Benefits of Standard Format and Content for Approval of Packaging for Radioactive Material

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1.0 Abstract

The U.S. Nuclear Regulatory Commission (NRC) uses Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material" to provide recommendations on the preparation of applications for approval of Type B and fissile material packages. The purpose of this Regulatory Guide is to assist the applicant in preparing an application that demonstrates the adequacy of a package in meeting the 10 CFR Part 71 packaging requirements. NRC recently revised Regulatory Guide 7.9 to reflect current changes to the regulations in Part 71 as a result of a recent rulemaking that included changes to the structural, containment, and criticality requirements for packages. Overall, the NRC issues Regulatory Guides to describe methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the NRC staff in evaluating specific problems, and to provide guidance to applicants. It is important to note the specific purpose of this Regulatory Guide. As the name indicates, this Guide sets forth a standard format for application submission that is acceptable to the NRC staff that, when used by the applicant, will accomplish several objectives. First, use of the guide provides a consistent and repeatable approach that indicates the information to be provided by the applicant. Second, the organization of the information in the application will assist the reviewer(s) in locating information. Ultimately, accomplishing these objectives will help to ensure the completeness of the information in the application as well as decrease the review time. From an international perspective, use of a standard format approach could enhance the efficiency with which Competent Authorities certify and validate packages for use in the packaging and transportation of radioactive material worldwide. This streamlined approach of preparing package applications could ultimately lead to uniform international certification of packagings. Use of a standard format by Competent Authorities is the next step in assuring a consistent framework for continuing to transport radioactive materials in a safe and efficient manner.

2.0 Background

In the U.S. the Nuclear Regulatory Commission approves designs for Type B and fissile material packages. For these designs, an applicant must show that they meet the performance requirements in 10 CFR Part 71, which are in general compatible with IAEA Regulations for the Safe Transport of Radioactive Material, TS-R-1. Part 71 and TS-R-1 both include provisions that specify the contents of an application for package approval. The contents of an application must include a package description, including design drawings and specifications and the identification of radioactive contents, and a package evaluation against the performance requirements. Applications for package approval may be lengthy, complex, and technically detailed documents.

3.0 Regulatory Guide 7.9

The NRC issues regulatory guidance documents to support its regulations. These guidance documents are intended to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits or licenses. The guides are issued in ten broad divisions, and Transportation is Division 7.

Regulatory Guide 7.9 is the "Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material." This Regulatory Guide was developed as an aid in the preparation of an application for package approval. The purpose of the Standard Format is to indicate the information to be provided in the application and to establish a uniform format for presenting the information. Use of the format will help ensure the completeness of the information provided, will assist the staff and others in locating the information, and will aid in shortening the time needed for the review process. The application is the principal document in which the applicant provides the information and bases for the staff to determine whether or not the package meets the requirements of 10 CFR Part 71. Regulatory Guide 7.9 was first published in March 1979, and has been revised several times.

Most recently, NRC updated Regulatory Guide 7.9 to reflect current changes to the regulations in Title 10 of the Code of Federal Regulations (10 CFR). These updates included changes in the structural, containment, and criticality requirements for packagings, and are based on adoption of the Regulations for the Safe Transport of Radioactive Material (TS-R-1). In its experience of providing Regulatory Guide 7.9 to applicants, NRC has determined over the years the value it provides when applied. First, use of the Guide provides a consistent and repeatable approach that indicates the information to be provided by the applicant. Thus, applicants are aware of the methods acceptable to the NRC during its review and can therefore provide accurate information to support the application. Second, the format of the information in the application will assist reviewers. For each Type B or fissile material package, Regulatory Guide 7.9 includes eight specific areas in which applicants are requested to provide supporting information. These areas include general information, structural evaluation, thermal evaluation, containment, shielding evaluation, criticality evaluation, package operations, and acceptance tests and maintenance programs. When applicants provide detailed and accurate information in a standardized format, the review time is decreased due to the completeness of the information. This benefits the review team by streamlining the review, and the applicant by the fact that they have provided thorough and complete information in the assembled application.

3.0 International Standard Format and Content

From an international perspective, use of a standard format and content approach will enhance the efficiency with which competent authorities certify and revalidate packagings for use in the packaging of radioactive materials worldwide. Many individual Member States of the International Atomic Energy Agency (IAEA) currently use a domestic standard format and content approach to packaging approval that is comparable to the approach of the NRC in Regulatory Guide 7.9. Since Member States' domestic requirements are based on the radioactive material packaging and transportation standards established by the IAEA, the infrastructure is clearly established to work through the appropriate channels to develop an international Standard Format and Content Guide. The pathway for such a document would include development and approval of an IAEA Technical Document and the eventual transition to an IAEA Guidance Document.

4.0 International Standard Format and Content Guidance Document

An International Standard Format and Content Guidance Document would include a Table of Contents which supports the location for each type of package, or material, including Type B, fissile material, Type C, special form, Low Dispersible Material, and Type H. Each packaging section would include the content requirements for the eight specific areas including general information, structural evaluation, thermal evaluation, containment, shielding evaluation, criticality evaluation, package operations, and acceptance tests and maintenance programs.

Internationally, the benefits to individual Competent Authorities of providing a Standard Format and Content Guidance Document would be expected to be similar to those currently experienced by the NRC (e.g., completeness of the information and reduction in review time). Use of a standard format and content guidance document would also facilitate review of applications by other Competent Authorities in the case of multilaterally approved designs. Further, there would be no question as to the content of the application because it would be structured within the format of the International Standard Format and Content Guidance Document and would be based on the IAEA transport standards. Thus, international commerce would benefit, as less time would be needed for review and approval of packagings from one competent authority to another.

Currently the United States is in discussion with competent authorities from other countries to begin development of a reviewers guide for transportation packages. The first step in achieving this goal may be to develop a Standard Format and Content Guidance Document that would be used between these countries. The Guide would be based on TS-R-1 and would be instrumental in facilitating unilateral approval of packages between two countries.

5.0 Conclusion

NRC's Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material", provides a consistent and repeatable approach that indicates the information to be provided by an applicant for approval of a Type B or fissile material packaging. The organization of the information in the application assists the reviewers in locating information. Ultimately, these points help to ensure the completeness of the information in the application as well as decrease the review time. From an international perspective, use of a standard format approach could enhance the efficiency with which Competent Authorities certify and validate

| packagings for use in the packaging and transportation of radioactive material worldwide. This standardized approach of documenting package applications would contribute to safety and efficiency in the transport of radioactive materials worldwide. |
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