

NUCLEAR REGULATORY COMMISSION

(NUREG-1600, Rev.1)

**NRC Enforcement Policy; Enforcement Action Against Nonlicensees under
10 CFR Part 72**

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy Statement; revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing a revision to its Enforcement Policy (NUREG-1600, Rev.1, "General Statement of Policy and Procedure for NRC Enforcement Actions") to clarify that enforcement action may be taken against nonlicensees for violations of 10 CFR Part 72.

DATES: This action is effective [date of publication in the *Federal Register*], while comments are being received. Submit comments on or before (45 days after publication in the *Federal Register*).

ADDRESSES: Submit written comments to: David L. Meyer, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mail Stop: T6D59, U. S. Nuclear Regulatory Commission, Washington, DC 20555. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm, Federal workdays. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street, 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.

In 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). While CoCs are legally binding documents, certificate holders or applicants for a CoC have not clearly been brought within the scope of certain 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 changes do not apply to contractors and subcontractors certain existing regulations provide for enforcement action to be taken against contractors and subcontractors, e.g., Parts 72.10 and 72.12.

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.

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.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 of OMB.

Accordingly, the NRC Enforcement Policy is revised to read as follows:

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR NRC ENFORCEMENT

ACTIONS

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X. Enforcement Action Against Non-Licensees

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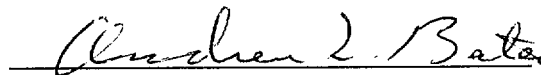
When inspections determine that violations of NRC requirements have occurred, or that contractors have failed to fulfill contractual commitments (e.g., 10 CFR Part 50, Appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken. Notices of Violation and civil penalties will be used, as appropriate, for

licensee failures to ensure that their contractors have programs that meet applicable requirements. Notices of Violation will be issued for contractors who violate 10 CFR Part 21. Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR 21.21(b)(1). Notices of Violation or orders will be used against nonlicensees who are subject to the specific requirements of Part 72. Notices of Nonconformance will be used for contractors who fail to meet commitments related to NRC activities but are not in violation of specific requirements.

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Dated at Rockville, Maryland, this 5th day of October, 1999.

For the Nuclear Regulatory Commission.



Andrew L. Bates, Acting
Secretary of the Commission.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN: 3150-AF93

**Expand Applicability of Part 72 to Holders of, and Applicants for,
Certificates of Compliance**

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to clarify the obligations of holders of, and applicants for, Certificates of Compliance (CoCs). These amendments will enhance the Commission's ability to take enforcement action against these persons when legally binding requirements are violated. This action will emphasize the safety and regulatory significance associated with violations of the regulations. In addition, a new section identifies recordkeeping and reporting requirements for certificate holders and applicants for a CoC.

EFFECTIVE DATE: This final rule is effective on (60 days from the date of publication in the Federal Register).

FOR FURTHER INFORMATION CONTACT: Anthony DiPalo, telephone (301) 415-6191, e-mail, ajd@nrc.gov, of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

Background

The Commission's regulations at 10 CFR Part 72 were established to provide requirements for the issuance of licenses for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI) (45 FR 74693; November 12, 1980). In 1990, the Commission amended Part 72 to include a process for approving the design of spent fuel storage casks and issuance of a CoC (Subpart L) and for granting a general license to reactor licensees (Subpart K) to use NRC-approved casks for storage of spent nuclear fuel (55 FR 29181; July 18, 1990). In the past, the Commission has experienced performance problems in the areas of design, design control, fabrication and quality control with holders of, and applicants for, a CoC under Part 72. When the NRC identifies a failure to comply with Part 72 requirements by these persons, the enforcement sanctions available have been limited to administrative actions.

The NRC Enforcement Policy¹ and its implementing program was established to support the NRC's overall safety mission in protecting public health and safety and the environment. Consistent with this purpose, enforcement actions are used as a deterrent to emphasize the

¹ NUREG-1600, Revision 1, "General Statement of Policy and Procedures for NRC Enforcement Actions," May 1998 (at 63 FR 26630; May 13, 1998).

importance of compliance with requirements and to encourage prompt identification and comprehensive correction of the violations. Enforcement sanctions consist of Notices of Violation (NOVs), civil penalties, and orders of various types. In addition to formal enforcement actions, the NRC also uses related administrative actions such as Notices of Nonconformance (NONs), Confirmatory Action Letters, and Demands for Information to supplement its enforcement program. The NRC expects licensees, certificate holders, and applicants for a CoC to adhere to any obligations and commitments that result from these actions and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met. The nature and extent of the enforcement action are intended to reflect the seriousness of the violation involved. An NOV is a written notice setting forth one or more violations of a legally binding requirement.

The Commission published a proposed rule in the Federal Register (63 FR 39526; July 23, 1998). The comment period ended on October 6, 1998, and four comment letters were received on the proposed rule.

Discussion

In promulgating Subpart L, the NRC intended that selected Part 72 provisions would apply to spent fuel storage cask certificate holders and applicants for a CoC. For example, § 72.234(b) requires that, as a condition for approval of a CoC, "[d]esign, fabrication, testing, and maintenance of spent fuel storage casks be conducted under a quality assurance program that meets the requirements of subpart G of this part." However, the quality assurance (QA) requirements in Subpart G refer only to licensees and applicants for licenses, and not to certificate holders. Further, some Subpart L regulations apply explicitly to "the applicant" (e.g., §

72.232) or to "the cask vendor" (e.g., § 72.234(d)(1)). Some of these provisions are written in the passive voice so that it is not clear who is responsible for meeting the requirement (e.g., § 72.236). Although CoCs are legally binding documents, certificate holders or applicants for a CoC have not clearly been brought within the scope of Part 72 requirements. Because the terms "certificate holder" and "applicant for a certificate of compliance" do not appear in the above-cited Part 72 regulations, 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 issued a NON rather than an NOV.

Although an NON and an NOV appear to be similar, the Commission prefers the issuance of an NOV because: (1) the issuance of an NOV effectively conveys to both the person violating the requirement and the public that a violation of a legally binding requirement has occurred; (2) the use of graduated severity levels associated with an NOV allows the NRC to effectively convey to both the person violating the requirement and the public a clearer perspective on the safety and regulatory significance of the violation; and (3) violation of a regulation reflects the NRC's conclusion that potential risk to public health and safety could exist.

Over the last 2 years, the Commission has observed repeated problems with the performance of several certificate holders. These problems have occurred in design, design control, fabrication and corrective action areas. Problems in these areas are typically covered under the QA program. In FY 1996, the NRC staff identified numerous instances when certificate holders and their contractors and subcontractors failed to comply with the requirements of Part 72. The Commission has concluded that use of the additional enforcement sanctions, which are available in the NRC Enforcement Policy, is required to address the

performance problems that have occurred in the spent fuel storage industry. Therefore, the Commission is revising Part 72 to explicitly state that certificate holders and applicants for a CoC must comply with Part 72 regulations.

Summary of the Proposed Rule Amendments

The following is a summary of the amendments that were discussed in the proposed rule (63 FR 39526; July 23, 1998). This summary does not include changes made in the final rule in response to public comments. A summary of the final amendments is discussed in a separate section in this notice.

Subpart A - General Provisions

§ 72.2 Scope.

The term *spent fuel storage cask* would be added to paragraph (b) of this section. This is a conforming amendment.

§ 72.3 Definitions.

The definitions for *spent fuel storage cask*, *certificate holder*, and *certificate of compliance* would be added to this section. The term *spent fuel storage cask* would be added to the existing definitions for *design bases and structures, systems, and components (SSC) important to safety*. The definition for *design capacity* would be revised to be consistent with the Commission's policy on use of metric units.

§ 72.9 Information collection requirements: OMB approval.

This section would be revised as a conforming amendment, because of the addition of new § 72.242.

§ 72.10 Employee protection and § 72.11 Completeness and accuracy of information.

The terms *certificate holder* and *applicants for a Commission license or a CoC* would be added for clarification.

Subpart D - Records, Reports, Inspections, and Enforcement

§ 72.86 Criminal penalties.

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph has been revised to delete the reference to § 72.236. This section is being revised to provide that failure to comply with the specific requirements for spent fuel storage cask approval would be subject to the criminal penalty provision of § 223 of the Atomic Energy Act. Similarly, certificate holders and applicants who fail to comply with the new § 72.242 (Recordkeeping and reports) would also be subject to criminal penalties. Therefore, § 72.242 will not be included in § 72.86(b).

Subpart G - Quality Assurance

§§ 72.140 through 72.176

In the proposed rule, the term "certificate holder and applicants for a CoC and their contractors and subcontractors" is added, as appropriate, to these sections to define explicitly

those responsibilities associated with QA requirements. In 1990, when the Commission added Subparts K and L to Part 72 to provide a process for approving the design of a spent fuel storage cask, which would be used under a general license, the Commission's intent was that certificate holders and applicants for a CoC follow the QA regulations of Part 72. Section 72.234(b) required that activities relating to the design, fabrication, testing, and maintenance of spent fuel storage casks must be conducted under a QA program that meets the requirements of Subpart G of Part 72. However, the 1990 amendments to Part 72 did not amend Subpart G to include certificate holders and applicants for a CoC. In addition, other changes have been made to individual sections of Subpart G as described below.

In § 72.140, paragraphs (a) and (b) have been revised to clarify the responsibilities of a certificate holder and a licensee with respect to who is responsible for ensuring that the QA program is properly implemented. Paragraph (c) has been revised to provide milestones for a licensee and a certificate holder when the NRC must approve their QA program. Paragraph (d) has been revised to permit use of an NRC-approved QA program that satisfies the requirements of Subpart H to Part 71 and Subpart G of Part 72, as well as an approved program under Appendix B to Part 50. The notification requirement in paragraph (d) would be revised to require that the NRC be notified in accordance with the standard notification requirements contained in § 72.4.

To provide clarity, § 72.142 has been rearranged. The new paragraph (a) has been revised to indicate that all of the persons associated with QA activities for an ISFSI or a spent fuel storage cask (i.e., the licensee, certificate holder, and applicants for a CoC or license, and in the proposed rule their contractors and subcontractors) are responsible for implementation of the QA program.

In § 72.144 paragraphs (a) and (b), § 72.154 paragraph (b), § 72.162, and § 72.168 paragraph (a), the term spent fuel storage cask has been added to the terms ISFSI and MRS.

Subpart L - Approval of Spent Fuel Storage Casks

§ 72.232 Inspection and tests.

This section has been reformatted by adding a new paragraph (b) and renumbering existing paragraphs (b) and (c). In paragraphs (a), (b), and (c), the term "applicant" has been 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) has been 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) includes 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 has been revised to clarify who is responsible for accomplishing these requirements. The term "cask vendor" has been replaced with "certificate holder." The term "cask user" has been 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 to "spent fuel storage casks." In addition, the acronym "CoC" would be used in place of the term "Certificate of Compliance," where appropriate.

§ 72.236 Specific Requirements for Spent Fuel Storage Cask Approval.

This section has been revised to clarify who is responsible for accomplishing these requirements. A new sentence would be added at the beginning of this section to specify who has responsibility for ensuring that each of the requirements contained in paragraphs (a) through (m) is met. This section has been reissued as being subject to the criminal penalty provisions of § 223 of the Atomic Energy Act. Applicants for a CoC would not be required to ensure that the requirements of paragraphs (j) and (k) were met because these requirements apply to activities that can only occur after a cask has been fabricated, and an applicant cannot begin fabrication of a cask until a CoC has been issued (see § 72.234(c)).

§ 72.240 Conditions for Spent Fuel Storage Cask Reapproval.

This section has been revised to clarify who is responsible for accomplishing these requirements. The term "user of a cask" has been replaced with "the licensee using the spent fuel storage cask" and the term "cask model" has been replaced with "design of a spent fuel storage cask." The term "representative of a cask user" has been replaced with "the representative of the licensee using the spent fuel storage cask." In addition, the acronym "CoC" is used in place of the term "Certificate of Compliance" where appropriate.

§ 72.242 Recordkeeping and Reports.

This new section identifies recordkeeping and reporting requirements for certificate holders and applicants for a CoC that are not already covered by the regulations in § 72.234(d). This includes records required to be kept by a condition of the CoC or records relating to design changes, nonconformances, QA audits, and corrective actions. Violations of this section are subject to the criminal penalty provisions of § 223 of the *Atomic Energy Act of 1954*. Paragraphs (a), (b), and (c) are similar to the recordkeeping requirements imposed on licensees in § 72.80(a), (c), and (d).

A new requirement has been established in paragraph (d) for certificate holders to submit written reports to the NRC when they identify design or fabrication deficiencies, in structures, systems, and components that are important to safety for spent fuel storage casks that have been delivered to licensees. This requirement would inform the NRC of deficiencies that may affect existing casks and thereby potentially affect public health and safety. This requirement would be similar to the event reporting requirement imposed on licensees in § 72.75(c)(2).

Summary of Public Comments on the Proposed Rule

The NRC received four comment letters on the proposed rule. The commenters included a member of the public, one cask fabricator, and two Part 72 certificate holders. Three of the four commenters favored the proposed amendments, and one was opposed. Copies of the public comments are available for review in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC 20003-1527. One commenter, a member of the public, raised many issues unrelated to this rulemaking (e.g., issues that are being addressed in a

separate petition for rulemaking (i.e., PRM-72-3), the NRC Enforcement Policy, the NRC Inspection Program, and NRC oversight of the overall spent fuel storage program). The NRC believes these issues are beyond the scope of this rule.

A review of the comments and the Commission's responses follow:

1. Comment: One commenter, a certificate holder, recommended for clarity that in the proposed definition of "certificate holder" in § 72.3, the words "company" or "organization" replace the word "person," because a certificate of compliance is not issued to a specific person.

Response: The NRC disagrees with the comment. The definition of "person" in the rule has the same meaning as "person" defined in section 11s. of the *Atomic Energy Act of 1954*. This definition encompasses a wide range of entities (i.e., individuals, corporations, trusts, government agencies, states, and foreign governments) who may wish to apply for a Part 72 license or certificate. Therefore, no change has been made in the final rule.

2. Comment: One commenter, a certificate holder, agreed that design changes should have appropriate controls. However, the commenter stated that it is not clear whether design changes undertaken by the certificate holder require prior NRC approval. Currently, § 72.48 identifies those changes that the licensee may make without prior NRC review, and § 72.70 addresses the licensee's responsibility to update its Safety Analysis Report (SAR). But, the rule does not apply §§ 72.48 and 72.70 to the certificate holders. The commenter stated that the rule did not address whether prior NRC approval is required for a design change made by a certificate holder that would necessitate a revision of the cask SAR, but would not specifically deviate from the CoC; and how the SAR will be updated to reflect these changes.

The commenter recommended that the proposed revision of § 72.146(c) needs clarification of when prior NRC approval is required for certificate holders and the means to

control changes to the SAR that do not require a change to the CoC. The commenter believed that the most direct method to address this concern is to revise Part 72 to apply §§ 72.48 and 72.70 to certificate holders. The commenter recognized that NRC intends to pursue changes to § 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 53582; October 4, 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.

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 recognizes the use of wording "but not limited to" and "to the extent practicable," could be viewed as subjective, when interpreting the regulations; however,

the changes to paragraphs (a), (i), and (m) did not change the substance of § 72.236. This wording is regularly used in statutes and regulations and the NRC believes this wording will be reasonably interpreted in enforcement actions.

5. Comment: One commenter, a member of the public, disagreed with the proposed language in § 72.140(a) stating that she ... “did not like the term licensee and certificate holder being simultaneously responsible for implementing the quality assurance (QA) requirements for oversight of contractors and subcontractors activities.” The commenter was concerned that imposing dual responsibility for the same activity was tantamount to implying that no one was responsible. The commenter believed there needed to be a clear cut line of responsibility to determine what the licensee is actually liable for.

Response: The NRC disagrees with the comment. The NRC intended that both licensees and CoC holders be held accountable for oversight of their contractor (i.e., fabricator) activities and that this redundant responsibility would ensure that the spent fuel storage casks are manufactured in conformance with the approved design and Part 72 QA requirements. The NRC believes that this approach will have an overall positive effect on improving quality in the manufacture of spent fuel storage casks.

6. Comment: One commenter, a certificate holder, agreed with the proposed change in § 72.140(c)(2) to require certificate holders to obtain NRC approval of its quality assurance program prior to commencing fabrication or testing of a spent fuel storage cask. However, this commenter also noted that § 72.140(d) states that a quality assurance program which satisfies Appendix B to Part 50 is acceptable for Part 72. The commenter also noted that a certificate holder may have a quality assurance program that has been approved by the NRC under

Part 71 or approved by the NRC for another Part 72 CoC application. The commenter suggested that § 72.140(d) be revised to include a quality assurance program which has been previously approved for Part 71 or Part 72 as acceptable for new CoC applications under Part 72.

Response: The NRC agrees with the comment. The QA requirements contained in 10 CFR Part 50, Appendix B; 10 CFR Part 71, Subpart H; and 10 CFR Part 72, Subpart G, are essentially equivalent. The proposed rule revises § 72.140(c), "Approval of Programs," to expand this paragraph to indicate that a certificate holder must have an NRC-approved QA program before commencing fabrication or testing of a spent fuel storage cask. The NRC agrees that the definition of an "approved" QA program found in § 72.140(d) should include other NRC-approved QA programs. This final rule is revised to allow for the use of all NRC-approved QA programs as satisfying the requirements of Subpart G.

Additionally, the language in § 72.140(d) is revised to reflect: (1) the recordkeeping requirement in § 72.174 and (2) the current location for submitting information to the NRC in § 72.4. These requirements were added to § 72.140(d) by a different rulemaking (see the final rule entitled "Miscellaneous Changes to Licensing Requirements for the Independent Storage of Spent Fuel and High-Level Radioactive Waste" (64 FR 33178; June 22, 1999)). The language in § 72.140(c) and (d) is revised to be consistent with paragraph (b) of this section to indicate that the requirements in these paragraphs apply to a licensee, applicant for a license, certificate holder, and applicant for a certificate, as appropriate.

7. Comment: One commenter, a member of the public, expressed concern with the NRC's process for issuing exemptions to the requirement in § 72.234(c). (Note: § 72.234(c)

currently prohibits beginning cask fabrication before the NRC issues a Certificate of Compliance.)

Response: The NRC believes this comment is beyond the scope of this rulemaking. While § 72.234, "Conditions for Approval," was revised in this rulemaking, no change to paragraph (c) of this section was proposed. Rather, this section was revised to clarify who is responsible for implementing these requirements. The process for granting an exemption to Part 72 under the provisions of § 72.7, including § 72.234(c), is adequate. An amendment to § 72.234(c) specifically addressing the issue of beginning cask construction before a CoC is issued is addressed in a different rulemaking currently under development by the NRC staff (see proposed rulemaking on "Clarification and Addition of Flexibility to Part 72," RIN-AG15).

8. Comment: One commenter, a certificate holder, raised the issue that the added requirement in § 72.242(d) requires a written report when the design or fabrication deficiency affects the ability of structures, systems, and components (SSCs) important to safety to perform their intended safety function. The commenter indicated that an individual SSC may perform more than one function. Some of these may be safety related while other functions may not serve a safety function. As an example, a coating may assist in heat removal as a function important to safety but may also serve as an aesthetic function. For this example, the proposed rule could be interpreted to require a written report addressing a deficiency associated with an aesthetic function, even though the particular component would be capable of performing its safety function. It would be an unwarranted use of industry and NRC resources to report deficiencies that do not affect a safety function. The commenter further raised the issue that the deficiency may affect the safety function of such SSCs, but the deficiency may not prevent such structure, system, or component from performing its intended safety function. As an example, a

deficiency in a coating may be discovered such that the manufacturer lowers its peak heat transfer rating. However, the cask design as stated in the Safety Analysis Report may not rely upon such a high rating. It also would be an unwarranted use of industry and NRC resources to report deficiencies that do not affect the ability of the component to perform its intended safety function. The commenter suggested revising § 72.242(d) to read as follows: "...deficiency affects the ability of structures, systems, and components important to safety to perform their intended safety function," (emphasis original).

Response: The NRC agrees with the comment and the final rule has been revised to incorporate the comment.

9. Comment: One commenter, a cask fabricator, had two objections to the proposed rule. First, the commenter was opposed to the potential for issuance of NOVs and civil penalties against cask fabricators because they have no responsibilities or involvement in developing the design configurations for the various spent fuel packages. Second, the commenter indicated that the proposed changes to §72.146(a) and (b), "Design Control," were troublesome because, under the current procurement process for spent fuel packages, the commenter believes fabricators are intentionally precluded from the development of front end design and licensing activities. The fabricator currently bases manufacturing planning documentation upon the adequacy of a customer provided specification package. The commenter indicated that the fabricator may or may not utilize customer provided drawings for manufacture and that where the fabricator generates the drawings the designer and/or licensee might require their review and approval, but that there is no accepted industry practice on this matter.

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 estimated burden is greater than 100 hours annually but believes that the purpose of the final rule justifies this burden.

Response: The NRC agrees with the comment. The NRC has reevaluated the recordkeeping and reporting burden estimated for § 72.242 and concluded that the commenter's estimate of 100 hours annually is reasonable. The NRC has verified with the Office of Management and Budget (OMB) that burden increase is an extremely small percentage increase of the present total 21,454-hour burden for Part 72.

Summary of Final Amendments

The amended sections listed below have not changed from the proposed rule and are included in the final rule, some editorial changes to improve the organization and readability of the existing language have also been made. These are: §§ 72.2, 72.3, 72.9, 72.10, 72.86, 72.234, 72.236, 72.240, and 72.242(a), (b), and (c).

In the final rule, §§ 72.140, 72.142, 72.144, 72.146, 72.148, 72.150, 72.152, 72.154, 72.156, 72.158, 72.160, 72.162, 72.164, 72.168, 72.170, 72.172, 72.174, 72.176, and 72.232 have been revised in response to comments, and the terms "contractor and subcontractor" are removed. However, this action has not been taken in § 72.10 and § 72.148, in part, because the current regulation contains those terms.

Additionally, in § 72.148, text at the end of the first sentence in the current regulation was inadvertently omitted in the proposed rule. It has been restored and will read as follows: "...for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, or by their contractors and subcontractors." (emphasis added)

In § 72.140 of the final rule, paragraphs (c) and (d) are revised in response to comments received on the proposed rule as follows:

Section 72.140 (c) and (d): The QA requirements contained in 10 CFR Part 50, Appendix B; 10 CFR Part 71, Subpart H; and 10 CFR Part 72, Subpart G, are essentially equivalent. The proposed rule revised § 72.140(c), "Approval of Programs," to expand this paragraph to indicate that a certificate holder must have an NRC-approved QA program before commencing fabrication or testing of a spent fuel storage cask. The NRC agrees that the definition of an "approved" QA program found in § 72.140(d) should include all other NRC-approved QA programs. The final rule is revised to allow for the use of all NRC-approved QA programs as satisfying the requirements of Subpart G. Additionally, the language in § 72.140(d) is revised to reflect the recordkeeping requirement in § 72.174 and the address for submitting information in § 72.4, which were added to this section by a different rulemaking (see Miscellaneous Changes to Licensing Requirements for the Independent Storage of Spent Fuel and High-Level Radioactive Waste (see 64 FR 33178; June 22, 1999)). The language in § 72.140(c) and (d) is revised to be consistent with paragraph (b) of this section to indicate that the requirements in these paragraphs apply to a licensee, applicant for a license, certificate holder, and applicant for a certificate, as appropriate.

In the final rule, § 72.242(d) is modified to accept the comment that written reports should be made when a design or fabrication deficiency affects the ability of SSCs important to safety to perform their intended safety function.

Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the final rule to amend 10 CFR Part 72: § 72.10, 72.11, 72.140 through 72.176, 72.232, 72.234, 72.236, and 72.242, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the Code of Federal Regulations, and although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

Voluntary Consensus Standards

The *National Technology Transfer Act of 1995* (Pub. L. 104-113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or

otherwise impractical. In this final rule, the NRC is expanding the applicability of Part 72 to holders of, and applicants for, certificates of compliance, and a voluntary consensus standard is not applicable.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(2) and (3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule increases the burden on licensees by expanding the applicability of Part 72 to holders of, and applicants for, Certificates of Compliance. The public burden for this information collection is estimated to average 100 hours annually. Because the burden for this information collection is insignificant by comparison with current Part 72's overall burden, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the OMB approval number 3150-0132.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

Statement of the Problem

The Commission's regulations at 10 CFR Part 72 were designed to provide specific licensing requirements for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI) (45 FR 74693; November 12, 1980). These requirements were later amended to include the storage of high-level waste (HLW) at a monitored retrieval storage (MRS) installation. In 1990, the Commission amended Part 72 to include a process for approving the design of spent fuel storage casks by issuance of a certificate of compliance (Subpart L) and for granting a general license to reactor licensees (Subpart K) to use NRC-approved casks for storage of spent nuclear fuel (55 FR 29181; July 18, 1990). In the past, the Commission experienced performance problems in design, design control, fabrication and quality control with holders of, and applicants for, a CoC under Part 72.

When the NRC identifies a failure to comply with Part 72 requirements by these persons, the NRC has issued Notices of Nonconformance (NONs). The issuance of an NON does not effectively convey that a violation of a legally binding requirement has occurred. Because the current regulations do not clearly impose requirements on these persons, the NRC has not taken enforcement action, such as a Notice of Violation (NOV), against certificate holders and applicants.

Some Part 72 provisions for cask storage of spent fuel (e.g., the quality assurance (QA) requirements) were intended to apply to cask certificate holders and applicants for cask CoCs, as well as to holders of licenses and applicants for a license to store spent nuclear fuel at an ISFSI. However, some of the Part 72 requirements intended to apply to certificate holders and applicants do not clearly bring these persons within the scope of the requirement. For this

reason, the NRC has not had a clear basis to cite certificate holders and applicants for a CoC for violations of those Part 72 requirements.

Additionally, broader requirements for recordkeeping and reporting for certificate holders and applicants for a CoC to include records required to be kept by a condition of the CoC, are needed. Therefore, the NRC is adding § 72.242. This will provide an enforcement basis equivalence to the recordkeeping and reporting regulations for licensees (§ 72.80).

Purpose of the Rulemaking

The purpose of this rulemaking is to expand the applicability of Part 72 to holders of, and applicants for, CoCs. This would allow the NRC staff to take enforcement action in the form of NOVs or orders, rather than administrative action in the form of a NON when requirements are violated. While it may appear that a NON and a NOV are similar, the NRC believes that the issuance of a NOV is preferred because: (1) the issuance of a NOV effectively conveys to both the person violating the requirement and the public that a violation of a legally binding requirement has occurred; (2) the use of graduated severity levels associated with a NOV allows the NRC to effectively convey to both the person violating the requirement and the public a clearer perspective on the safety and regulatory significance of the violation; and (3) violation of a regulation reflects the NRC's conclusion that potential risk to public health and safety could exist.

Current Regulatory Framework and Proposed Changes

In promulgating Subpart L, the NRC intended that selected Part 72 provisions would apply to cask certificate holders and applicants for a CoC. For example, § 72.234(b) requires that, as a condition for approval of a CoC, "[d]esign, fabrication, testing, and maintenance of

spent fuel storage casks be conducted under a QA program that meets the requirements of subpart G of this part." However, the QA requirements in Subpart G refer only to licensees and applicants for licenses and not to certificate holders. Some of the Subpart L regulations apply explicitly only to "the applicant" (e.g., § 72.232), or to "the cask vendor" (e.g., § 72.234(d)(1)). Some are written in the passive voice so that it is not clear who is responsible for meeting the requirement (e.g., § 72.236). Because of these regulatory deficiencies, certificate holders or applicants for a CoC have not clearly been brought 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. Presently, when the NRC has identified a failure to comply with Part 72 requirements by these persons, it has issued an administrative action under the NRC's Enforcement Policy.

The NRC Enforcement Policy and implementing program have been established to support the NRC's overall safety mission in protecting public health and safety and the environment. Consistent with this purpose, enforcement actions are intended to be used as a deterrent to: (1) emphasize the importance of compliance with requirements; and (2) encourage prompt identification and comprehensive correction of the violations. Enforcement sanctions consist of NOVs, civil penalties, and orders of various types. In addition to the formal enforcement actions, the NRC also uses related administrative actions such as NONs, Confirmatory Action Letters, and Demands for Information to supplement the NRC's enforcement program. The NRC expects licensees and holders of, and applicants for, a CoC to adhere to any obligations and commitments resulting from these actions and will not hesitate to issue appropriate orders to ensure that these obligations and commitments are met. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved.

This rule revises the regulations in Part 72 to place explicit requirements on certificate holders and applicants for a CoC. Additionally, terms contained in Subpart L, such as cask user, representative of a cask user, cask model, and cask vendor, have been clarified. Changes are made to § 72.10, "Employee Protection," and § 72.11, "Completeness and Accuracy of Information," to include certificate holders and applicants for a CoC. Section 72.3 is revised to: (1) incorporate definitions for "certificate holder," "certificate of compliance," and "spent fuel storage cask"; (2) amend the definitions for "design bases" and "structures, systems, and components important to safety" to include the term "spent fuel storage cask"; and (3) amend the definition for "design capacity" to be consistent with the NRC's policy on the use of metric units. Section 72.236 is revised and reissued as being subject to the criminal penalty provisions of § 223 of the *Atomic Energy Act of 1954*, and § 72.86(b), "Criminal Penalties," is revised to delete mention of § 72.236 as a conforming change. Section 72.232 is reformatted by adding a new paragraph (b) and renumbering existing paragraphs (b) and (c). The term "applicant" is replaced by the term "certificate holder and applicant for a CoC." Requirements to permit inspection of records, premises, and activities related to the design, fabrication, and testing of spent fuel storage casks have been clarified. Lastly, a new § 72.242 is added to Subpart L to address additional recordkeeping and reporting requirements for certificate holders and applicants for a CoC, in addition to those already required by § 72.234(d). This new section is similar to the requirements imposed on licensees in § 72.80.

Alternatives

This regulatory analysis considered three alternatives:

Alternative 1: Revise Part 72 to expand the applicability of certain provisions to certificate holders, applicants for a CoC, and their contractors and subcontractors.

The NRC believes that problems in the areas of quality assurance, quality control, fabrication control, and design control exist, are significant, and, in part, reflect the fact that certificate holders and applicants, and their contractors and subcontractors, have not been explicitly included in certain Part 72 requirements despite the NRC's intent that these persons follow these requirements. Contractors and subcontractors actually accomplish the manufacturing and testing of spent fuel storage casks.

Alternative 1 would allow the NRC to issue NOV's or orders against these persons, as necessary, by allowing the issuance of an NOV when they fail to comply with the requirements of Part 72. Presently the NRC issues an NON in these instances.

The NRC has estimated that each certificate holder or applicant for a CoC, on average, has three contractors and subcontractors. Consequently, the NRC estimates that a total of 60 contractors and subcontractors would be affected by changes to Part 72 described in Alternative 1. Because certificate holders, applicants for a CoC, and their contractors and subcontractors, for the most part, have already been meeting the requirements of Part 72 as either a condition of a CoC or as a condition of a contract between a certificate holder and its contractors and subcontractors, the burdens imposed by this alternative are not significantly increased.

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.

Therefore, the NRC has reconsidered and concluded that contractors and subcontractors should not be included in these regulations. Consequently, Alternative 2 is adopted.

Alternative 3: No action.

This alternative was rejected, even though staff resources for rulemaking would have been conserved. Under this alternative, it is expected that the difficulties the NRC has observed in the past will continue.

Decision Rationale For Preferred Alternative

Alternative 2 is the preferred choice. The major benefit of this alternative is to allow the NRC to issue NOVs or Orders against certificate holders and applicants for a CoC under the current NRC Enforcement Policy, without imposing an unnecessary burden on contractors and subcontractors; and ensures that quality assurance requirements imposed on contractors and subcontractors are consistent for both reactor and material activities. This would enable both the person violating the regulation and the public to clearly perceive the regulatory and safety significance and consequences of the violation.

Because certificate holders and applicants for a CoC, for the most part, already have been meeting the requirements of Part 72 as a condition of a CoC, the burdens imposed by this amendment are not significantly increased. Additional requirements for recordkeeping and reporting for certificate holders are needed, to include records required to be kept by a condition of the CoC.. This will provide an enforcement basis equivalence to the recordkeeping and reporting regulations for licensees (§ 72.80). Therefore, the NRC is adding § 72.242. The new § 72.242 will add new burdens for recordkeeping and reporting requirements. The staff estimates this burden associated with the new § 72.242 to be approximately 100 hours annually. This recordkeeping and reporting burden will vary by certificate holders. The NRC 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. The final rule may appear to impose new requirements on some small entities on the assumption that could be a certificate holder or applicant able to qualify 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.

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.

Backfit Analysis

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, in any event, adds only reporting and recordkeeping requirements for holders of, and applicants for, CoCs. The Commission has determined that reporting and recordkeeping requirements are not considered backfits even though they may result in changes to procedures. If the reporting or recordkeeping requirements had to meet the standards for a backfit analysis, the Commission would have to find that the information would substantially increase public health or safety or common defense and security without knowing the results of the request. In addition, the existence or non-existence of a record or report usually has no independent safety significance as compared to actions taken by the licensee, certificate holder, or NRC as a result of the information contained in the record or report. It is this resulting action that affects public health and safety or the common defense or security that should be measured under the backfit standard and not the method for obtaining or maintaining the information.

However, the NRC has prepared a regulatory analysis which sets forth the objectives of the rulemaking changes, the alternatives that were considered, and the expected costs and benefits associated with the rulemaking changes. The NRC regards this analysis as providing for a disciplined approach for evaluating the impacts of the proposed changes, which satisfies the underlying purposes of the backfitting requirements in § 72.62.

List of Subjects in 10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 72.

PART 72--LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

1. The authority citation for Part 72 is revised to read as follows:

AUTHORITY: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95-601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 102-486, sec. 7902, 106 Stat. 3123 (42 U.S.C. 5851); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97-425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100-203, 101 Stat. 1330-232, 1330-236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97-425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100-203, 101 Stat. 1330-235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97-425, 96 Stat. 2202, 2203, 2204, 2222, 2224 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.2, paragraph (b) is revised to read as follows:

§ 72.2 Scope.

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(b) The regulations in this part pertaining to an independent spent fuel storage installation (ISFSI) and a spent fuel storage cask apply to all persons in the United States, including persons in Agreement States. The regulations in this part pertaining to a monitored retrievable storage installation (MRS) apply only to DOE.

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3. In § 72.3, the definitions of Certificate holder, Certificate of Compliance or CoC, and Spent fuel storage cask or cask are added in alphabetical order, and the definitions of Design bases, Design capacity, and Structures, systems, and components important to safety are revised to read as follows:

§ 72.3 Definitions.

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Certificate holder means a person who has been issued a Certificate of Compliance by the Commission for a spent fuel storage cask design.

Certificate of Compliance or *CoC* means the certificate issued by the Commission that approves the design of a spent fuel storage cask in accordance with the provisions of Subpart L of this part.

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Design bases means that information that identifies the specific functions to be performed by a structure, system, or component of a facility or of a spent fuel storage cask and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be restraints derived from generally accepted state-of-the-art practices for achieving functional goals or requirements derived from analysis (based on calculation or experiments) of the effects of a postulated event under which a structure, system, or component must meet its functional goals. The values for controlling parameters for external events include —

(1) Estimates of severe natural events to be used for deriving design bases that will be based on consideration of historical data on the associated parameters, physical data, or analysis of upper limits of the physical processes involved; and

(2) Estimates of severe external man-induced events to be used for deriving design bases that will be based on analysis of human activity in the region, taking into account the site characteristics and the risks associated with the event.

Design capacity means the quantity of spent fuel or high-level radioactive waste, the maximum burn up of the spent fuel in MWD/MTU, the terabequerel (curie) content of the waste,

and the total heat generation in Watts (btu/hour) that the storage installation is designed to accommodate.

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Spent fuel storage cask or cask means all the components and systems associated with the container in which spent fuel or other radioactive materials associated with spent fuel are stored in an ISFSI.

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Structures, systems, and components important to safety means those features of the ISFSI, MRS, and spent fuel storage cask whose functions are —

(1) To maintain the conditions required to store spent fuel or high-level radioactive waste safely;

(2) To prevent damage to the spent fuel or the high-level radioactive waste container during handling and storage; or

(3) To provide reasonable assurance that spent fuel or high-level radioactive waste can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

4. Section 72.9 is revised to read as follows:

§ 72.9 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). OMB has

approved the information collection requirements contained in this part under control number 3150-0132.

(b) The approved information collection requirements contained in this part appear in §§ 72.7, 72.11, 72.16, 72.19, 72.22 through 72.34, 72.42, 72.44, 72.48 through 72.56, 72.62, 72.70 through 72.82, 72.90, 72.92, 72.94, 72.98, 72.100, 72.102, 72.104, 72.108, 72.120, 72.126, 72.140 through 72.176, 72.180 through 72.186, 72.192, 72.206, 72.212, 72.216, 72.218, 72.230, 72.232, 72.234, 72.236, 72.240, and 72.242.

5. In § 72.10, paragraph (a), the introductory text of paragraph (c), and paragraphs (c)(1) and (e)(1) are revised to read as follows:

§ 72.10 Employee protection.

(a) Discrimination by a Commission licensee, certificate holder, an applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these, against an employee for engaging in certain protected activities, is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

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(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, certificate holder, applicant for a Commission license or a CoC, or a contractor or subcontractor of any of these may be grounds for:

(1) Denial, revocation, or suspension of the license or the CoC.

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(e)(1) Each licensee, certificate holder, and applicant for a license or CoC must prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c). This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. The premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license or CoC, and for 30 days following license or CoC termination.

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6. Section 72.11 is revised to read as follows:

§ 72.11 Completeness and accuracy of information.

(a) Information provided to the Commission by a licensee, certificate holder, or an applicant for a license or CoC; or information required by statute or by the Commission's regulations, orders, license or CoC conditions, to be maintained by the licensee or certificate holder, must be complete and accurate in all material respects.

(b) Each licensee, certificate holder, or applicant for a license or CoC must notify the Commission of information identified by the licensee, certificate holder, or applicant for a license or CoC as having, for the regulated activity, a significant implication for public health and safety or common defense and security. A licensee, certificate holder, or an applicant for a license or CoC violates this paragraph only if the licensee, certificate holder, or applicant for a license or CoC fails to notify the Commission of information that the licensee, certificate holder, or

applicant for a license or CoC has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

7. In § 72.86, paragraph (b) is revised to read as follows:

§ 72.86 Criminal penalties.

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(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.238, and 72.240.

8. Section 72.140 is revised to read as follows:

§ 72.140 Quality assurance requirements.

(a) Purpose. This subpart describes quality assurance requirements that apply to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of structures, systems, and components, and decommissioning that are important to safety. As used in this subpart, "quality assurance"

comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. The certificate holder and applicant for a CoC are responsible for the quality assurance requirements as they apply to the design, fabrication, and testing of a spent fuel storage cask until possession of the spent fuel storage cask is transferred to the licensee. The licensee and the certificate holder are also simultaneously responsible for these quality assurance requirements through the oversight of contractors and subcontractors.

(b) Establishment of program. Each licensee, applicant for a license, certificate holder, applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this subpart, and satisfying any specific provisions which are applicable to the licensee's, applicant's for a license, certificate holder's, and applicant's for a CoC activities. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements' importance to safety. The quality assurance program must cover the activities identified in this subpart throughout the life of the activity. For licensees, this includes activities from the site selection through decommissioning prior to termination of the license. For certificate holders, this includes activities from development of the spent fuel storage cask design through termination of the CoC.

(c) Approval of program:

(1) Each licensee, applicant for a license, certificate holder, and applicant for a CoC shall file a description, in accordance with § 72.4, of its quality assurance program that includes a

discussion of which requirements of this subpart are applicable and the methodology used to satisfy these requirements.

(2) Each licensee shall obtain Commission approval of its quality assurance program prior to receipt of spent fuel at the ISFSI or spent fuel and high-level radioactive waste at the MRS.

(3) Each certificate holder shall obtain Commission approval of its quality assurance program prior to commencing fabrication or testing of a spent fuel storage cask.

(d) *Previously approved programs.* A quality assurance program previously approved by the Commission and which is established, maintained, and executed with regard to an ISFSI or spent fuel storage cask will be accepted as satisfying the requirements of paragraph (b) of this section. Previously approved quality assurance programs that satisfy the requirements of Appendix B to part 50 of this chapter, subpart H to part 71 of this chapter, or subpart G to this part are considered acceptable, except each licensee, applicant for a license, certificate holder, and applicant for a CoC who are using an Appendix B or subpart H quality assurance program shall also meet the recordkeeping requirements of § 72.174. Prior to initial use of a previously approved program, each licensee, applicant for a license, certificate holder, and applicant for a CoC shall notify the NRC, in accordance with § 72.4, of its intent to apply its previously approved quality assurance program to ISFSI or spent fuel storage cask activities. The notification must identify the quality assurance program by date of submittal to the Commission, docket number, and date of Commission approval.

9. Section 72.142 is revised to read as follows:

§ 72.142 Quality assurance organization.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee and certificate holder may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, but the licensee and the certificate holder shall retain responsibility for the program. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall clearly establish and delineate in writing the authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components which are important to safety. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are --

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions.

(c) The persons and organizations performing quality assurance functions shall report to a management level that ensures that the required authority and organizational freedom, including sufficient independence from cost and schedule considerations when these

considerations are opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

10. Section 72.144 is revised to read as follows:

§ 72.144 Quality assurance program.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program which complies with the requirements of this subpart. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with these procedures throughout the period during which the ISFSI or MRS is licensed or the spent fuel storage cask is certified. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall identify the structures, systems, and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC, through their quality assurance program(s), shall provide control over activities affecting the quality of the identified structures, systems, and components to an extent commensurate with the importance to safety and, as necessary, to ensure conformance with the approved design of each ISFSI, MRS, or spent fuel storage cask. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall ensure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools and skills to attain the required quality and the need for verification of quality by inspection and test.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall base the requirements and procedures of their quality assurance program(s) on the following considerations concerning the complexity and proposed use of the structures, systems, or components:

- (1) The impact of malfunction or failure of the item on safety;
- (2) The design and fabrication complexity or uniqueness of the item;
- (3) The need for special controls and surveillance over processes and equipment;
- (4) The degree to which functional compliance can be demonstrated by inspection or test; and
- (5) The quality history and degree of standardization of the item.

(d) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained.

(e) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program must regularly review the status and adequacy of that part of the quality assurance program which they are executing.

11. Section 72.146 is revised to read as follows:

§ 72.146 Design control.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license or CoC application for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee and certificate holder shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee and certificate holder shall include suitable qualification testing of a prototype or sample unit under

the most adverse design conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

12. Section 72.148 is revised to read as follows:

§ 72.148 Procurement document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, or by their contractors and subcontractors. To the extent necessary, the licensee, applicant for a license, certificate holder, and applicant for a CoC, shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this subpart.

13. Section 72.150 is revised to read as follows:

§ 72.150 Instructions, procedures, and drawings.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

14. Section 72.152 is revised to read as follows:

§ 72.152 Document control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

15. Section 72.154 is revised to read as follows:

§ 72.154 Control of purchased material, equipment, and services.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection; objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(b) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee and certificate holder shall retain or have available this documentary evidence for the life of the ISFSI, MRS, or spent fuel storage cask. The licensee and certificate holder shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee, applicant for a license, certificate holder, and applicant for a CoC, or a designee of either, shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

16. Section 72.156 is revised to read as follows:

§ 72.156 Identification and control of materials, parts, and components.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

17. Section 72.158 is revised to read as follows:

§ 72.158 Control of special processes.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

18. Section 72.160 is revised to read as follows:

§ 72.160 Licensee and certificate holder inspection.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points that require witnessing or inspecting by the licensee's or certificate holder's designated representative, and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

19. Section 72.162 is revised to read as follows:

§ 72.162 Test control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish a test program to ensure that all testing, required to demonstrate that the structures, systems, and components will perform satisfactorily in service, is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the

requirements and acceptance limits contained in the ISFSI, MRS, or spent fuel storage cask license or CoC. The test procedures must include provisions to ensure that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, applicant for a license, certificate holder, and applicant for a CoC shall document and evaluate the test results to ensure that test requirements have been satisfied.

20. Section 72.164 is revised to read as follows:

§ 72.164 Control of measuring and test equipment.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

21. Section 72.166 is revised to read as follows:

§ 72.166 Handling, storage, and shipping control.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with work and inspection instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

22. Section 72.168 is revised to read as follows:

§ 72.168 Inspection, test, and operating status.

(a) The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the ISFSI, MRS, or spent fuel storage cask. These measures must provide for the identification of items which have satisfactorily passed required inspections and tests where necessary to preclude inadvertent bypassing of the inspections and tests.

(b) The licensee shall establish measures to identify the operating status of structures, systems, and components of the ISFSI or MRS, such as tagging valves and switches, to prevent inadvertent operation.

23. Section 72.170 is revised to read as follows:

§ 72.170 Nonconforming materials, parts, or components.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

24. Section 72.172 is revised to read as follows:

§ 72.172 Corrective action.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

25. Section 72.174 is revised to read as follows:

§ 72.174 Quality assurance records.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall maintain sufficient records to furnish evidence of activities affecting quality. The records must include the following: design records, records of use, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any noted deficiencies. Records must be identifiable and retrievable. Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components

important to safety must be maintained by or under the control of the licensee or certificate holder until the NRC terminates the license or CoC.

26. Section 72.176 is revised to read as follows:

§ 72.176 Audits.

The licensee, applicant for a license, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including reaudit of deficient areas, must be taken where indicated.

27. Section 72.232 is revised to read as follows:

§ 72.232 Inspection and tests.

(a) The certificate holder and applicant for a CoC shall permit, and make provisions for, the NRC to inspect the premises and facilities where a spent fuel storage cask is designed, fabricated, and tested.

(b) The certificate holder and applicant for a CoC shall make available to the NRC for inspection, upon reasonable notice, records kept by them pertaining to the design, fabrication, and testing of spent fuel storage casks.

(c) The certificate holder and applicant for a CoC shall perform, and make provisions that permit the NRC to perform, tests that the Commission deems necessary or appropriate for the administration of the regulations in this part.

(d) The certificate holder and applicant for a CoC shall submit a notification under § 72.4 at least 45 days prior to starting fabrication of the first spent fuel storage cask under a Certificate of Compliance.

28. Section 72.234 is revised to read as follows:

§ 72.234 Conditions of approval.

(a) The certificate holder and applicant for a CoC shall ensure that the design, fabrication, testing, and maintenance of a spent fuel storage cask comply with the requirements in § 72.236.

(b) The certificate holder and applicant for a CoC shall ensure that the design, fabrication, testing, and maintenance of spent fuel storage casks are conducted under a quality assurance program that meets the requirements of subpart G of this part.

(c) The certificate holder and applicant for a CoC shall ensure that the fabrication of spent fuel storage casks under a CoC does not begin prior to receipt of the CoC for the spent fuel storage cask.

(d)(1) The certificate holder shall ensure that a record is established and maintained for each spent fuel storage cask fabricated under the CoC.

(2) This record must include:

(i) The NRC CoC number;

(ii) The spent fuel storage cask model number;

- (iii) The spent fuel storage cask identification number;
- (iv) Date fabrication was started;
- (v) Date fabrication was completed;
- (vi) Certification that the spent fuel storage cask was designed, fabricated, tested, and repaired in accordance with a quality assurance program accepted by NRC;
- (vii) Certification that inspections required by § 72.236(j) were performed and found satisfactory; and

(viii) The name and address of the licensee using the spent fuel storage cask.

(3) The certificate holder shall supply the original of this record to the licensees using the spent fuel storage cask. A current copy of a composite record of all spent fuel storage casks manufactured under a CoC, showing the information in paragraph (d)(2) of this section, must be initiated and maintained by the certificate holder for each model spent fuel storage cask. If the certificate holder permanently ceases production of spent fuel storage casks under a CoC, the certificate holder shall send this composite record to the Commission using instructions in § 72.4.

(e) The certificate holder and the licensees using the spent fuel storage cask shall ensure that the composite record required by paragraph (d) of this section is available to the Commission for inspection.

(f) The certificate holder shall ensure that written procedures and appropriate tests are established prior to use of the spent fuel storage casks. A copy of these procedures and tests must be provided to each licensee using the spent fuel storage cask.

29. Section 72.236 is revised to read as follows:

§ 72.236 Specific requirements for spent fuel storage cask approval and fabrication.

The certificate holder shall ensure that the requirements of this section are met. An applicant for a CoC shall ensure that the requirements of this section are met, except for paragraphs (j) and (k).

(a) Specifications must be provided for the spent fuel to be stored in the spent fuel storage cask, such as, but not limited to, type of spent fuel (i.e., BWR, PWR, both), maximum allowable enrichment of the fuel prior to any irradiation, burn-up (i.e., megawatt-days/MTU), minimum acceptable cooling time of the spent fuel prior to storage in the spent fuel storage cask, maximum heat designed to be dissipated, maximum spent fuel loading limit, condition of the spent fuel (i.e., intact assembly or consolidated fuel rods), the inerting atmosphere requirements.

(b) Design bases and design criteria must be provided for structures, systems, and components important to safety.

(c) The spent fuel storage cask must be designed and fabricated so that the spent fuel is maintained in a subcritical condition under credible conditions.

(d) Radiation shielding and confinement features must be provided sufficient to meet the requirements in §§ 72.104 and 72.106.

(e) The spent fuel storage cask must be designed to provide redundant sealing of confinement systems.

(f) The spent fuel storage cask must be designed to provide adequate heat removal capacity without active cooling systems.

(g) The spent fuel storage cask must be designed to store the spent fuel safely for a minimum of 20 years and permit maintenance as required.

(h) The spent fuel storage cask must be compatible with wet or dry spent fuel loading and unloading facilities.

(i) The spent fuel storage cask must be designed to facilitate decontamination to the extent practicable.

(j) The spent fuel storage cask must be inspected to ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could significantly reduce its confinement effectiveness.

(k) The spent fuel storage cask must be conspicuously and durably marked with --

(1) A model number;

(2) A unique identification number; and

(3) An empty weight.

(l) The spent fuel storage cask and its systems important to safety must be evaluated, by appropriate tests or by other means acceptable to the NRC, to demonstrate that they will reasonably maintain confinement of radioactive material under normal, off-normal, and credible accident conditions.

(m) To the extent practicable in the design of spent fuel storage casks, consideration should be given to compatibility with removal of the stored spent fuel from a reactor site, transportation, and ultimate disposition by the Department of Energy.

30. Section 72.240 is revised to read as follows:

§ 72.240 Conditions for spent fuel storage cask reapproval.

(a) The certificate holder, a licensee using a spent fuel storage cask, or the representative of a licensee using a spent fuel storage cask shall apply for reapproval of the design of a spent fuel storage cask.

(b) The application for reapproval of the design of a spent fuel storage cask must be submitted not less than 30 days prior to the expiration date of the CoC. When the applicant has submitted a timely application for reapproval, the existing CoC will not expire until the application for reapproval has been determined by the NRC. The application must be accompanied by a safety analysis report (SAR). The new SAR may reference the SAR originally submitted for the approved spent fuel storage cask design.

(c) The design of a spent fuel storage cask will be reapproved if the conditions in § 72.238 are met, and the application includes a demonstration that the storage of spent fuel has not significantly adversely affected structures, systems, and components important to safety.

31. Section 72.242 is added to read as follows:

§ 72.242 Recordkeeping and reports.

(a) Each certificate holder or applicant shall maintain any records and produce any reports that may be required by the conditions of the CoC or by the rules, regulations, and orders of the NRC in effectuating the purposes of the Act.

(b) Records that are required by the regulations in this part or by conditions of the CoC must be maintained for the period specified by the appropriate regulation or the CoC conditions. If a retention period is not specified, the records must be maintained until the NRC terminates the CoC.

(c) Any record maintained under this part may be either the original or a reproduced copy by any state-of-the-art method provided that any reproduced copy is duly authenticated by authorized personnel and is capable of producing a clear and legible copy after storage for the period specified by NRC regulations.

(d) Each certificate holder shall submit a written report to the NRC within 30 days of discovery of a design or fabrication deficiency, for any spent fuel storage cask which has been delivered to a licensee, when the design or fabrication deficiency affects the ability of structures, systems, and components important to safety to perform their intended safety function. The written report shall be sent to the NRC in accordance with the requirements of § 72.4. The report shall include the following:

(1) A brief abstract describing the deficiency, including all component or system failures that contributed to the deficiency and corrective action taken or planned to prevent recurrence;

(2) A clear, specific, narrative description of what occurred so that knowledgeable readers familiar with the design of the spent fuel storage cask, but not familiar with the details of a particular cask, can understand the deficiency. The narrative description shall include the following specific information as appropriate for the particular event:

(i) Dates and approximate times of discovery;

(ii) The cause of each component or system failure, if known;

(iii) The failure mode, mechanism, and effect of each failed component, if known;

(iv) A list of systems or secondary functions that were also affected for failures of components with multiple functions;

(v) The method of discovery of each component or system failure;

(vi) The manufacturer and model number (or other identification) of each component that failed during the event;

(vii) The model and serial numbers of the affected spent fuel storage casks;

(viii) The licensees that have affected spent fuel storage casks;

(3) An assessment of the safety consequences and implications of the deficiency. This assessment shall include the availability of other systems or components that could have performed the same function as the components and systems that were affected;

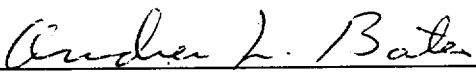
(4) A description of any corrective actions planned as a result of the deficiency, including those to reduce the probability of similar occurrences in the future;

(5) Reference to any previous similar deficiencies at the same facility that are known to the certificate holder; and

(6) The name and telephone number of a person within the certificate holder's organization who is knowledgeable about the deficiency and can provide additional information.

Dated at Rockville, Maryland, this 5TH day of October, 1999.

For the Nuclear Regulatory Commission.


Andrew L. Bates, Acting
Secretary of the Commission.