 CFR 72.212(b)(5) requires that the GL, before use and before applying changes authorized by an amended CoC to a cask loaded under the initial CoC or an earlier amended CoC, perform written evaluations to establish that the storage cask, once loaded, will conform to terms and conditions of the CoC.

- 10 CFR 72.212(b)(6) requires that the GL review, and document the review of, the Safety Analysis Report referenced in the CoC or amended CoC and the related NRC Safety Evaluation Report, to determine whether or not the reactor site parameters are enveloped by the cask design bases considered in these reports.
- 10 CFR 72.212(b)(7) requires the GL to evaluate any changes to written evaluations required by paragraphs (b)(5) and (6) of 10 CFR 72.212, using the requirements of 10 CFR 72.48(c).
- 10 CFR 72.48, as published on October 4, 1999 (64 FR 53582) and amended on February 26, 2001 (66 FR 11527), has provisions under which general and specific licensees and CoC holders may make changes to the facility or spent fuel storage cask design as described in the Final Safety Analysis Report without obtaining NRC review and approval. *Change* means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

Under the current NRC regulations, if a GL chooses to adopt a change the CoC holder made pursuant to a CoC holder's change authority under 10 CFR 72.48 (referred to herein as a "CoC holder-generated change"), a GL must perform a separate review using the requirements of 10 CFR 72.48(c). This is in addition to the requirement that the GL evaluate any additional resulting site-specific, technical changes the GL makes to written evaluations required by paragraphs (b)(5) and (6) of 10 CFR 72.212 using the requirements of 10 CFR 72.48(c), when adopting the CoC holder's change. Further, the GL is required, by various provisions of 10 CFR 72.212, to only use casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214.

Accordingly, when a GL chooses to adopt a CoC holder-generated change, and that change results in a non-conforming cask, there is a violation of 10 CFR 72.48 and certain provisions of 10 CFR 72.212 by the GL, in addition to a CoC holder violation of 10 CFR 72.48. And, when a GL chooses to adopt a CoC holder-generated change without performing a separate 10 CFR 72.48 analysis, the GL is in violation of 10 CFR 72.48.

These requirements have led to enforcement actions issued against both the GL's 10 CFR 72.48 program (as well as certain 10 CFR 72.212 violations) and CoC holder's 10 CFR 72.48 program for changes that originated with the CoC holder. The NRC has concluded that this enforcement approach is inconsistent with efficiency, which is one of the NRC's Principles of Good Regulation, and NRC's mission of efficient and reliable oversight.

The NRC staff will review the regulations in 10 CFR Part 72 and guidance documents to determine what changes are needed to focus requirements on the entity that initiated the change. Until such time as regulatory changes are developed, the Interim Enforcement Policy will be:

(1) The NRC will exercise enforcement discretion and not issue an enforcement action to a GL, for a noncompliance with the requirements of paragraphs (c)(1) and (2) and (d)(1) of 10 CFR 72.48 and with provisions of 10 CFR 72.212 that require GLs to ensure use of casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214, when the noncompliance results from a CoC holder's failure to comply with 10 CFR 72.48 for a CoC holder-generated change. In granting this discretion, the GL will be expected to come into compliance with the 72.212 provisions

that require each cask to conform to the terms, conditions, and specifications of a CoC or an amended CoC listed in § 72.214 using established processes. The NRC staff will monitor the GL's actions to determine if additional regulatory actions will be necessary.

(2) The NRC will exercise enforcement discretion and not issue an enforcement action to the GL for failure to perform a 10 CFR 72.48 screening and/or evaluation when the GL adopts a CoC holder-generated change that does not result in the GL making a change to the site-specific, technical aspects of the GL's 10 CFR 72.212 report.

(3) When the GL adopts a CoC holder-generated change and the accompanying 10 CFR 72.48 screening and/or evaluation that was performed by the CoC holder, the GL does not have to perform a separate 10 CFR 72.48 evaluation of CoC holder-generated changes. The GL only needs to review the CoC holder's change for applicability to their spent fuel storage cask and for impact on the site-specific, technical evaluations and analyses described in the 10 CFR 72.212 report, and site programs and procedures. The NRC's inspections of the GL and enforcement actions against the GL will focus on the GL's assessment for the site-specific applicability of the CoC holder-generated change to its spent fuel storage cask.

(4) The GL is responsible for performing written evaluations to establish that the storage cask conforms to terms and conditions of the CoC, in accordance with paragraphs (b)(5) and (6) of 10 CFR 72.212. If the GL chooses to adopt a CoC holder-generated change, the GL does not need to follow the requirements of 10 CFR 72.212(b)(7) unless the GL determines that GL-initiated site-specific, technical changes are needed to the GL's written evaluations required by paragraphs (b)(5) and (b)(6) of 10 CFR 72.212. Additionally, the GL is responsible for ensuring compliance with applicable

requirements of Appendix B to 10 CFR Part 50, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” and Subpart G to 10 CFR Part 72, “Quality Assurance.”

(5) NRC enforcement actions will focus on the entity that initiated the change. The CoC holder will be accountable for a noncompliance identified within CoC holder-generated 10 CFR 72.48 screenings and/or evaluations of a change made pursuant to the CoC holder’s 10 CFR 72.48 change authority. The GL will be accountable for any noncompliance identified within GL-initiated changes.

An enforcement panel is not required to disposition a noncompliance using this discretion; however, each time discretion is granted, an enforcement action number will be assigned to document the use of discretion under this IEP.

This IEP will remain in place until the underlying regulatory issue is dispositioned through rulemaking or other regulatory action.