

of a standard plant design under the new subpart D of 10 CFR part 52. This requirement was included in 10 CFR part 52 because, at the time of the original rulemaking, the NRC had no experience with design certification applications. By requiring an FDA as a prerequisite for certification, the NRC indicated that the licensing processes for design certifications and FDAs were similar, even though the requirements for and finality of design certifications differ from that of FDAs. The NRC has considerable experience with design certification applications and the requirement to apply for an FDA as part of an application for design certification is no longer needed.

In a letter dated April 3, 2001 (comment 2), NEI commented "Industry prefers to retain modified provisions. We agree that an FDA should be an option but not a prerequisite. Also, deletion recommended for 52.47(b)(2)(ii)." The Commission has decided not to retain these provisions. The proposed processes in subparts D and E allow future applicants for design certification the option to apply for an FDA for the same design information.

The proposed rule would also amend the current § 52.45(d) (proposed § 52.105(c)) to correct the reference to the filing requirements in § 50.30(a) and delete the reference to § 50.4. The applicability of the requirements in § 50.4 is set forth in the new § 52.5. No substantive change in the filing requirements is intended by this correction.

The proposed rule would amend the current § 52.47 (proposed § 52.107) to conform the statement of the requirements for acceptable inspections, tests, analyses, and acceptance criteria (ITAAC) in § 52.107 with the Atomic Energy Act (AEA) and the requirements in the current § 52.97(b) [proposed § 52.227(b)]. This clarification of the previous regulatory text, which condensed the language in § 52.79(c) and § 52.97(b), is intended to avoid any future misunderstandings.

Design Certification Backfit Requirement

The proposed rule would amend the special backfit requirement in the current § 52.63(a)(1) (proposed § 52.127(a)(1)) to provide the Commission with the ability to make changes to the design certification rules or the certification information in the generic design control documents that reduce unnecessary regulatory burdens. Section 52.63(a)(1) currently states that the Commission may not modify, rescind, or impose new requirements on the certification unless the change is: (1)

Necessary for compliance with Commission regulations applicable and in effect at the time the certification was issued, or (2) necessary to provide adequate protection of the public health and safety or common defense and security. The regulation does not appear, on its face, to permit changes to the certification which reduce unnecessary regulatory burdens, in circumstances where the change continues to maintain protection to public health and safety and common defense and security. An example of a change which may not be able to be made under the current § 52.63(a)(1) is a proposed change to the three design certification rules in Appendices A, B and C of 10 CFR part 52, to incorporate into the Tier 2 change process the revised change criteria in 10 CFR 50.59. Section 50.59 was revised in 1999 to provide new criteria for, *inter alia*, making changes to a facility, as described in the final safety analysis report, without prior NRC approval, in order to reduce unnecessary regulatory burden (64 FR 53582, October 4, 1999).

To allow the Commission to modify the design certification rules in 10 CFR part 52 to incorporate the revised § 50.59 change criteria, and to allow the Commission to make future changes to reduce unnecessary regulatory burden, the Commission is proposing to amend § 52.127(a)(1) to include a new provision that explicitly allows the Commission to change the design certification rules or certification information if the change provides a reduction in regulatory burden and maintains protection to public health and safety and common defense and security. Maintaining protection generally embodies the same safety principles used by the NRC in applying risk-informed decision making, *e.g.*, ensuring that adequate protection is provided, applicable regulations are met, sufficient safety margins are maintained, defense-in-depth is maintained, and that any changes in risk are small and consistent with the Commission's Safety Goal Policy Statement (refer to NRC's Regulatory Guide 1.174). Changes to the design certification rules must be accomplished through rulemaking, with opportunity for public comment. Once a design certification rule is changed through rulemaking, under proposed § 52.127(a)(2) the provisions would apply to all future applications referencing the design certification rule as well as all current plans referencing the design certification, unless the change has been rendered "technically irrelevant" through other action taken

under paragraphs (a)(3) or (b)(1) of § 52.127. Thus, standardization is maintained by ensuring that any changes to a design certification rule intended to reduce regulatory burden are imposed upon all nuclear power plants referencing the design certification rule.

In a letter dated November 13, 2001, NEI stated:

Furthermore, we do not think it is necessary to modify 10 CFR 52.63(a)(1) in order to make conforming, administrative or similar changes to the DCRs, such as those needed to conform the DCRs to the revised 10 CFR 50.59. Nor do we think the Commission intended the DCR backfit provisions to inhibit these types of changes. Rather, we believe 10 CFR 52.63(a)(1) is intended to apply to changes in the standard design approved via the DCR. We recommend the Commission clarify this intent and provide guidance to the NRC staff allowing certain changes to the DCRs (such as those needed to conform to the revised 10 CFR 50.59) within the existing DCR backfit provisions.

The Commission received similar comments from General Electric Company, Entergy, and Exelon in November 2001. The Commission disagrees with these comments and has concluded that it is necessary to amend § 52.63(a)(1) to allow changes to the design certification rules that reduce unnecessary regulatory burden, or do not constitute a backfit.

The current § 52.63(a)(1) (proposed § 52.127(a)(1)) was also modified to replace "a modification" with "the change," in order to clarify that the three criteria for changes apply to modifications, rescissions or imposition of new requirements. Also, the Commission is clarifying the proposed § 52.127 to be consistent with its original intent (refer to 54 FR 15372; April 18, 1989) that the special backfit requirements apply to the certification information in the generic design control documents, not to the provisions in the design certification rules, *e.g.*, Section VI.E of Appendix A to 10 CFR part 52. Any proposed changes to these provisions that set forth how the design certification rules are to be used are controlled by the normal backfit requirements in 10 CFR 50.109.

The proposed rule would amend the current § 52.63(a)(2) (proposed § 52.127(a)(2)) to delete the reference to § 52.63(a)(4) (proposed § 52.127(a)(4)). The reference to § 52.63(a)(4) was in error because this paragraph discusses the finality of the findings required for issuance of a combined license or operating license, whereas § 52.63(a)(2) deals with modifications that the NRC may impose on a design certification rule under § 52.63(a)(3) or § 52.63(b)(1)