

September 24, 1997

FOR: The Commissioners

FROM: L. Joseph Callan /s/ Executive Director for Operations

SUBJECT: CHANGES TO 10 CFR PART 72, EXPAND APPLICABILITY TO INCLUDE CERTIFICATE HOLDERS AND APPLICANTS AND THEIR CONTRACTORS AND SUBCONTRACTORS

## PURPOSE:

To inform the Commission that the EDO intends to sign the enclosed [Rulemaking Plan](#) to amend certain sections in 10 CFR Part 72. This rulemaking will place appropriate Part 72 requirements on certificate holders and applicants and their contractors and subcontractors.

## BACKGROUND:

The Commission's regulations at 10 CFR Part 72 were originally designed to provide specific licenses for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI). Later, these were amended to include the storage of high-level waste (HLW) at a monitored retrieval storage (MRS) installation. In 1990, the NRC amended Part 72 to include a process for certifying spent fuel storage casks (Subpart L) and for granting a general license to reactor licensees using NRC-certified casks (Subpart K) for storage of spent nuclear fuel. Some Part 72 provisions for cask storage of spent fuel, e.g., the quality assurance requirements, are 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. Because 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, the NRC has not had a clear basis to cite certificate holders/applicants for violations of those Part 72 requirements. Presently, when the NRC discovers such a violation, it issues an administrative action in the form of a Notice of Nonconformance (NNC). The issuance of an NNC does not effectively convey that a violation of a legally binding requirement has occurred. Since 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, as well as their contractors and subcontractors.

## DISCUSSION:

The purpose of this rulemaking is to clearly place appropriate Part 72 requirements on certificate holders and applicants, as well as their contractors and subcontractors. This should enhance the staff's capability to take enforcement action in the form of NOVs rather than administrative action in the form of a NNC when applicable requirements are violated. The staff believes that issuance of NOVs will clearly identify that a violation of a legally binding requirement has occurred.

The current regulations in 10 CFR Part 72, Subpart G explicitly apply only to licensees. The proposed rulemaking will primarily focus on amending regulations in Subpart G, "Quality Assurance," and Subpart L, "Approval of Spent Fuel Storage Casks," to explicitly make certificate holders/applicants subject to those requirements. Some of the Subpart L regulations apply explicitly only to "the applicant," e.g., 10 CFR 72.232, or to "the cask vendor," e.g., 10 CFR 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., 10 CFR 72.236. This proposed rulemaking will revise those sections of 10 CFR Part 72 listed in the Appendix of the enclosed rulemaking plan to explicitly place requirements on certificate holders and applicants, as well as their contractors and subcontractors. In addition to these changes, 10 CFR 72.11, "Completeness and Accuracy of Information," will be revised to include certificate holders; 10 CFR 72.3 will be revised to incorporate a definition of "spent fuel storage cask"; and a records and reports requirement similar to that in 10 CFR 72.80 will be placed in Subpart L.

## COORDINATION:

The Office of the General Counsel has no legal objection to the Rulemaking Plan. The Office of the Chief Financial Officer has no objections to the resource estimates contained in this paper. The Office of the Chief Information Officer has reviewed the rulemaking plan for information technology and information implications and concurs in it. However, the plan suggests possible information collection requirements that must be submitted to the Office of Management and Budget prior to publication of the proposed rule.

## RECOMMENDATION:

It is my intent to approve the Rulemaking Plan within 10 days from the date of this paper in the absence of further direction from the Commission.

L. Joseph Callan  
Executive Director  
for Operations

Enclosure: [Rulemaking Plan](#)

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CONTACT: Anthony DiPalo, WMB/DRA/RES  
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**RULEMAKING PLAN**  
**CHANGES TO 10 CFR 72**

**Lead Office:** Office of Nuclear Regulatory Research

**Staff Contact:** Tony DiPalo, WMB

**Concurrences:**

<b>A. Thadani, RES</b>	<b>Date</b>
<b>C. Paperiello, NMSS</b>	<b>Date</b>
<b>J. Lieberman, OE</b>	<b>Date</b>
<b>W. Olmstead, OGC</b>	<b>Date</b>
<b>J. L. Funches, CFO</b>	<b>Date</b>
<b>A. J. Galante, CIO</b>	<b>Date</b>
<b>R. Bangart, OSP</b>	<b>Date</b>
<b>B. J. Shelton, IRM</b>	<b>Date</b>
<b>L. Joseph Callan, EDO</b>	<b>Date</b>

**Approval:**

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**RULEMAKING PLAN**

**CHANGES TO 10 CFR PART 72, EXPAND APPLICABILITY  
TO INCLUDE CERTIFICATE HOLDERS AND APPLICANTS,  
AND THEIR CONTRACTORS AND SUBCONTRACTORS**

**Regulatory Issue**

The Commission's regulations at 10 CFR Part 72 were originally designed to provide specific licenses for the storage of spent nuclear fuel in an independent spent fuel storage installation (ISFSI). Later, these were amended to include the storage of high-level waste (HLW) at a monitored retrieval storage (MRS) installation. In 1990, the NRC amended Part 72 to include a process for certifying spent fuel storage casks (Subpart L) and for granting a general license to reactor licensees using NRC-certified casks (Subpart K) for storage of spent nuclear fuel. Some Part 72 provisions for cask storage of spent fuel, e.g., the quality assurance requirements, are 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. Because 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, the NRC has not had a clear basis to cite certificate holders/applicants for violations of those Part 72 requirements. Presently, when the NRC discovers such a violation, it issues an administrative action in the form of a Notice of Nonconformance (NNC). The issuance of an NNC does not effectively convey that a violation of a legally binding requirement has occurred. Since 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.

**Current Rule Requirements**

The current regulations in 10 CFR PART 72, Subpart G, explicitly apply only to licensees. Some of the Subpart L regulations apply explicitly only to "the applicant," e.g., 10 CFR 72.232, or to "the cask vendor," e.g., 10 CFR 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., 10 CFR 72.236.

**Regulatory Problem to be Resolved**

NRC's Enforcement Policy describes the enforcement sanctions available to the NRC (see Section VI of the Enforcement Policy). These sanctions include a Notice of Violation ("a written notice setting forth one or more violations of a legally binding requirement"). The NRC's enforcement sanctions are supplemented by related administrative actions such as a Notice of Nonconformance ("written notices describing vendor's failures to meet commitments which have not been made legally binding requirements by NRC").

The regulations that are the subject of this proposed rulemaking have not been made explicitly applicable to certificate holders and applicants. Accordingly, NNCs have typically been issued when these regulations are violated by certificate holders. This rulemaking would allow the staff to issue

NOVs in these situations. The staff believes that issuance of NOVs would clearly identify that a violation of a legally binding requirement has occurred.

The NRC staff's experience in administering the Part 72 regulations has shown that significant problems have occurred with respect to spent nuclear fuel storage because of the failure of certificate holders and applicants to observe Part 72 requirements. In FY 1996, the NRC issued 15 NNCs to certificate holders and their subcontractors indicating a pattern of poor engineering in the areas of design, design controls, and corrective action by certificate holders.

The purpose of this rulemaking is to clearly place appropriate Part 72 requirements on certificate holders and applicants and their contractors and subcontractors. This should enhance the staff's capability to take enforcement action in the form of NOVs rather than administrative action in the form of a NNC when requirements are violated that apply to certificate holders and applicants and their contractors and subcontractors.

The proposed rulemaking would amend regulations in Subpart G, "Quality Assurance," and Subpart L, "Approval of Spent Fuel Storage Casks," to explicitly make certificate holders and applicants subject to those requirements. This proposed rulemaking would revise those sections of 10 CFR Part 72 listed in the Appendix of this rulemaking plan to explicitly place requirements on certificate holders and applicants and their contractors and subcontractors. In addition to these changes, 10 CFR 72.11, "Completeness and Accuracy of Information," would be revised to include certificate holders; 10 CFR 72.3 would be revised to incorporate a definition of "spent fuel storage cask"; and a records and reports requirement similar to that in 10 CFR 72.80 would be placed in Subpart L.

#### Preliminary Regulatory Analysis

The following options are considered in this rulemaking plan:

- **Option 1** - Revise appropriate sections of 10 CFR Part 72 (listed in the appendix) to explicitly place requirements on certificate holders and applicants and their contractors and subcontractors. The benefit of this option is that all who have a responsibility for assuring safety -- i.e., licensees, certificate holders, applicants, contractors, subcontractors -- would be named explicitly as subject to the requirements in 10 CFR Part 72. This in turn will make possible issuance of notices of violation, if appropriate, when the requirements are violated by any person having a responsibility for assuring safety, thereby allowing the NRC to conduct its business of protecting public health and safety more efficiently and effectively. However, because the regulation would explicitly include non-licensees this action could be challenged in court as an unwarranted expansion of the scope of the Commission's authority.
- **Option 2** - Revise Part 72 to add certificate holders and applicants but not their contractors and subcontractors. The advantages of this option are that the regulatory scheme of Part 72 would remain more consistent with other NRC regulations in that certificate holders and applicants would be responsible for the behavior of their contractors and subcontractors, and because this action would be limited to certificate holders and applicants, it may not be as likely to be challenged as an expansion of NRC authority. The cons are that contractors and subcontractors of licensees, certificate holders, and applicants do have responsibility for safety, and omitting them from Part 72 will continue the present difficulty that NRC has encountered in reaching these persons with its enforcement tools.
- **Option 3** - No Action. The pros of this option are that staff resources are conserved (in that a rulemaking does not take place). However, under this option the present difficulty that the NRC has had in reaching all persons with responsibility for safety with its enforcement tools will continue.

The current regulations do not fully reflect the NRC's authority to protect public health and safety and impede NRC from conducting its business efficiently and effectively. Option 1 is selected because it will clearly place Part 72 requirements on all persons who have safety responsibility. It would allow the NRC to issue NOVs. Experience has indicated that contractors and subcontractors, rather than only certificate holders and applicants, need clear direction that it is necessary to comply with applicable Commission regulations. The impact on affected persons in compliance with the regulations should be small because these affected persons have generally complied with these regulations even though the regulations do not explicitly include them. For affected persons in non-compliance, the effort to respond to a NNC or NOV is similar. The impact on the NRC will be small because there is no significant difference in expenditure of staff resources in issuing a NOV instead of a NNC.

OGC has no legal objection to initiation of this rulemaking. The Commission has in the past placed unlicensed persons within the scope of its regulations, notably in the Deliberate Misconduct Rule (DMR) (56 Fed. Reg. 40664 - (1991)). In the DMR, the Commission asserted broad authority under the Atomic Energy Act to place regulatory prohibitions on non-licensees whose actions relate to licensed activities and to take enforcement action against such persons when violations occur. Recently, the Commission issued a proposed rule which expands the scope of the DMR to include additional categories of persons, including certificate holders and applicants. See 61 Fed. Reg. 51835 (1996).

Since this proposed rulemaking is based on the same legal principle used to support the DMR and its amendments, OGC believes that there is a sound legal basis for proceeding with this rulemaking. However, the bounds of the Commission's authority over non-licensees are not clear-cut, and the same objections to the Commission's assertion of such authority that were made to the DMR and to its proposed amendment may be anticipated here. OGC does not anticipate a successful legal challenge to the rule.

#### Backfit Analysis

The NRC staff has determined that the backfit rule, 10 CFR 72.62, does not apply to this proposed rule and, therefore, a backfit analysis is not required.

#### Agreement State Considerations

The NRC has determined that this rule addresses a regulatory area which is reserved to the NRC. This an NRC program element that cannot be relinquished to Agreement States pursuant to the Atomic Energy Act.

## Supporting Documents

An OMB clearance package will be prepared for this rulemaking.

## Resources Required

It is anticipated that 0.85 NRC FTEs will be needed to complete this action (0.45 RES, 0.2 NMSS, and 0.2 all other). These resources are within existing budget allocations.

## Lead Office Staff and Staff From Supporting Offices

RES - T. DiPalo, P. Norian	OCG - N. Jensen
OE - G. Cant	ADM - M. Lesar
NMSS - P. Brochman	OSP - L. Bolling

## Steering Group

These amendments are not considered significant enough to warrant consideration by a steering group.

## Public Participation

The proposed amendments will be published in the Federal Register as a proposed rule for public comment.

Is It Recommended That the EDO Issue the Rule in Accordance With Management Directive 9.17?

No. The proposed rule constitutes an expanded application of NRC jurisdictional authority. Therefore, issuance of the proposed and final rule will require Commission approval.

## Schedule

The schedule is expressed in terms of time from approval of the rulemaking plan. In addition, the OMB clearance package will be submitted to OMB at the time the proposed rule will be published in the Federal Register.

Proposed rule to EDO	Approval of rulemaking plan + 3 months
SRM from Commission	Approval of rulemaking plan + 4 months
Public comment period ends	Approval of rulemaking plan + 8 months
Final rule to EDO	Approval of rulemaking plan + 15 months

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## APPENDIX

### Proposed Changes to 10 CFR Part 72

1. Include certificate holders and applicants and their contractors and subcontractors as appropriate, in 10 CFR 72.2(b), 72.11(a),(b), 72.80(a),(c), 72.84(b)(1)(iv), 72.140(a),(b), 72.142, 72.144(a),(b),(c),(d), 72.146(a),(b),(c), 72.148, 72.150, 72.152, 72.154(a),(b),(c), 72.156, 72.158, 72.160, 72.162, 72.164, 72.166, 72.168(a), 72.170, 72.172, 72.174, 72.176, and Subpart L, 72.230 - 72.240.
2. Revise 10 CFR 72.3 to incorporate a definition of "spent fuel storage cask."
3. Revise Subpart L to include the records and reports requirement in 10 CFR 72.80.