



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

July 6, 1979

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The Honorable Ron Paul
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Paul:

Your letter of April 11, 1979 posed questions concerning (1) Appendix E, "Quality Assurance Criteria for Shipping Packages for Radioactive Material" to 10 CFR Part 71 and (2) the Commission's policy in regard to notifying Agreement States of developments at the Commission.

Appendix E to 10 CFR Part 71

I appreciate your concern about the potential economic consequences of Appendix E to 10 CFR Part 71. Although we did not perform a formal detailed cost/impact analysis of Appendix E, we believe its implementation has not resulted in any appreciable increase in licensee costs. The history of our quality assurance requirements and adoption of Appendix E provides insight into our reason for this conclusion.

Requirements for operating and inspection procedures have been a part of the transportation regulations since 1966, as have some specific quality assurance tests and determinations. Criteria similar to those in Appendix E have been applied to shippers of fissile material, high level waste, and plutonium since 1972 through the NRC licensing program. Criteria similar to those in Appendix E have been applied to the use of byproduct material in industrial radiography when done in connection with civilian nuclear programs.

Appendix E was part of revised quality assurance (QA) requirements for 10 CFR Part 71 that were published as proposed regulations on December 28, 1973 (38 FR 35490). Comments were received at that time from ten persons who manufacture or use shipping packages and from one State regulatory agency. In response to the comments, a number of specific provisions in the proposed requirements were deleted. No broad objections to the Appendix E criteria were raised. The effective QA regulations, with Appendix E, were published August 4, 1977 (42 FR 39364). The implementation date, i.e., the date by which licensees had to file descriptions of their QA programs with the Nuclear Regulatory Commission (NRC), was extended from the original date of July 1, 1978 to January 1, 1979 as a direct result of a petition (PRM 71-7), filed on May 10, 1978, which requested such an extension.

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The purpose of the revision of 10 CFR Part 71 was to upgrade existing QA requirements -- in view of the increasing operational and shipping activities involving radioactive materials -- and to make them more explicit and more uniform for licensees. It should be noted that the requirements apply to persons who are subject to 10 CFR Part 71, i.e., to shippers of fissile material and Type B quantities (larger and more hazardous quantities) of other radioactive material, and generally do not apply to shippers of Type A quantities (i.e., smaller quantities) of radioactive material. Type A and Type B quantities of radioactive material defined in 10 CFR §71.4(q) are categories that originated with the International Atomic Energy Agency and distinguish between quantities of radioactive material that, on the basis of toxicity and potential hazard in transport, are of lesser and greater significance to health and safety.

Furthermore, as stated in Appendix E, the criteria in Appendix E are to be applied to an extent consistent with their importance to safety. For example, shipping of radiographic sources (encapsulated solid form material) requires only a simple program involving small costs that can be described on two pages. This graded approach relates the costs of QA programs to the potential hazards of the shipment.

An analysis of the costs to licensees for preparing and maintaining the initial reports describing the QA programs to meet the criteria in Appendix E and costs to NRC for reviewing those reports was completed and sent for General Accounting Office (GAO) clearance on July 27, 1977. A copy of that letter and the GAO response dated September 12, 1977 is enclosed (Enclosure 1).

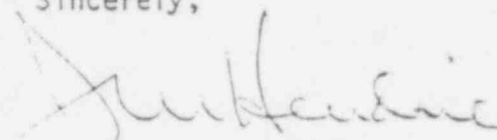
Notification of Agreement States

In response to your question regarding a complaint you have received that the Commission ". . . does not keep Agreement States totally informed of developments at the Commission . . .", I would emphasize that the agreements executed between the Commission and Agreement States provide for cooperative arrangements for development of rules, regulations, and procedures covering agreement materials. For example, drafts of proposed amendments of the Commission's regulations affecting Agreement States (i.e., 10 CFR Parts 10, 20, 30-35, 70, 71, and 150) are distributed to the Agreement States for comment, and those comments are taken into account before the proposed regulations are submitted to the Commission for approval. An annual Agreement State meeting is held at which developing regulations and other items of mutual interest are discussed by Agreement State representatives and Commission staff.

In addition to these direct contacts with Agreement States, each proposed regulation is published in the Federal Register, accompanied by a preamble explaining the basis for the proposed regulation and inviting all interested persons who so desire to submit written comments or suggestions to the Commission. To encourage additional public participation, the NRC's staff has adopted a procedure (see Enclosure 2) that all proposed and effective regulations of a substantive nature will be mailed to affected licensees and other known interested persons and organizations such as standards writing groups, trade associations, trade publications likely to be read by affected licensees, and public interest groups. In the case of a regulation affecting Agreement State licensees, the Commission's staff provides copies to officials in all Agreement States.

I hope the above is responsive to your questions. If I can be of further assistance, please let me know.

Sincerely,



Joseph M. Hendrie

Enclosures:

1. Correspondence with GAO
2. Policy and Procedures