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

OCT 2 1979

Mr. L. D. Santman, Director
Materials Transportation Bureau
Department of Transportation
2100 2nd Street, Southwest
Washington, D.C. 20590

Dear Mr. Santman:

Subject: Regulatory Requirements for Quality Assurance Programs for Packagings Containing Radioactive Materials

Many surveys concerning radioactive materials in transport have been made, and several incidents involving radioactive materials in transport have occurred, over the past 10 years. Much of the information and analyses which have been compiled on this subject point to benefits that are achieved, with respect to the health and safety of all individuals concerned, when careful attention is applied to compliance with regulatory requirements, package specifications and good safety practices.

In 1970, we wrote to the DOT encouraging an expanded program of inspection and enforcement for shipments of radioactive materials. We understand that positive efforts have been made to provide additional training and instruction on radioactive materials for the inspection force, along with a stepped-up number of inspections of shipments involving radioactive material. In addition, increased attention has been placed on these shipments by the NRC inspection program; and several states, under contract with DOT and NRC, are performing surveillance studies concerning these shipments.

A more direct approach to improving compliance with safety standards is to encourage greater self-action by shippers and carriers by increasing the emphasis placed on quality assurance (QA). QA programs appear to offer shippers an ideal means to assure a high degree of reliability in the performance of packagings in transportation, and regulatory agencies an effective and responsible way to assure the public health and safety. Therefore, we recommend that consideration be given to requiring QA programs for all shippers of radioactive material, including those shipping low specific activity materials and type A quantities. Such programs should apply the graded approach, i.e., the extent of the program should be commensurate with the degree of hazard involved. The bases for our recommendations are given in Attachment A. For other than type B, large quantity or fissile material packagings, there is no apparent need for prior review and approval of QA programs because of the less hazardous nature of the quantity of radioactive material which would be contained in these packagings. However, to be consistent with the present DOT requirements, the descriptions of QA programs for package designs for fissile material and type B and large quantities of other radioactive material should be reviewed and approved by the NRC prior to first use.

In 1977, NRC published in 10 CFR Part 71 requirements that each person subject to 10 CFR Part 71 establish a quality assurance program applicable to his transport activities and submit a description of that program to NRC for review and approval. These QA requirements apply to shippers of fissile material and Type B and large quantities of other radioactive material, predominately. Other shippers, i.e., those not subject to Part 71 such as Agreement State licensees and NRC licensees who ship less than type B quantities of other than fissile material, are not covered by these requirements. The Commission believes that these other shippers, who normally fall under the jurisdiction of DOT regulations, should have acceptable QA programs for the shipment of packagings containing radioactive material.

We feel that initiation of early actions on these recommendations is warranted. We would be pleased to assist in defining regulatory approaches at an early date.

Lee V. Gossick
Executive Director for Operations

Enclosure: Attachment A

Task No. TP 821-3
Distribution:

LVGossick	WMMorrison, SD
RBMinogue	LBHigginbotham, IE
RGSmith	GHBidinger, IE
GAArlotto	CEMacDonald, NMSS
RMBernero	EEJakel, ELD
RJJones	Docket File (PRM 71-7)
DRHopkins	PDR
RJDoda	SECY
DNussbaumer, NMSS	Central File
MMalsch, ELD	SD Alpha File
JFelton, DRR	SD r/f

EDO	DRR	NMSS	ELD	TPAC	IE
/ /79	8/29/79	9/5/79	9/20/79	8/9/79	9/14/79

CRESS:NL	TPSB:ES:SD	TPSB:ES:SD	A/MSS:SD	DIR:ES:SD	DD:SD	DIR:SD
Job L-1	RJDoda:tr	RJJones	RMBernero	GAArlotto	RGSmith	RBMinogue
8/15/79	8/20/79	/ /79	/ /79	9/12/79	/ /79	/ /79

ATTACHMENT A

RECOMMENDATIONS ON REGULATORY REQUIREMENTS CONCERNING QUALITY ASSURANCE PROGRAMS FOR PACKAGES CONTAINING RADIOACTIVE MATERIAL

INTRODUCTION

In 1977, the Nuclear Regulatory Commission (NRC) published (42 FR 39364 dated August 4, 1977) general requirements for quality assurance (QA) programs for persons who are subject to Title 10, Code of Federal Regulations, Part 71, Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions. These QA requirements apply to licensee-shippers (of fissile material, type B and large quantities of other radioactive material) who are subject to 10 CFR Part 71. However, the requirements do not apply to other shippers, i.e., those not subject to 10 CFR Part 71 such as Agreement State licensees or most shippers of type A quantities of radioactive material.

These regulations require the approval of a licensee's QA program by the Commission. The implementation date, i.e., the date by which licensees had to file descriptions of their QA programs with the Commission, was January 1, 1979.

BACKGROUND

The NRC has been active in upgrading its regulations on packaging QA since 1973 when a report by the General Accounting Office (GAO) recommended development of additional QA requirements for the more hazardous radioactive materials packages

(report dated July 31, 1973, "Opportunity for AEC to Improve its Procedures for Making Sure that Containers Used for Transporting Radioactive Materials are Safe"). The GAO again, in a letter report, dated May 11, 1977, to Chairman Christopher J. Dodd of the House Committee on Government Operations, recommended that the NRC complete the container quality assurance regulations "on a priority basis."

The QA regulations, which were published, contained an appendix of QA criteria (Appendix E - Quality Assurance Criteria for Shipping Packages for Radoactive Material) which were listed within 18 subject headings. The Appendix E criteria provide a sound basis for the establishment of any comprehensive QA program and, as such, the criteria may be applied to many different types of activities. In recognition of the varying complexity of QA programs for different types of activities, the Commission encourages the use of a graded approach in establishing QA programs; i.e., the applicable criteria should be applied to an extent consistent with their importance to safety. The regulations require that quality assurance programs satisfy the applicable criteria in Appendix E. Subject headings of these criteria are listed below:

1. Organization
2. Quality Assurance Program
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures, and Drawings
6. Document Control
7. Control of Purchased Material, Equipment, and Services

8. Identification and Control of Materials, Parts, and Components
9. Control of Special Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Nonconforming Materials, Parts, or Components
16. Corrective Action
17. Quality Assurance Records
18. Audits

These criteria indicate, in a broad and encompassing manner, all of the measures and controls necessary for an adequate quality assurance program.

The regulations require licensees who are designers, manufacturers, or users of any NRC-approved packaging to establish and maintain a quality assurance program to ensure that the packaging is designed, manufactured, tested, used, maintained, and repaired in accordance with all regulatory requirements, design requirements, package specifications, and conditions of package approval. The purpose of these QA programs is to ensure that appropriate engineering and management practices are applied to packagings and to assure a high degree of reliability in the performance of packagings in transportation to provide protection of public health and safety and the environment.

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. The transport safety regulations establish minimum standards for practical achievement of a defined level of safety in transport and require careful conscientious efforts toward compliance to achieve that level. Efforts to assure compliance with the safety requirements and to provide an added degree of safety, are in the interest of the persons involved, if only to avoid incurring liability. Added safety is also in the interest of the general public and others who are necessarily and intimately involved with the transportation activity.

The shipper bears the primary responsibility for safety in transportation of his materials. He must be prepared to demonstrate that each shipment is in compliance with the pertinent regulatory requirements. Any evaluation or documentation of the safety of a package or shipment to demonstrate compliance with applicable standards is part of a program of quality assurance. In many cases, only a small amount of planning and additional effort is required to satisfy the regulatory requirements for a QA program.

Operational and shipping activities involving radioactive materials are increasing in number at the present time and may become more complex in the future. This is resulting in differing opinions among industry, regulatory agencies,

and the public as to what comprises adequate safety in and proper regulation of these operations. Industry desires the application of reasonable regulatory requirements which are based on comparable risk analyses for safety in transportation activities involving radioactive materials. Regulatory agencies are faced with providing assurance of safe operations without imposing undue or burdensome inspection and compliance procedures. The public demands that efforts be taken to reduce the probability of radiological incidents before incidents occur. Responding to incidents on an ad hoc basis is not a disciplined way to provide for the public health and safety. No reasonable amount of regulatory effort, however, can ensure absolute safety; and no reasonable amount of inspection and enforcement can ensure total compliance. Application of quality assurance in transportation can help achieve adequate safety and satisfy, to a considerable extent, the needs of industry, the public, and regulatory agencies. Effective quality assurance programs can provide: (1) the public with knowledge that safety programs are in force, (2) industry with a means of control by which the desired degree of safety can be achieved with minimal effort, and (3) regulatory agencies with a viable means of protecting the public health and safety. The implementation of QA programs is a means of preventing problems and costs before incidents occur as opposed to reacting to incidents after they occur. QA programs can assure a high degree of reliability in the performance of packagings in transportation. Most industrial organizations already follow many specific procedures that pertain to quality-related controls for their packaging and transportation activities. Many actions, which may not have been considered or termed quality assurance, are taken by designers, manufacturers, and users to assure satisfactory performance of transportation packaging operations. Many of these actions are currently

carried out without any specific requirements being imposed by 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 deemed necessary for safety or required by regulation. 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. 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.

RECOMMENDATIONS

That QA programs be required to ensure that all types of packagings for radioactive materials, including those for low specific activity materials and type A quantities of 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. Such programs should satisfy the applicable portions of NRC's 18 criteria, although persons should be encouraged to use the 'graded approach' in developing their QA programs; i.e., the extent of the program should be consistent with its importance to safety. As is the case with package designs, review and prior approval of QA programs for other than type B, large quantity or fissile material packagings would not be required. However, consistent with the present DOT requirements that fissile material and type B quantities of other radioactive material package designs be reviewed and approved by the NRC, the descriptions of QA programs should also be reviewed and approved by the NRC, prior to first use, for these same packagings. The NRC staff considers this necessary to achieve an adequate level of quality assurance and to provide consistency in the regulatory requirements for most shippers of radioactive material.[1]

[1] The regulatory requirement for prior NRC review and approval of QA programs for packagings containing a type B or greater quantity of radioactive material could be added to 49 CFR Part 173 at § 173.393, General Packaging and Shipment Requirements, as a new paragraph (q) "Prior to the first shipment of any package containing fissile or a type B, or greater, quantity of other radioactive material, the shipper shall have a QA program, that has been approved by the NRC, for the use of this package."

In addition, the QA criteria of Appendix E to 10 CFR Part 71 could be referenced in the DOT regulations, thus eliminating the need for separate criteria in the DOT regulations. The graded approach for the establishment of QA programs is an integral part of Appendix E to 10 CFR Part 71.