# VALUE/IMPACT STATEMENT

# CONCERNING

# RESPONSE TO REQUEST TO REMOVE

# FROM 10 CFR PART 71

# APPENDIX E - QUALITY ASSURANCE CRITERIA FOR

# SHIPPING PACKAGES FOR RADIOACTIVE MATERIAL

SEPTEMBER 1979

DOCKET NO. PRM 71-7



U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF STANDARDS DEVELOPMENT

PRM 71-7

# VALUE/IMPACT STATEMENT

## I. The Proposed Action

### A. Description

The proposed action is a denial of a petition for rulemaking, PRM 71-7. Primarily, the petition asked for the revocation of Appendix E, "Quality Assurance Criteria for Shipping Packages for Radioactive Material," to 10 CFR Part 71. Appendix E was part of effective quality assurance (QA) regulations that were published in 1977 (42 FR 39364, August 4, 1977) for licensees subject to 10 CFR Part 71. The implementation date, i.e., the date by which licensees had to file descriptions of their QA programs with the Commission, was July 1, 1978 (but was subsequently extended to January 1, 1979). These requirements for QA programs apply to persons subject to 10 CFR Part 71; thus, they apply to shippers of fissile material and type B quantities (i.e., the larger quantities) of other radioactive material; however, they generally do not apply to shippers of less than type B quantities of radioactive material.

### B. Need for Proposed Action

The proposed action is a response to a petition for rulemaking (PRM 71-7), submitted by letter dated May 10, 1978 by the Non Destructive Testing Management Association, P.O. Box 1214, Magnolia Park Station, Burbank, California, and by seven undesignated radiography camera manufacturers and

six undesignated source manufacturers. The petitioners requested that the Commission (1) revoke Appendix E - Quality Assurance Criteria for Shipping Packages for Radioactive Material - to 10 CFR Part 71, and (2) delay the effective date of implementation of Appendix E until a hearing could be conducted. The Commission also received requests from Nuclear Energy Services Inc., Automation Industries, Inc., and the Yuba Heat Transfer Corporation to delay implementation of the QA requirements of 10 CFR Part 71. In response to these requests to delay the implementation date, the Commission extended the date by which licensees had to file descriptions of their QA programs from July 1, 1978 to January 1, 1979.

The petitioners further noted that there was a lack of uniformity in quality assurance (QA) requirements between Agreement State licensees and NRC licensees. Presently, Agreement State licensees who are shippers comply with DOT packaging regulations and are affected by 10 CFR Part 71 requirements only indirectly. DOT requires that shippers use either Type B packaging specified in the regulations or packaging specifically approved by the NRC. Users of NRC-approved packages are required to have a QA program description that has been approved by the NRC. Therefore, there is not a direct QA regulatory requirement for Agreement State licensees who are shippers, while there is a direct QA regulatory requirement (§ 71.51) for NRC licensees who are shippers. Currently, the NRC staff is in the process of addressing the question of applicability of similar QA requirements to Agreement State licensees, with the purpose of imposing a direct

regulatory requirement for QA programs, by recommending that the DOT add quality assurance (QA) requirements to its regulations for packages containing radioactive materials. The purpose of this recommendation is to extend QA requirements to all packages containing radioactive material and to produce uniform QA requirements for all shippers of radioactive material. This action would encourage greater diligence on the part of the persons involved to ensure that all types of packagings for radioactive material are designed, manufactured, tested, used, maintained and repaired in accordance with all regulatory requirements, design requirements, package specifications and conditions of package approval.

C. Valve/Impact of the Proposed Action

The value of the proposed action of denying PRM 71-7 would be retaining the Appendix E, QA criteria in the Commission's regulations, and the requirement for shippers of fissile and type B or greater quantities of other radioactive material to have an approved QA program. The benefits of QA programs for packagings for radioactive material are emphasized in the following discussion:

Assurance of safety in transportation of radioactive materials is necessary for all types of shipments, including low specific activity materials, type A packages, type B packages and other special categories. It is particularly important for persons subject 10 CFR Part 71, i.e., shippers of fissile or type B or greater quantities of other radioactive material. The transport safety regulations establish minimum standards for practical achievement of a defined level of safety in transport and require careful

the regulatory authorities, while other actions do have a specific regulatory base. A QA program, in these cases, simply provides management with an effective way of assuring the proper implementation of all procedures required by regulation or otherwise deemed necessary for safety. Only an incremental increase in effort for recordkeeping and audit procedures may be required for implementation of a QA program.

Quality assurance is a management process to achieve product excellence and, indirectly, public acceptance and confidence. In actual practice, management can use the QA program to assure controlled product performance and safe packaging operations. Since the nuclear industry bears the primary responsibility for assuring safety and full compliance with the regulations, it is imperative that management take an active role in quality assurance and, also, translate into practice all significant quality assurance procedures. Quality assurance, to be most effective, should be the proper concern of everyone within an organization.

An obvious benefit of a functional QA program is the early consideration of safety factors in the design phase of any packaging. Safety must be considered in the design phase to be most effective for the use, maintenance, repair, or modification of a packaging. The adequacy of the package design could be compromised by errors that occur during fabrication, maintenance or use of the packaging. Good QA programs increase the likelihood that such errors would be detected and corrected prior to packaging use.

II. Technical Approach

A. Technical Alternatives

There exist four technical alternatives for this issue: (1) Deny the petition for rulemaking and retain the status quo, (2) require some modified QA program for special form packages, (3) revoke Appendix E to 10 CFR Part 71, or (4) initiate a rulemaking proceeding to exempt from the QA requirements certain licensees, such as, shippers of special form materials.

B. Discussion of Technical Alternatives

(1) Denial of the petition for rulemaking will result in the retention of the QA criteria of Appendix E to 10 CFR Part 71 in the regulations, and shipping packagings for radioactive material will continue to be covered by QA program controls. (2) The second technical alternative is inherent in the present regulations due to the use of a graded approach in establishing QA programs and, therefore, is actually part of the first technical alternative. (3) Revocation of Appendix E to 10 CFR Part 71 would probably necessitate the addition of specific quality control procedures for specific packaging types to the regulations. (4) Exempting special form shippers from QA program requirements would effectively incorporate a further distinction in the categorization of radioactive material; i.e., type B quantities of radioactive material would be split into two groups that would have potential transportation hazards that are: (1) significant - requiring QA programs, and (2) less significant - not requiring QA programs.

C. Decision on Technical Approach

The preferable alternative is to deny the petition and to keep the QA requirements in 10 CFR Part 71. The staff finds no inconsistency in the application of QA requirements to an entire category (type B quantities of radioactive material) that has been long established both internationally (International Atomic Energy Agency's transportation regulations) and in this country (DOT's and NRC's regulations). Use of the graded approach provides the mechanism by which a particular group of licensees, such as industrial radiographers, can provide safety assurance in radioactive material packaging through the use of optimal QA programs. The Commission has never envisioned a large and expensive QA program for industrial radiography licensees, and the guidance that has been provided (draft regulatory guides) reflects this intent.

III. Procedural Approach

A. Procedural Alternatives

There are no procedural alternatives to the approach of denying PRM 71-7. However, procedural efforts may be required for further guidance to specific groups of licensees.

B. Value/Impact of Procedural Alternatives

One other regulatory guide is in the present program action plan, in addition to two draft regulatory guides [Ref 1 and 2] which we expect to be developed as regulatory guides. No other guides are contemplated at this time.

C. Decision on Procedural Approach

The staff will complete the regulatory guide scheduled in the present program action plan.

## IV. Statutory Considerations

A. NRC Authority

This regulatory action derives its statutory authority from the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

B. Need for NEPA Assessment

In accordance with 10 CFR 51.5(d)(3), neither an environmental impact statement nor negative declaration need be prepared in connection with this action.

## V. Relationship to Other Existing or Proposed Regulation or Policies

Coordination with DOT may produce an amendment of DOT's regulations which would provide direct QA requirements for Agreement State licensees who ship radioactive material, thereby attaining compatibility with the QA requirements for NRC licensees.

## VI. Summary and Conclusions

A denial of the petition for rulemaking (PRM 71-7) by the Executive Director for Operations under 10 CFR Part 1 (§1.40(o)) will retain the QA criteria of Appendix E to 10 CFR Part 71. QA requirements for persons subject to Part 71 will keep a common base of accepted criteria for QA

programs. Thus, type B quantities of radioactive material will be afforded a base of control in QA programs which is dependent on this category as a whole. Program costs for licensees such as shippers of irradiated fuel, high level waste, and plutonium, will remain the same as before the Part 71 QA requirements were promulgated. Other licensees, such as shippers of special form material, will incur costs that are related to the risks associated with the packaging and its contents. It is expected that industrial radiography licensees will incur program costs near the minimum for all persons subject to the QA requirements of 10 CFR Part 71.

## REFERENCES


1. Draft Regulatory Guide 7.XX, "Establishment of a Quality Assurance Program for Shipping Packages for Irradiated Fuel, High Level Waste, and Plutonium," May 15, 1978.

2. Draft Regulatory Guide 7.XX, "Content of the Description of a Quality Assurance Program for the Use, Maintenance and Repair of Shipping Packages for Certain Special Form Radioactive Material," May 1, 1978.