radiation dose hypothesis, resulted in a maximum of 1.7 genetic effects and 1.2 latent cancer effects per year. More than half this impact resulted from shipment of medical-use radioactive materials. Accident related impacts were established at a maximum of one genetic effect and one latent cancer fatality for 200 years of transporting radioactive materials. The principal nonradiological impacts were found to be two injuries per year, and less than one accidental death per 4 years. In contrast, nonaccident related radiation exposures associated with this rulemaking would be increased by 0.75 person-Sv/y (75.0 person-rem/y), whereas accident related impacts would be decreased by approximately 0.006 person-Sv/y (0.6 person-rem/y). Nonradiological traffic injuries would be increased by 0.06 per year and nonradiological traffic deaths by 0.003 per year (less than 1 accidental death per 330 years). These impacts are judged to be insignificant compared with the baseline impacts established in NUREG-0170.

The environmental assessment and finding of no significant impact on which this determination is based are available, for inspection, at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the environmental assessment and finding of no significant impact are also available from the contact listed under the Addresses heading.

## Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, Approval Number 3150–0008.

The public reporting burden for this collection of information is estimated to average 7 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0008), Office of Management and Budget, Washington, D.C. 20503.

## **Regulatory Analysis**

The NRC has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by NRC. Interested persons may examine a copy of the regulatory analysis at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained from the contact listed under the Addresses heading.

## **Regulatory Flexibility Act Certification**

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This final rule affects NRC licensees, including operators of nuclear power plants, who transport or deliver to a carrier, for transport, relatively large quantities of radioactive material, in a single package. These companies do not generally fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC (10 CFR 2.810).

## **Backfit Analysis**

The Commission has determined that the backfit rule does not apply to the Part 71 final rule because the final rule is not a backfit under 10 CFR Part 50.109. However, NRC analyzed the accident-resistant packaging requirement for the specified LSA shipments and found that there is an increase in overall protection to be derived from the requirement and that direct and indirect costs of implementation are justified in view of this increased protection.

The factors normally considered in a backfit analysis are evaluated in the "Regulatory Analysis of Changes to 10 CFR Part 71—NRC Regulations on Packaging and Transportation of Radioactive Material," dated April 1995. That evaluation shows very small changes in accident risks as a result of the adoption of the revision, but some reduction in maximum consequences given an accident. The evaluation shows broad improvement in NRC regulatory consistency with IAEA, at an initial cost of \$1.375 million to industry, and continual annual costs to industry of \$1.0 million (See Table S.1 of Regulatory Analysis). NRC costs are estimated at \$0.463 million.

The continuing costs are associated with the addition of new limits on the quantity of LSA radioactive material allowed in a single transportation package. Internationally, a new limit is considered to be a necessary safety requirement to limit the consequences of a severe transportation accident involving LSA material.

The one-time costs are chiefly associated with industry upgrading of its package safety analyses to include the proposed new accident crush and immersion tests and with NRC review of those new analyses. The estimated costs are overstated because of the assumption that all licensees using packages approved under earlier regulatory standards would take immediate steps to upgrade the package analyses so the package approvals would reflect approval, under the latest revised standards. Although that is a prudent assumption, absent any reasonable basis for predicting actual licensee reaction, there is little reason licensees would take any immediate action to upgrade their package approvals. Both domestic and international regulations are based on the responsible agency's confidence that packages built to a design approved under earlier standards are adequately safe for continued use, although new package construction to that design would be limited, and international use requires approval by all countries through which the package is to be transported. In actual practice, some package approvals would never be upgraded. Those that would be upgraded would be done over a period of several years as guidance and experience in upgrading become available.

Although the regulatory analysis shows a small reduction in accident risks from the amendments to this rule and some reduction in maximum consequences given an accident, the primary benefit of this rulemaking is to achieve consistency in radioactive material transportation regulations between the United States and the rest of the world. This consistency would not only facilitate the free movement of radioactive materials between countries for medical, research, industrial, and nuclear fuel cycle purposes, but it would also contribute to safety by concentrating the efforts of the world's experts on a single set of safety standards and guidance (those of the IAEA) from which individual countries could develop their domestic regulations. In addition, the accident experience of every country that bases its domestic regulations on those of the IAEA could be applied to every other country with consistent regulations to improve its safety program.

In summary, the effort to make U.S. regulations compatible with those of the IAEA provides major benefits including