

PDR
AF93-2

From: E. Neil Jensen
To: Anthony DiPalo, Philip Brochman
Date: Wed, Sep 22, 1999 1:59 PM
Subject: Part 72 Scope Final Rule Revision

This is to inform you that the Office of the General Counsel has no legal objection to staff's revision, pursuant to the Commission's August 25, 1999 SRM, of the Federal Register Notices for the "Expand Applicability of Part 72 to Holders of, and Applicants for, Certificates of Compliance" final rule and the "NRC Enforcement Policy; Enforcement Action Against Nonlicensees under 10 CFR Part 72" revision to the Enforcement Policy, subject to additional changes and edits. A package of these additional changes will be provided to you shortly.

CC: Patricia Holahan

Subpart L - Approval of Spent Fuel Storage Casks

§ 72.232 Inspection and tests.

This section would be reformatted by adding a new paragraph (b) and renumbering existing paragraphs (b) and (c). In paragraphs (a), (b), and (c), the term "applicant" would be replaced with "certificate holder and applicant for a CoC." In paragraph (d), the term "applicant" would be replaced with "certificate holder and applicant for a CoC."

Paragraph (a) would be revised to permit the inspection of the premises and activities related to the design of a spent fuel storage cask as well as to the fabrication and testing of such casks. This change would be made to ensure completeness.

A new paragraph (b) would include a requirement to permit the inspection of records related to design, fabrication, and testing of spent fuel storage casks. This requirement would make clear the responsibility of certificate holders and applicants for a CoC to permit access to these records. This requirement is similar to the existing inspection and testing regulations in 10 CFR Parts 30, 40, 50, and 70.

§ 72.234 Conditions of Approval.

This section would be revised to clarify who is responsible for accomplishing these requirements. The term "cask vendor" would be replaced with "certificate holder." The term "cask user" would be replaced with "the licensee using the spent fuel storage cask." Although the replacement term in the proposed rule was "the general licensee using the cask" because a specific licensee cannot utilize the provisions of Subparts K and L, it is conceivable that, in the future, a specific licensee could become a user of a certified cask. Accordingly, the NRC prefers the broader term. A similar change is made in § 72.240 as proposed. Further, edits would be made in §§ 72.234 and 72.236 to clarify that all references to "casks" are references

§ 72.48 in the future. However, without changes to §§ 72.48 and 72.70 at this time, the commenter believes that some clarifications are necessary in order to implement the proposed revisions to § 72.146(c).

Response: The NRC agrees in part with the comment. Revising the proposed rule to add provisions to permit a certificate holder to use the provisions of § 72.48 to make changes to the design of a spent fuel storage cask, without prior NRC approval is beyond the scope of this rulemaking. However, the Commission has approved a separate final rule on "Changes, Tests, and Experiments" (64 FR ?????; September ??, 1999) that addresses the issues raised by the commenter. The "Changes, Tests, and Experiments" final rule revises § 72.48 to permit a certificate holder to make certain changes to the design of a spent fuel storage cask, without NRC prior approval. The "Changes, Tests, and Experiments" final rule also revises the requirements in § 72.70 on licensees in updating their SAR; and adds requirements in a new § 72.248 on certificate holders updating their SARs.

With respect to the comment on § 72.146(c), the current regulation explicitly indicates that changes to the conditions specified in a CoC requires prior NRC approval. No changes § 72.146(c) were made in the "Changes, Tests, and Experiments" final rule; and no changes to § 72.146(c) are necessary in this final rule.

3. Comment: One commenter, a certificate holder, concurs with proposed changes for clarification, but believes that the imposition of enforcement actions may not be necessary. If the NRC decides that enforcement actions are necessary, then the commenter believes that it should not apply to the subcontractors of certificate holders, because in the commenter's view, (1) it does not seem fair to extend enforcement actions to organizations which do not have a direct regulatory link to the NRC; and (2) subjecting such contractors and subcontractors to

enforcement action exposes them to business risks which could cause them to refuse to become contractors and subcontractors of certificate holders or cause them to increase their prices. Another commenter believed that subjecting parties to NRC enforcement actions that have no formal regulatory connection presents severe business risks that have a real cost to small businesses and could prove detrimental to a “rather small and highly specialized group of fabricators.”

Response: The NRC agrees with the commenters. The NRC expects that persons involved in the manufacture of a spent fuel storage cask will take full responsibility for their obligations to implement the requirements of the Part 72 QA regulations. ~~The~~ NRC has reconsidered and now believes that the imposition of enforcement actions against contractors and subcontractors is not necessary. Section 72.148 requires that, to the extent necessary, the licensee, certificate holder, and applicants shall require contractors or subcontractors to provide a QA program consistent with Part 72. Licensees, certificate holders, and applicants are responsible for assuring that their contractors and subcontractors are implementing adequate QA programs. Therefore, the NRC has revised the final rule to remove references to contractors and subcontractors.

4. Comment: One commenter, a certificate holder, raised a concern with the proposed extension of enforcement actions to cover § 72.236. Several paragraphs in this section, such as (a), (i), and (m), contain wording like “but not limited to” and “to the extent practicable” that the commenter believes are highly subjective. The commenter does not believe that certificate holders should be subject to enforcement actions based on someone’s opinion regarding what is practicable.

Response: The NRC agrees that contractors and subcontractors need not be included within the scope of the changes made in the final rule. See the response to comment number 3. Licensees and certificate holders are responsible for QA requirements through their oversight of contractors and subcontractors, and fabricators are generally contractors or subcontractors. However, if the contract calls for the fabricator to build according to a design provided by the certificate holder, the NRC expects the fabricator to do just that. The NRC needs assurance that the spent fuel storage casks are manufactured in accordance with the NRC approved design and will hold licensees and certificate holders and applicants responsible for meeting design and QA requirements. Regarding the commenter's concern on the subject of the use of civil penalties; i.e., whether a civil penalty is the appropriate response to a violation of Part 72, the NRC notes that this rulemaking does not provide authority for issuing a civil penalty to nonlicensees, other than under the Deliberate Misconduct Rule. The final rule does allow the use of issuance of NOV's or Orders, rather than administrative sanctions.

10. Comment: One commenter, a certificate holder, while agreeing with the purpose of the proposed rulemaking, raised a concern with the added requirement that identifies additional recordkeeping and reporting requirements for certificate holders. The NRC estimated the burden associated with these new requirements in the Paperwork Reduction Act Statement provided with the Supplementary Information in the proposed rule as 6 hours annually. The commenter notes that the annual burden for recordkeeping and reporting proposed by the revised Part 72 would far exceed 6 hours annually. The estimate of 6 hours for annual training would be sufficient to address the training of personnel to implement these new requirements but would not be sufficient to address the actual recordkeeping and reporting. Of course, the actual burden any individual certificate holder would incur because of the required recordkeeping and reporting would vary by certificate holder. This commenter believes that the

The NRC believes that Alternative 1 would have enabled the NRC to make more effective use of the Enforcement Policy against the certificate holders, and their contractors and subcontractors of spent fuel storage casks.. However, holding contractors and subcontractors responsible as contemplated by the proposed rule would dilute the message that the Commission's regulations would otherwise make clear — that licensees and certificate holders are ultimately responsible for assuring quality. Furthermore, the current regulations in § 72.148 make clear that “[t]o the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this subpart [Subpart G].”

Alternative 2: Revise Part 72 to expand the applicability of certain provisions to certificate holders and applicants for a CoC.

The difference between Alternatives 1 and 2 is that the latter does not include contractors and subcontractors in clarifying the responsibilities for compliance with Part 72. Therefore, the NRC would not issue NOVs or orders against these persons under this alternative but would continue to use administrative actions. Several comments were received that were opposed to adding contractors and subcontractors to the regulations. Overall, the commenters felt this action was unnecessary and an excessive burden on small entities. The proposed rule to extend NRC's regulatory requirements under Part 72, Subpart G, to contractors and subcontractors would be inconsistent with the way in which the NRC regulates quality assurance in other arenas, including reactor parts and equipment. In both instances, there is a potential that deficiencies in the quality assurance program could lead to safety related problems. However, NRC's longstanding regulatory approach has been to make it clear that licensees are responsible for ensuring that the parts and equipment are safe.

believes that the purpose of the final rule justifies this burden on certificate holders. This burden is insignificant by comparison with Part 72's overall burden which is in excess of 21,000 hours. In addition, the current backfit regulation in § 72.62 applies only to Part 72 licensees and not to holders of, and applicants for, a CoC. This rule adds recordkeeping and reporting requirements for holders of, and applicants for, CoCs. Therefore, a backfit analysis is not required for this rule.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The final rule amends the regulations to expand the applicability of 10 CFR Part 72 to holders of, and applicants for, CoCs. This requirement will enhance the Commission's ability to take enforcement action by issuing NOVs or orders rather than administrative action in the form of NONs when legally binding requirements are violated.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not "a major" rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

The final rule may appear to impose new requirements on some small entities (~~i.e. a certificate holder or applicant that qualifies as a small entity~~). However, these entities, for the most part, are already implementing the actions required by the final rule. Therefore, the NRC believes that this amendment will not have a significant economic impact on any such small entity.

On the assumption that there could be a certificate holder or applicant able to qualify as a "small entity":

NW (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Richard W. Borchardt, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, (301) 415-2741.

SUPPLEMENTARY INFORMATION:

The Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy or Policy) primarily addresses violations by licensees and certain nonlicensed persons, including certificate holders, as discussed further in footnote 3 to Section I, Introduction and Purpose, and in Section X, Enforcement Action Against Nonlicensees.

10 CFR Part 72 of the NRC's regulations addresses licensing requirements for the independent storage of spent nuclear fuel and high-level radioactive waste. Over the past two years, the Commission has observed problems with the performance of several certificate holders and their contractors and subcontractors in the manufacture of spent fuel storage casks. The Commission has concluded that additional enforcement sanctions; e.g., issuance of Notices of Violations (NOVs) and orders, are required to address the performance problems which have occurred in the spent fuel storage industry. Also, concurrent with publication of this change to the Enforcement Policy, the Commission is amending Part 72 to expand its applicability to holders of, and applicants for, Certificates of Compliance (CoCs) ~~and their contractors and subcontractors~~. While CoCs are legally binding documents, certificate holders or applicants for a CoC ~~and their contractors and subcontractors~~ have not clearly been brought

*contain existing regulations
provide for enforcement action to be taken against
contractors or subcontractors, e.g., §§ 72.10
3 and 72.12.*

within the scope of Part 72 requirements, and the NRC has not had a clear basis to cite these persons for violations of Part 72 requirements in the same way it treats licensees. When the NRC has identified a failure to comply with Part 72 requirements by these persons, it has taken administrative action by issuing a Notice of Nonconformance (NON) or a Demand for Information rather than an NOV. With these changes to Part 72, the Commission will be in a position to issue NOV's and Orders. ^{to certificate holders and applicants. While the Part 72} A Notice of Violation (NOV) is a written notice that sets forth one or more violations of a legally binding requirement. The NOV effectively conveys to both the person violating the requirement and the public that a violation of a legally binding requirement has occurred and permits use of graduated severity levels to convey more clearly the safety significance of the violation. Therefore, in addition to the changes to Part 72, the Commission is amending Part X of the Enforcement Policy, Enforcement Action Against Non-Licensees, to make clear that nonlicensees who are subject to specific regulatory requirements; e. g., Part 72, will be subject to enforcement action, including NOV's and orders. The final Part 72 rule does not provide authority for issuing civil penalties to nonlicensees other than that already provided under the Deliberate Misconduct Rule in § 72.12.

changes do not apply to contractors and subcontractors

Paperwork Reduction Act

This policy statement does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0136. The approved information collection requirements contained in this policy statement appear in Section VII.C.