

NUCLEAR REGULATORY COMMISSION

[NUREG-1600]

Revision of NRC Enforcement Policy;  
Packaging and Transportation of Radioactive Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: revision.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing a revision to its Enforcement Policy (NUREG-1600, "General Statement of Policy and Procedure for NRC Enforcement Actions") to clarify that enforcement action may be taken against non-licensees for violations of the Commission's regulations governing the packaging and transportation of radioactive material.

EFFECTIVE DATE: October 1, 2004.

ADDRESSES: You may submit comments by any of the following methods. Comments submitted in writing or in electronic format will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, ATTN: Rulemaking and Adjudications Staff.

E-mail comments to: [SECY@nrc.gov](mailto:SECY@nrc.gov) If you do not receive a reply e-mail confirming that we have received your comments, contact us directly (301) 415-1966. You may also submit comments via the NRC's interactive rulemaking website at <http://ruleforum.llnl.gov>. Address questions about our rulemaking website to Carol Gallagher at (301) 415-5905 (e-mail: [CAG@nrc.gov](mailto:CAG@nrc.gov)).

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays. (Telephone (301) 415-1966)

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101

Publicly available documents related to this action may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee. Selected documents, including comments, may be viewed and downloaded electronically via the NRC's interactive rulemaking website at <http://ruleforum.llnl.gov>.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, the public can gain entry into the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the document located in ADAMS, contact the NRC PDR Reference staff at 1-800-397-4209, 301-415-4737, or email to [pdr@nrc.gov](mailto:pdr@nrc.gov).

The NRC maintains the current Enforcement Policy on its web site at [www.nrc.gov](http://www.nrc.gov), select **What We Do, Enforcement**, then **Enforcement Policy**.

FOR FURTHER INFORMATION CONTACT: Frank J. Congel, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, (301) 415-2741, email [fjc@nrc.gov](mailto:fjc@nrc.gov).

SUPPLEMENTARY INFORMATION: The Commission's Enforcement Policy primarily addresses violations by licensees and certain non-licensed persons, including certificate holders, as discussed further in footnote 3 to Section I, Introduction and Purpose, and in Section X, Enforcement Action Against Non-licensees. In 10 CFR Part 71, the NRC's regulations address licensing requirements for packaging and transport of radioactive material. For several years, the Commission has observed problems with the performance of some certificate holders and their contractors and subcontractors in the packaging and transport of radioactive material. The Commission has concluded that additional enforcement sanctions (e.g., issuance of Notices of Violations (NOVs) and Orders), are required to address the performance problems which have occurred in the packaging and transportation of radioactive material. Therefore, concurrent with publication of this change to the Enforcement Policy, the Commission is amending 10 CFR Part 71 to expand its applicability to holders of, and applicants for, Certificates of Compliance (CoCs). While CoCs are legally binding documents, certificate holders or applicants for a CoC had not clearly been brought within the scope of certain Part 71 requirements, and the NRC has not had a clear basis to cite these persons for violations of Part 71 requirements in the same way it treats licensees. When the NRC has identified a failure to comply with Part 71 requirements by these persons, it has taken

administrative action by issuing a Notice of Nonconformance (NON) or a Demand for Information rather than an NOV. With these changes to Part 71, the Commission will be in a position to issue NOVs and Orders to certificate holders and applicants.

An NOV is a written notice that sets forth one or more violations of a legally binding requirement. The NOV effectively conveys to both the person violating the requirement and the public that a violation of a legally binding requirement has occurred and permits use of graduated severity levels to convey more clearly the safety significance of the violation. Therefore, in addition to the changes to 10 CFR Part 71, the Commission is amending Part X of the Enforcement Policy, Enforcement Action Against Non-Licensees, to make clear that non-licensees who are subject to specific regulatory requirements (e.g., Part 71), will be subject to enforcement action, including NOVs and Orders. The final Part 71 rule does not provide authority for issuing civil penalties to non-licensees other than that already provided under the Deliberate Misconduct Rule (January 13, 1998; 63 FR 1890 ) in §71.8.

#### Paperwork Reduction Act

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

## Public Protection Notification

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

### Small Business Regulatory Enforcement Fairness Act

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

Accordingly, the NRC Enforcement Policy amended by revising the last paragraph of section X to read as follows:

#### General Statement of Policy and Procedure for NRC Enforcement Actions

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#### X. Enforcement Action Against Non-Licensees

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When inspections determine that violations of NRC requirements have occurred, or that contractors have failed to fulfill contractual commitments (e.g., 10 CFR Part 50, appendix B) that could adversely affect the quality of a safety significant product or service, enforcement action will be taken. Notices of Violation and civil penalties will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements. Notices of Violation will be issued for contractors who violate 10 CFR Part 21. Civil penalties will be imposed against individual directors or responsible officers of a contractor organization who knowingly and consciously fail to provide the notice required by 10 CFR

