VALUE/IMPACT STATEMENT

1. BACKGROUND

Assurance that packaging used to transport radioactive materials will not be hazardous to public health and safety depends greatly on the integrity of the features of the container that are important to safety.

To increase confidence that designated features important to safety of particular packaging are designed, built, and used so as to minimize the risk to the public from exposure to radioactivity, prescribed systematic management and administrative controls need to be invoked during each phase of their design, production, and use.

These management controls are embodied in the 18 criteria of Appendix E, "Quality Assurance Criteria for Shipping Packages for Radioactive Material," to 10 CFR Part 71.

Prior to October 1977, when Appendix E became effective, quality assurance programs were required only for packaging designed to transport plutonium, high-level waste, and irradiated fuel. The description of the quality assurance program was to be included in the application for package approval and was reviewed against the criteria identified in Appendix E to Part 71.

After Appendix E became effective and pursuant to paragraph 71.24(a) and § 71.51, "Establishment and Maintenance of a Quality Assurance Program," all applicants for and holders of licenses to use, possess, design, or build packages to transport radioactive material in excess of Type A quantities as defined in paragraph 71.4(g) have been required to provide documented evidence of a QA program acceptable to the NRC. A special provision of the rule allows any licensee with an NRC-approved QA program covering activities under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," as delineated in Appendix B to Part 50 to apply it without further approvals to activities covered by Part 71.

An NRC licensee cannot use packaging subject to 10 CFR Part 71 if its use is not covered by an NRC-approved QA program. Also, the rule clarified NRC's position as to responsibility for quality assurance by stating that it was the licensee who delivers a package to a carrier for transport who must ensure that all quality assurance provisions for the package have been followed.

The effective date to submit to the NRC the QA program descriptions was initially set as July 1, 1978, but because of large numbers of inquiries, primarily from radiographers, the date was extended to January 1, 1979. Licensees filing their QA program descriptions by January 1, 1979, were authorized continued use of their packages contingent upon the determination of acceptability by the NRC.

2. THE PROPOSED ACTION

2.1 Description

The proposed action provides guidance to persons needing information on the essential elements needed to develop, establish, and maintain quality assurance programs in accordance with the requirements of Appendix E to Part 71 for packaging used to transport radioactive materials. The guide includes three annexes: (1) Quality Assurance Programs Applicable to Design, Fabrication, Assembly, and Testing of Packaging Used in the Transport of Radioactive Material, and (2) Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used in the Transport of Radioactive Material, and (3) Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packages Designed to Transport Radiographic Exposure Devices.

2.2 Need

According to § 71.24, applicants for package approval are required to identify their quality assurance program, and, according to § 71.51, licensees are required to establish and maintain a quality assurance program.

Guidance is needed by persons establishing QA programs and by persons having NRC-approved QA programs who need to maintain them. Guidance is also needed by the NRC staff to develop inspection plans and procedures.

Furthermore, because there is a wide disparity of applicability of the requirements of Appendix E, specific guidance concerning grading of a particular QA program to fit its potential impact on safety is needed. The economic penalties for overcommitment to QA requirements resulting from uniform application of quality assurance without regard to its specific impact on safety can be as severe as not applying any quality requirements at all to achieve design objectives.

2.3 Value/Impact Assessment

2.3.1 NRC

Staff time required for evaluation and inspection should be reduced because standardized QA programs should allow the use of standard review plans and uniform inspection plans and procedures.

Other than the allocation of staff resources to developing, reviewing, and issuing this guide, no impact on the NRC is anticipated.

2.3.2 Other Government Agencies

Impact on other government agencies would be essentially the same as that on industry to the extent that these agencies are regulated by NRC.

2.3.3 Industry

Specific guidance on QA criteria applicable to particular packaging should aid in developing, establishing, and maintaining a QA program that meets the spirit and intent of the so-called "graded approach." Formulating a program in which the QA effort expended on an activity is consistent with its importance to safety can be interpreted quite differently by different licensees. Spelling out only the applicable criteria as well as the specific applicable safety elements will result in a graded approach. Proliferation of documentation prevalent in industry should be reduced.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Worker

No impact on the worker is foreseen.

2.4 Decision

The proposed action, developing and issuing a regulatory guide, should be completed because of the benefits previously discussed.

3. PROCEDURAL APPROACH

3.1 Alternatives

No meaningful alternative exists. Use of the general description of the QA criteria in Appendix E without further amplification would place too much responsibility on licensees for judging what constitutes an acceptable commitment. The ANSI N14.4 Subcommittee is chartered to produce a standard based on Appendix E, but its ongoing effort is not expected to be completed in the near future.

3.2 Discussion

A regulatory guide is the most efficient way to transmit information about the subject QA programs that would be acceptable to the NRC. In addition, a regulatory guide ensures uniform transmission of information and responses from applicants and licensees.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

The proposed guide provides guidance for the implementation of regulations promulgated in paragraph 71.24(a) and § 71.51 and described in Appendix E to 10 CFR Part 71. Authority for these regulations is derived from the Atomic Energy Act of 1954, as amended, and from the Energy Reorganization Act of 1974.

4.2 Need for NEPA Assessment

The proposed action is not a major action as defined in paragraph 51.5(a)(10) of 10 CFR Part 51 and, therefore, does not require an environmental impact statement.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

The structure of Appendix E to 10 CFR Part 71 is identical to that of Appendix B to 10 CFR Part 50, which describes quality assurance criteria now in effect for nuclear power plants and certain fuel cycle facilities; the only changes were made to accommodate terminology specific to transportation.

6. SUMMARY AND CONCLUSIONS

The proposed action will provide persons involved in activities related to the packaging for transportation of radioactive material much needed information on the essential elements of QA programs acceptable to the NRC. The regulatory guide discussed herein should be prepared and issued.

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