



The Advantages of Using Standardized Review Procedures in Certifying Type B Radioactive Material Packages

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1.0 Abstract

This paper presents the advantages of adopting well-documented standardized review practices for reviewing Type B package designs. The US experience using standardized review plans and guidance has shown them to be a valuable tool in achieving more consistent and efficient package reviews, in training and qualifying technical reviewers, and in enhancing public and industry understanding of the package certification process. In addition, the standardized review practices, as living documents, have proven to be an effective method of incorporating new technical advances into the review process, and have provided a vehicle to make that knowledge widely available to fellow reviewers, the public and industry. Canada implemented a new internal review process in early 2003 to standardize the review of applications for certification of Type B Packages.

Based on the similarity of these approaches, the United States and Canada have started discussions on a ^ANorth American System[®] for the unilateral approval of Type B (U) packages. This initiative is looking into how each country is currently reviewing transportation package applications to see if agreement can be reached on accepting Type B certifications on a reciprocal basis, i.e., without additional review. Based on the experience in Canada and the United States, the authors believe that the use of standardized review processes, coupled with the knowledge and experience resident in IAEA's Transportation Advisory Material (TS-G-1.1) and series of TECDOCS, could also be used to develop a standard internationally accepted review process that could enhance the acceptance of unilateral approvals for Type B packages.

2.0 Background

The universal acceptance of unilateral approvals for Type B packages, without additional package review by affected member states, has remained an elusive goal for many types of transport packages (e.g., spent fuel and fissile material packages). In principle, each member state should use IAEA Regulations as the basis for package approval, and that approval could be accepted on a reciprocal basis by all other member states, with little or no requirement for additional technical review. In practice, member states have routinely insisted upon the need to re-review unilaterally approved Type B packages. As always the devil resides in the details.

While member states share essentially the same regulations, it is widely held that there are significant differences in the way that regulations are implemented, and perhaps, in the qualifications of technical reviewers among member states. Implementation issues are also heavily influenced by the perspectives that individual member states have concerning risk, safety margins, and because of differences in engineering standards and quality assurance requirements applied by various countries. Additional difficulties arise when review processes and results are not adequately documented by member states. If any progress is to be made towards the universal acceptance of unilateral approvals of Type B packages, a framework needs to be developed in which these different perspectives, as well as the minimum requirements for qualifying technical reviewers, can be addressed, resolved, and documented. It is in this context that the US and Canada have started discussions on the applicability of using or modifying their current processes to establish a basis for a "North American System" for the unilateral approval of Type B (U) packages.

3.0 Current Review Process in the United States

The review process currently used in the United States has evolved over the past several years based on the NRC's experience in interacting with fellow regulators (such as the IAEA and its individual member states), the nuclear and transportation industries, and the general public. Drawing upon this experience, the NRC review process has been designed with several key objectives in mind. These include maintaining a high level of consistency in technical reviews, optimizing efficiency in using human and technical resources, maintaining an ability to rapidly review and incorporate technical innovations in package designs, ensuring uniform training and qualification of technical reviewers, and enhancing public and industry understanding of the package certification

process through openness and transparency. These key objectives have been integrated into the NRC review process by the development of standard reviews plans for transportation package reviews, the implementation of qualification journals for technical reviewers, and the development of a standard format and content guide for applicants requesting review of package designs.

3.1 Standard Review Plans and Interim Staff Guidance

The NRC published its standard review plan (SRP) for radioactive material shipping packages in March 1999¹, and its SRP for spent fuel casks in March 2000². The nine years of accumulated experience using the two SRP's have shown them to be valuable tools in achieving consistent and efficient package reviews. The SRP's provide a summary of the transport regulations (10 CFR Part 71) and acceptance criteria applicable to a package design, a description of the procedures by which NRC staff determines that its regulations have been satisfied, and a documentation of review practices used by staff. The SRP's are organized around major disciplines (e.g., separate chapters are allocated to structural, thermal, containment, and criticality safety) to facilitate review by technical specialists, and provide sufficient guidance to orient and achieve consistency from new reviewers.

To remain current, the SRP's are scheduled to be updated on a periodic basis, approximately every three years. Technical issues that arise between updates are incorporated into the review process through the issuance of interim staff guidance (ISG). The issuance of ISG's provides a relatively effective and timely method to incorporate new information and technical innovations in the review of package designs. The SRP's and ISG's are also made publicly available, so that the review process is transparent and can be understood by the US public, as well as reviewers in fellow member states.

3.2 Standard Format for Documenting Package Approvals and Requests for Additional Information

In addition to SRP's, the NRC has developed standard formats for requests for additional information (RAI) from applicants, and for documenting package approvals. The format for requesting additional information includes a detailed description of the information required, a paragraph explaining why the information is needed and how it is intended to be used, and a citation to the applicable regulation for which the application is required. Use of the RAI format assures that there is a clear need for all information requested, and provides a clear description of how the additional information will be integrated into a package approval. It also provides valuable guidance for new reviewers, in that the format helps new reviewers focus on the link between the need for requesting additional information and meeting regulatory requirements.

A standard format for documenting package approvals provides staff and the public with a clear record of decisions made during a package review. The format is structured to enable the public to see how individual regulatory requirements were considered, analyzed, and decided. It also serves as an informal "QA check" on packages reviews to assure that all regulatory requirements were considered, decided, and documented.

3.3 Qualification Journals

The NRC has recently adopted qualification journals for newly hired individuals involved in the project management and technical review of transport packages. The journal tracks a project manager's or reviewer's progress in completing the training required to be "qualified" to manage a package review or conduct a technical review in a specific discipline. When the qualification journal is completed, the individual undergoes a final examination by a qualifications review board made up of managers and senior technical staff. Upon successful completion of the exam, the successful individual is presented with a certificate of qualification. More experienced employees have been "grand-fathered" based on their work history and experience.

¹ Standard Review Plan for Transportation Packages for Radioactive Material, NUREG-1609, U.S. Nuclear Regulatory Commission, March 1999.

² Standard Review Plan for Transportation Packages for Spent Nuclear Fuel, NUREG-1617, U.S. Nuclear Regulatory Commission, March 2000.

3.4 Standard Format and Content Guide

The NRC has recently updated Regulatory Guide 7.9, "Standard Format and Content of Part 71 Applications for Approval of Packaging for Radioactive Material" to provide potential applicants with guidance on the preparation of applications for approval of Type B and fissile material packagings. The purpose of this Regulatory Guide is to assist the applicant in preparing an application that thoroughly and completely demonstrates the adequacy of a package design in meeting the requirements in 10 CFR Part 71. Use of this regulatory guide by applicants has greatly improved the efficiency of package reviews as it assures that the information in an incoming applicant for package approval is compatible with the SRP's described in Section 3.1.

4.0 Current Review Process in Canada

The review process currently used in Canada has changed over the last few years due to changes in the organization. The Canadian Nuclear Safety Commission (CNSC) has recently developed written procedures to assure that package approvals are consistent, clearly documented, and risk informed. These procedures were mainly developed on the review practices in effect prior to 2003 but not documented. These written procedures assure that every request for package approval, foreign or domestic, is reviewed in the same way. In addition, a risk based approach is applied to assure that attention and resources are focused on package approvals that pose higher risk, while reducing unnecessary burden for low risk categories of approvals.

No application guide is currently available in Canada; the review of the application is based on the relevant IAEA paragraphs. Guidelines regarding request for additional information and documentation of the review of an application are to be developed.

4.1 Risk-based Approach

The CNSC has developed a risk based approach for the review of applications for package approval. Under this approach, the level of review and resources is based on the effort required to review a package design approval. This risk based approach is stratified into three groups, high, medium and low risk. The high risk category includes new domestic designs and amendment to domestic designs, since no other competent authority would have reviewed these packages. The medium risk category includes new foreign packages and amendments for foreign packages, and upgrades of domestic packages approved more than fifteen years ago. The low risk category includes renewal without changes to domestic and foreign packages and upgrades of foreign packages.

4.2 Review Procedure and Process

Once an application is categorized, the review is performed using a set of criteria outlined in the procedure for the approval of certified packages. The procedure includes a number of safety related aspects of a package design such as the material properties, the assumptions used, the boundary conditions, the safety margins and verification of calculations related to the safety of the package.

An internal document is produce when the assessment is complete. This document includes a description of the package and its content and a description of the area reviewed (structure, thermal ...) and a recommendation with regards to the approval of the package. For application in the high risk group and upgrade of domestic packages, the application and the internal document is given to another reviewer who conduct a peer review to ensure that the safety of the package has been adequately verified.

4.3 Format for Documenting Package Approvals and Requests for Additional Information

Currently, the CNSC does not have a standard in place for dealing with request for additional information and to document the review of an application. The request for additional information is generally based on areas identified in the procedure for approval of certified packages. An internal document describing the review of the application is produce when the review is completed.

5.0 Joint U.S. – Canadian Initiative on Unilaterally Approved Package Approvals

In May 2004, Canada and the United States initiated an effort to explore ways in which their package review programs could be integrated to enhance the acceptance of unilaterally approved packages without the need for additional review. This effort is focused on establishing a framework for package reviews that includes clearly documented review processes and technical positions, reviewer qualifications and training, optimization of resources based on risk, and the flexibility to incorporate innovation.

A key component in developing a “North American System” is the standardization of the review process, including establishing standard review plans, and standard formats for documenting and sharing positions on technical issues and package approvals. The NRC’s SRP’s, ISG’s and standard format for package applications and approvals (described above) currently form the basis for discussion between the two countries in the standardization process. The North American System will also incorporate experiences gleaned from the Canadian review process, and consider the Canadian risk-informed approach as a way to prioritize and optimize the use resources on package approvals.

Finally, the US and Canada realize that the review process does not need to be identical for both countries, as long as each country is satisfied and has confidence in the way the other is conducting the review process. In order to better understand how each country is looking at package design, Canada and the United States have decided to share their experiences on how the review process is being conducted in their own country, and to seek agreement on how reviews performed in one country could be accepted in the other.

6.0 Conclusion

It is believed that the results of this cooperation might be useful for the international community in that it might serve as a starting point in resolving the issues related to the unilateral approval of certified packages.