

- 7/2/99, Provide final rule package to NRC staff working group for comment
- 8/13/99, Provide final rule package to formal concurrence chain
- 9/17/99, Provide final rule package to CRGR and ACRS
- 11/5/99, Complete briefing of CRGR and ACRS
- 11/26/99, Provide final rule package to Commission
- 1/7/00, Publish final rule

Comments requested: The Commission invites advice and recommendations from all interested persons regarding changes to the event reporting requirements for nuclear power reactors contained in 10 CFR 50.72 and 50.73. Comments and supporting reasons are particularly requested on:

- (1) the objectives;
 - (2) the contemplated amendments, including:
 - (a) the clarity and specificity of the contemplated criteria for reporting design and analysis defects and deviations; and
 - (b) the proposed initial reporting time of 8 hours for events that warrant prompt telephone notification but do not involve emergencies;
 - (3) the contemplated schedule.
- To the extent feasible, commenters are requested to address the following factors.

- (1) Identify a specific reporting requirement.
- (2) Describe the problem with that requirement.
- (3) Describe the proposed resolution.
- (4) Estimate the change in resource burden as a result of the proposed resolution.

In order to support meaningful consideration, comments on resource burden should provide the basis for the burden estimate in sufficient detail to allow specific identification of what causes the burden and how particular changes might affect the burden.

Other Reactor Reporting Requirements

Objectives: The NRC is also interested in evaluating other reactor reporting rules (beyond 10 CFR 50.72 and 50.73) to identify areas where reporting requirements can be risk-informed and/or simplified. For example, the time limit for reporting could be adjusted based on the safety significance of the event or issue and the need for NRC's immediate action. The burden associated with reporting events, conditions or issues with little or no safety or risk significance should be minimized.

Comments requested: Public comments are requested to identify and propose changes to other reactor

reporting requirements (beyond 10 CFR 50.72 and 50.73) that are potential candidates for modifying to a simplified, less burdensome, more risk-informed approach. This issue will be included in the agenda for the public meeting to discuss this ANPR, which is identified in the schedule provided above.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

The authority citation for this document is: 42 U.S.C. 2201; 42 U.S.C. 5841.

Dated at Rockville, Maryland, this 16th day of July, 1998

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations

[FR Doc. 98-19637 Filed 7-22-98; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150-AF93

Expand Applicability of Regulations to Holders of, and Applicants for, Certificates of Compliance and Their Contractors and Subcontractors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to expand the applicability of its regulations to holders of, and applicants for, Certificates of Compliance and their contractors and subcontractors. This amendment would enhance the Commission's ability to take enforcement action against these persons when legally binding requirements are violated. The intent of this action is to emphasize the safety and regulatory significance associated with violations of the regulations.

DATES: The comment period expires October 6, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Comments may be sent to: Secretary, U.S. Nuclear Regulatory

Commission, Washington, DC 20555-0001, Attn: Rulemakings and Adjudications Staff. Hand deliver comments to 11555 Rockville Pike, Rockville, MD, between 7:45 am and 4:15 pm on Federal workdays.

You may also provide comments via the NRC's interactive rulemaking web site through the NRC's home page (<http://www.nrc.gov>). This site provides the availability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail CAG@nrc.gov.

Certain documents related to this rulemaking, including comments received by the NRC, may be examined at the NRC Public Document Room, 2120 L Street NW., (Lower Level), Washington, DC. These same documents also may be viewed and downloaded electronically via the interactive rulemaking website established by NRC for this rulemaking.

FOR FURTHER INFORMATION CONTACT:

Anthony DiPalo, telephone (301) 415-6191, e-mail, ajd@nrc.gov, or Philip Brochman, telephone (301) 415-8592, e-mail, pgb@nrc.gov, of the Office of Nuclear Materials 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 originally established to provide specific licenses for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI) (45 FR 74693; November 12, 1980). Later, Part 72 was 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 has noted performance problems with holders of, and applicants for, a certificate of compliance under Part 72. When the NRC identifies a failure to comply with Part 72 requirements by these persons, the enforcement sanctions available under the current NRC Enforcement Policy have been limited to administrative actions.

The NRC Enforcement Policy¹ and its 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 emphasize the importance of compliance with requirements and to encourage prompt identification and prompt, comprehensive correction of the violations. Enforcement sanctions consist of Notices of Violation (NOV), 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 (NON), 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 certificate of compliance 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. An NOV is a written notice setting forth one or more violations of a legally binding requirement.

Discussion

In promulgating Subpart L, the Commission intended that selected Part 72 provisions would apply to cask certificate holders and applicants for a cask certificate of compliance (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 requirements in Subpart G do not refer to certificate holders, but only to licensees and applicants for licenses. Further, some 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 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 certificates of compliance are legally binding documents, certificate holders or applicants for a CoC and their contractors and subcontractors 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 NOV.

Although a NON and a NOV appear to be similar, the Commission prefers the issuance of a NOV 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 conclusion that potential risk to public health and safety could exist. This evidence can then be used to support the issuance of further enforcement sanctions such as orders.

Over the last 2 years, the Commission has observed problems with the performance of several certificate holders and their contractors and subcontractors. These problems have occurred in design, design control, fabrication and corrective action areas. Problems in these areas are typically covered under the quality assurance program. In FY 1996, the NRC staff identified numerous instances of nonconformance by certificate holders and their contractors and subcontractors failing to comply with requirements. The Commission has concluded that use of the additional enforcement sanctions which are available in the NRC Enforcement Policy are required to address the performance problems which have occurred in the spent fuel storage industry. Consequently, the Commission would revise Part 72 to explicitly make certificate holders and applicants for a CoC, and their contractors and subcontractors, subject to those requirements and thereby allow the use of enforcement sanctions against these persons, rather than administrative sanctions. The Commission believes that these amendments will have the effect of allowing both the public and those persons designing and building spent fuel storage casks to clearly understand the expectations which have been placed on them.

The proposed rulemaking will primarily focus on amending

regulations in Subpart G to explicitly include certificate holders, applicants for a CoC, and their contractors and subcontractors. Further, in Subpart L, this proposed rulemaking would also revise §§ 72.232, 72.234, and 72.236 to clarify who is responsible for ensuring that these requirements are met. Terms such as cask user, cask model, cask vendor, and representative of a cask user used in these sections are not defined and would be replaced with defined terms. Additionally, changes would also be made to § 72.10, "Employee Protection," and § 72.11, "Completeness and Accuracy of Information," to include certificate holders and applicants for a certificate. Section 72.3 would be revised to (1) incorporate definitions for "certificate holder," "certificate of compliance," and "spent fuel storage cask," (2) revise the definitions for "design bases" and "structures, systems, and components important to safety" to include the term "spent fuel storage cask," and (3) revise the definition for "design capacity" to be consistent with the Commission's policy on the use of metric units. Section 72.236 would be revised and would be reissued as being subject to the criminal penalty provisions of § 223 of the Atomic Energy Act and § 72.86(b), "Criminal Penalties," would be revised to delete mention of § 72.236 as a conforming change.

Lastly, a new § 72.242 would be added to Subpart L to identify recordkeeping and reporting requirements for certificate holders and applicants for a CoC. Paragraphs (a), (b), and (c) would require the certificate holder or applicant for a CoC to maintain any records or make any reports which are required by the conditions of a CoC or by the rules, regulations, and orders of the Commission. Paragraph (d) would require that a certificate holder submit a written report to the NRC within 30 days when the certificate holder identifies certain deficiencies in the design or fabrication of a spent fuel storage cask which has been delivered to a licensee. This requirement would apply when the deficiency affects the ability of structures, systems, and components which are important to safety to perform their function. This requirement is intended to address instances where the deficiency does not rise to the level of a "substantial safety hazard" which 10 CFR Part 21 requires certificate holders and applicants to report to the NRC. The Commission believes that by requiring this information, it will be in a position to more effectively evaluate the scope of

¹ NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions," July 1995 (60 FR 34381; dated June 30, 1995).

any potential impacts on public health and safety from cask deficiencies and to ensure that a licensee (who is responsible for evaluating and resolving the problem) completes those actions in a timely manner. The Commission believes that this regulation need only apply to casks which have been delivered to licensees (i.e., they are out of the control of the certificate holder). Any deficiencies identified in casks over which the certificate holder still has custody would be identified in accordance with the certificate holder's quality assurance program. Overall, this new section would be similar to the reporting and recordkeeping requirements imposed on licensees in §§ 72.75 and 72.80.

Discussion of Proposed Amendments by Section

Subpart A—General Provisions

Section 72.2 Scope

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

Section 72.3 Definitions

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 important to safety. The definition for design capacity would be revised to be consistent with the Commission's policy on use of metric units.

Section 72.10 Employee Protection, and

Section § 72.11 Completeness and Accuracy of Information

The terms certificate holder and applicants for a CoC would be added.

Subpart D—Records, Reports, Inspections, and Enforcement

Section 72.86 Criminal penalties

Paragraph (b) currently includes those sections under which criminal sanctions are not issued. This paragraph would be revised to delete reference to § 72.236, because this section is being reissued as being 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 would also be subject to criminal penalties. Therefore, § 72.242 will not be included in § 72.86(b).

Subpart G—Quality Assurance

Sections 72.140 Through 72.176

The term "certificate holder and applicants for a CoC and their contractors and subcontractors" would be added, as appropriate, to these sections to explicitly define responsibilities associated with quality assurance 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 quality assurance regulations of Part 72. Section 72.234(b) required that activities relating to the design, fabrication, testing, and maintenance of spent fuel storage casks shall be conducted under a quality assurance 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 would be made to individual sections of Subpart G as described below.

In § 72.140, paragraphs (a) and (b) would be revised to clarify the responsibilities of a certificate holder and a licensee with respect to who is responsible for ensuring that the quality assurance program is properly implemented. Paragraph (c) would be revised to provide milestones for a licensee and a certificate holder when the NRC must approve their quality assurance program. 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 would be rearranged. The new paragraph (a) would be revised to indicate that all of the persons associated with quality assurance activities for an ISFSI or a spent fuel storage cask (i.e., the licensee, certificate holder, applicants, and their contractors and subcontractors) are responsible for implementation of the quality assurance 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 would be added to the terms ISFSI and MRS.

Subpart L—Approval of Spent Fuel Storage Casks

Section 72.232 Inspection and Tests

This section would be reformatted by adding a new paragraph (b) and

renumbering existing paragraphs (b) and (c). In paragraphs (a), (b), and (c) the term "applicant" would be replaced with "certificate holder, applicant for a CoC, and their contractors and subcontractors." In paragraph (d), the term "applicant" would be replaced with "certificate holder and applicant for a CoC." Contractors and subcontractors would not be added to Paragraph (d) because the Commission holds the certificate holder or applicant for a CoC responsible for meeting this requirement.

Paragraph (a) would be revised to permit the inspection of 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 is made for the sake of completeness.

New paragraph (b) would include a requirement to permit the inspection of records related to design, fabrication, and testing of spent fuel storage casks. This requirement is intended to make clear the responsibility of certificate holders, applicants for a CoC, and their contractors and subcontractors 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.

Section 72.234 Conditions of Approval

This section would be revised to clarify who is responsible for accomplishing these requirements. The term "cask vendor" would be replaced with "certificate holder." The term "cask user" would be replaced with "a general licensee using a cask." The term "general licensee" has been used because a site-specific licensee cannot utilize the provisions of Subparts K and L. In addition, the acronym "CoC" is used in place of the term "Certificate of Compliance" where appropriate.

Section 72.236 Specific Requirements for Spent Fuel Storage Cask Approval

This section would be revised to clarify who is responsible for accomplishing these requirements. A new sentence has been added at the beginning of this section which indicates who has responsibility for ensuring that each of the requirements contained in paragraphs (a) through (m) is met. This section also would be 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 which can only occur after a cask has been fabricated; and an applicant cannot

begin fabrication of a cask until a CoC has been issued and an applicant has become a certificate holder (see § 72.234(c)).

Section 72.240 Conditions for Spent Fuel Storage Cask Reapproval

The term "user of a cask" would be replaced by "a general licensee using a cask" and the term "cask model" would be replaced by "design of a spent fuel storage cask." The term "representative of a cask user" would be replaced with "the representative of a general licensee using a cask." In addition, the acronym "CoC" is used in place of the term "Certificate of Compliance" where appropriate.

Section 72.242 Recordkeeping and Reports

This new section identifies additional recordkeeping responsibilities for certificate holders and applicants for a CoC and reporting requirements for certificate holders. This section is intended to provide for any other recordkeeping responsibilities which are not already covered by the regulations in § 72.234(d). This would include records required to be kept by a condition of the CoC or records relating to design changes, nonconformances, quality assurance audits, and corrective actions. Violations of this section would be subject to the criminal penalty provisions of § 223 of the Atomic Energy Act. Paragraphs (a), (b) and (c) are similar to the recordkeeping requirements imposed on licensees in § 72.80(a), (c), and (d).

A new requirement would be 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 which are important to safety, for casks which have been delivered to licensees. This requirement is intended to inform the NRC of deficiencies which may affect existing casks and thereby potentially affect public health and safety. This requirement is similar to the event reporting requirement imposed on licensees in § 72.75(c)(2).

Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act (AEA), the Commission is issuing the proposed rule to amend 10 CFR 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.

Compatibility of Agreement State Regulations

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** 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.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed 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 proposed rule.

Paperwork Reduction Act Statement

This proposed rule contains a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). However, the burden from this proposed rule is insignificant as compared to the existing information collection burden of Part 72. The section added by this amendment (§ 72.242) will add new burdens for recordkeeping and reporting requirements. The staff estimates this burden as six hours annually. Therefore, the Commission believes that this burden is insignificant by comparison with Part 72's overall burden which is in excess of 21,000 hours. Existing requirements were approved by the Office of Management and Budget, approval numbers 3150-0017, 3150-0151, 3150-0127, 3150-0135, 3150-0009, 3150-0132, 3150-0036, and 3150-0032. The amendments of the proposed rule currently fall under the existing approval numbers unless OMB decides otherwise. Therefore, under the Paperwork Reduction Act of 1995, a new clearance submittal is not required.

Public Protection Notification

If 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 collections.

Regulatory Analysis

Statement of the Problem

The Commission's regulations at 10 CFR Part 72 were originally 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). Later, these requirements were 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 with holders of and applicants for a certificate of compliance under Part 72. In FY 1996, the NRC staff identified numerous instances of nonconformance by certificate holders and their contractors and subcontractors failing to comply with requirements.

When the NRC identifies a failure to comply with Part 72 requirements by these persons, the NRC has issued Notices of Nonconformance (NON). The issuance of a 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 and their contractors and subcontractors.

Some Part 72 provisions for cask storage of spent fuel (e.g., the quality assurance requirements) were intended to apply to cask certificate holders and applicants for cask certificates of compliance, 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 violations of those Part 72 requirements.

Purpose of the Rulemaking

The purpose of this rulemaking is to expand the applicability of Part 72 to holders of, and applicants for, certificates of compliance and their contractors and subcontractors. This would allow the NRC staff to take enforcement action in the form of NOV's 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 Commission 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 conclusion that potential risk to public health and safety could exist and this evidence can then be used to support the issuance of further enforcement sanctions such as orders.

Current Regulatory Framework and Proposed Changes

In promulgating Subpart L, the Commission intended that selected Part 72 provisions would apply to cask certificate holders and applicants for a certificate of compliance (CoC). For example, § 72.234(b) requires that, as a condition for approval of a certificate of compliance, "[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 requirements in Subpart G do not refer to certificate holders, but only to licensees and applicants for licenses. 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 and their contractors and subcontractors 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 its 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 (1) as a deterrent to emphasize the importance of compliance with requirements and (2) to encourage prompt identification and prompt, comprehensive correction of the violations.

Enforcement sanctions consist of Notices of Violation (NOV), civil penalties, and orders of various types. In addition to the formal enforcement actions, the NRC also uses related administrative actions such as Notices of Nonconformance (NON), 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 certificate of compliance 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. A NOV is a written notice setting forth one or more violations of a legally binding requirement.

While it may appear that a NON and a NOV are similar, the Commission 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 conclusion that potential risk to public health and safety could exist. This evidence can then be used to support the issuance of further enforcement sanctions such as orders.

The proposed rulemaking will primarily focus on amending regulations in Subparts G and L to make certificate holders/applicants explicitly subject to those requirements. 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), or are written in the passive voice so that it is not clear who is responsible for meeting the

requirement, e.g., § 72.236. This proposed rule would revise the regulations to place explicit requirements on certificate holders and applicants and their contractors and subcontractors. Additionally, terms contained in Subpart L such as cask user, cask model, cask vendor, and representative of a cask user are not defined and would be replaced with defined terms. Changes would be 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 would be revised to (1) incorporate definitions for "certificate holder," "certificate of compliance," and "spent fuel storage cask," (2) to revise the definitions for "design bases" and "structures, systems, and components important to safety" to include the term "spent fuel storage cask," and (3) to revise the definition for "design capacity" to be consistent with the Commission's policy on the use of metric units. Section 72.236 would be revised and would be reissued as being subject to the criminal penalty provisions of § 223 of the Atomic Energy Act and § 72.86(b), "Criminal Penalties," would be revised to delete mention of § 72.236 as a conforming change. Section 72.232 would be reformatted by adding a new paragraph (b) and renumbering existing paragraphs (b) and (c). The term "applicant" would be replaced by the terms "certificate holder, applicant for a CoC, and their contractors and subcontractors" or "certificate holder and applicant for a CoC" as appropriate. 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 would be 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 would be similar to the requirements imposed on licensees in §§ 72.75 and 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 Commission 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. In the past, the Commission has been unable to take enforcement action against these persons when they did not comply with the regulations, because they have not been explicitly subject to the requirements of Part 72. However, the Commission believes that the need to be able to take enforcement action to the level of contractors and subcontractors is important because these persons actually accomplish the manufacturing and testing of spent fuel storage casks. These contractors and subcontractors have typically established quality assurance programs as a consequence of their contracts with the certificate holder.

Alternative 1 would allow the NRC to take enforcement actions against these persons, as necessary, by allowing the issuance of a NOV when they fail to comply with the requirements of Part 72. Presently the NRC issues a NON in these instances. While it may appear that a NON and a NOV are similar, the Commission 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 conclusion that potential risk to public health and safety could exist.

This evidence can then be used to support the issuance of further enforcement sanctions such as orders.

The NRC has estimated that each certificate holder or applicant for a CoC, on average, has three contractors and subcontractors. Consequently, the NRC estimates a total of 60 contractors and subcontractors would be affected by these 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 certificate of compliance or as a condition of a contract between a certificate holder and their contractors and subcontractors, the burdens imposed by this alternative are not significantly increased. Alternative 2 would not impose these impacts.

The Commission believes that alternative 1 will enable the NRC to make more effective use of the Enforcement Policy against the designers, fabricators, and testers of spent fuel storage casks and that this will lead to an overall improvement in the safety and quality of spent fuel storage casks.

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 be able to take enforcement actions against these persons under this alternative, but would be forced to continue to use administrative actions. The NRC believes that by taking enforcement actions against these people, it will be able to enhance the protection of public health and safety. Consequently, alternative 2 was rejected.

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 experienced in the past will continue.

Decision Rationale for Preferred Alternative

Alternative 1 is the preferred choice. The major benefit of this alternative is to allow the NRC to take more effective enforcement actions against certificate holders, applicants for a CoC, and their contractors and subcontractors under the current NRC Enforcement Policy. 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, applicants for a CoC, and their contractors and subcontractors for the most part already have been meeting the requirements of Part 72, as either a condition of a certificate of compliance or as a condition of a contract between a certificate holder and their contractors and subcontractors, the burdens imposed by this amendment are not significantly increased. The new section added by this amendment (72.242) will add new burdens for recordkeeping and reporting requirements. The staff estimates this burden associated with the new § 72.242 to be 6 hours annually. Therefore, the Commission believes that this burden is insignificant by comparison with Part 72's overall

burden which is in excess of 21,000 hours.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. The proposed rule would amend the regulations to expand the applicability of 10 CFR Part 72 to holders of, and applicants for, Certificates of Compliance (CoC) and their contractors and subcontractors. This requirement would enhance the Commission's ability to take enforcement action in the form of Notices of Violation rather than administrative action in the form of Notices of Nonconformance when legally binding requirements are violated. The proposed rule may appear to impose new requirements on a significant number of small entities (i.e., the contractors and subcontractors associated with certificate holders and applicants for a CoC). These requirements would involve actions such as compliance with quality assurance program requirements in Subpart G of Part 72. However, these entities, for the most part, are already implementing the actions required by Subpart G as a condition of their contracts with the certificate holder or applicant for a CoC. Therefore, the NRC believes that this amendment will not have a significant economic impact on these small entities.

Backfit Analysis

The NRC staff has determined that the backfit rule, 10 CFR 72.62, does not apply to this proposed rule because these amendments do not involve any provisions that would impose backfits as described in 10 CFR 72.62(a). Therefore, a backfit analysis is not required.

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. 553, the NRC is proposing to adopt 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.

* * * * *

(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.

* * * * *

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.

* * * * *

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.

* * * * *

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 shall 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.

* * * * *

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.

* * * * *

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

(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, 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.

* * * * *

(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.

* * * * *

(e)(1) Each licensee, certificate holder, and applicant for a license or CoC shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c). This form shall 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. Premises shall 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.

* * * * *

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, shall be complete and accurate in all material respects.

(b) Each licensee, certificate holder, or applicant for a license or CoC shall 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 shall 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.

* * * * *

(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, applicant for a CoC, and their contractors and subcontractors 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 via the oversight of contractors and subcontractors.

(b) *Establishment of program.* Each licensee, applicant for a license, certificate holder, applicant for a CoC, and their contractors and subcontractors 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, applicant's for a CoC, and their contractor's and subcontractor's activities. The licensee, applicant for a license, certificate holder, applicant for a CoC, and their contractors and subcontractors shall execute the applicable criteria in a graded approach to an extent that is commensurate with the importance to safety. The quality assurance program shall 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) The 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.

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

(3) Each licensee or certificate holder shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, in accordance with § 72.4.

(d) *Previously approved programs.* A Commission-approved quality assurance program which satisfies the applicable criteria of appendix B to part 50 of this chapter and which is established, maintained, and executed with regard to an ISFSI will be accepted as satisfying the requirements of paragraph (b) of this section. Prior to initial use, the licensee shall notify the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of its intent to apply its previously approved appendix B program to ISFSI activities. The licensee shall identify the 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors, 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 to the approved design of each ISFSI, MRS, or spent fuel storage cask. The licensee, applicant for a license, certificate holder, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and

subcontractors 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, applicant for a CoC, and their contractors and subcontractors shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures shall 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, applicant for a CoC, and their contractors and subcontractors shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures shall 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 in-service 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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. 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors shall establish measures for the identification and control of materials, parts, and components. These measures shall 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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 shall be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed shall 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 shall be provided. Both inspection and process monitoring shall be provided when quality control is inadequate without both. If mandatory inspection hold points, which 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall include provisions for assuring 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall 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, applicant for a CoC, and their contractors and subcontractors 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 shall 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 shall 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, applicant for a CoC, and their contractors and subcontractors shall maintain sufficient records to furnish evidence of activities affecting quality. The records shall 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 shall include closely related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, 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 shall be identifiable and retrievable. Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety shall be maintained by or under the control of the licensee or certificate holder until the Commission 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, applicant for a CoC, and their contractors and subcontractors 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 shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, shall be taken where indicated.

27. Section 72.232 is revised to read as follows:

§ 72.232 Inspection and tests.

(a) The certificate holder, applicant for a CoC, and their contractors and subcontractors shall permit, and make provisions for, the Commission to inspect the premises and facilities at

which a spent fuel storage cask is designed, fabricated, and tested.

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

(c) The certificate holder, applicant for a CoC, and their contractors and subcontractors shall perform, and make provisions that permit the Commission 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 be 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 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 cask fabricated under the CoC.

(2) This record shall include:

- (i) The NRC CoC number;
- (ii) The cask model number;
- (iii) The cask identification number;
- (iv) Date fabrication was started;
- (v) Date fabrication was completed;
- (vi) Certification that the 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 general licensee using the cask.

(3) The certificate holder shall supply the original of this record to the general licensee using the cask. A current copy of a composite record of all casks

manufactured under a CoC, showing the information in paragraph (d)(2) of this section, shall be initiated and maintained by the certificate holder for each model cask. If the certificate holder permanently ceases production of 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 general licensee using the 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 casks. A copy of these procedures and tests shall be provided to each general licensee using the cask.

29. Section 72.236 is revised to read as follows:

§ 72.236 Specific requirements for spent fuel storage cask approval.

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 shall be provided for the spent fuel to be stored in the 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 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 shall be provided for structures, systems, and components important to safety.

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

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

(e) The cask shall be designed to provide redundant sealing of confinement systems.

(f) The cask shall be designed to provide adequate heat removal capacity without active cooling systems.

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

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

(i) The cask shall be designed to facilitate decontamination to the extent practicable.

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

(k) The cask shall be conspicuously and durably marked with —

- (1) A model number;
- (2) A unique identification number; and
- (3) An empty weight.

(l) The cask and its systems important to safety shall be evaluated, by appropriate tests or by other means acceptable to the Commission, 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 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 general licensee using a spent fuel storage cask, or the representative of a general 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 shall 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 finally determined by the Commission. The application shall 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, in fact, 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 Commission in effectuating the purposes of the Act.

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

(c) Any record that shall be 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 Commission 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 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 casks;

(viii) The licensees that have affected 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 16th day of July, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98-19556 Filed 7-22-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. 98-NM-159-AD]

RIN 2120-AA64

Airworthiness Directives; Aerospatiale Model ATR72-212A Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Aerospatiale Model ATR72-212A series airplanes. This proposal would require installation of bushings on the lower attachment fittings of the flap support beam. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent rupture of the lower attachment fittings of the flap support beam due to fatigue, and

consequent damage to the flaps; these conditions could result in reduced controllability of the airplane.

DATES: Comments must be received by August 24, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 98-NM-159-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT:

Norman B. Martenson, Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2110; fax (425) 227-1149.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 98-NM-159-AD." The