



I disapprove publication of the final rule in its present form. As I have stated previously, NRC licensees manage their plants. For the issue at hand, accordingly, I believe that licensees are responsible for assuring that their contractors and subcontractors are implementing adequate quality assurance programs. As I have also stated previously, NRC should not extend its regulatory reach into new areas beyond matters of adequate protection without a compelling safety benefit that justifies the costs to all. Applying these principles, I do not find a demonstration of a substantial safety benefit in expanding the applicability of 10 CFR Part 72, nor do I find adequate consideration of costs.

A licensee has direct relationships with its vendors under which it has controls and tools to assure compliance with 10 CFR Part 72. Imposition of this proposed final rule could dilute the licensees' accountability and the NRC's strong focus on the licensee's responsibilities.

The NRC already has effective tools at its disposal to assure compliance with quality assurance requirements. In addition to the NRC's existing control of cask certification and licensees' acceptance and use of casks, the staff can address noncompliance with quality assurance requirements through orders to licensees, and notices of nonconformance, confirmatory action letters and demands for information to certificate holders and their contractors and subcontractors. For situations involving deliberate misconduct or substantial safety hazards, certificate holders and their contractors and subcontractors are already subject to 10 CFR § 72.12, "Deliberate Misconduct," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." Moreover, to the extent that the rule would largely turn into regulatory requirements those quality assurance requirements that certificate holders or licensees already impose, it is difficult to discern the safety benefit to be achieved.

I am also concerned about the potential costs to the NRC, certificate holders, and their contractors and subcontractors. The rule is, in spirit, a backfit. Although the applicable backfit provision (§ 72.62) does not apply to certificate holders or their contractors or subcontractors, the rule would treat these entities more like licensees without the protection of a backfit provision. For contractors and subcontractors of certificate holders, there may be additional quality assurance requirements, and needs for additional management and legal review of contractual obligations or notices of violation relating to new regulatory requirements. These burdens would be imposed on small businesses, including some mom-and-pop size facilities that supply materials, equipment or services to certificate holders. Thus, the rule could increase the costs and decrease the availability of materials, equipment or services with no commensurate increase in safety.

For these reasons, I believe that current wording in 10 CFR 72.148, "Procurement document control," is adequate. It is noteworthy that other quality assurance regulations (e.g., 10 CFR Part 50, Appendix B, 10 CFR Part 71) require licensees and certificate holders to assure the quality of the materials, equipment, or services provided by contractors or subcontractors while still affording flexibility. If we approve this rule, it would be difficult to prevent proliferation of requirements similar to those proposed in this rule into other areas.

Should further experience in this area lead the staff to identify problems that amply demonstrate a need for new requirements, it can return to the Commission and recommend appropriate action.

A handwritten signature in black ink, appearing to be the initials 'WJ' or similar, located below the final paragraph of text.