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# Package Certification and Validation of Certificates from an Industry Perspective

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Lyn Farrington, WNTI

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**Dedicated to the  
safe, efficient  
and reliable  
transport of radioactive  
materials**

## Abstract

This paper considers the many aspects of the package certification and validation process, from an industry perspective, to identify ways to further enhance the efficiency of the regulatory function. The challenge is to achieve these enhancements without a conflict of interest, or the perception of a conflict of interest, whilst ensuring that the regulator remains clearly independent. The competent authorities responsible for regulating the transport of radioactive materials around the world have developed procedures for the overview of the package design and shipment approval process that includes pre-transport licence application activities, package testing programmes, licence application guidance and technical reviews of the applications. There is an impressive degree of competence, experience, and knowledge among the competent authorities in the provision of the regulatory function. There is a great deal of constructive interaction between team members, the different competent authorities, and the competent authorities with industry, considering the quantity of work. In providing its radioactive material transport regulatory programme, over recent years, the competent authorities have demonstrated a commendable openness and a strong desire to be transparent with regard to the vital regulatory activities. The manner in which the competent authorities support industry is a demonstration of the commitment to an excellent safety culture in its transport regulations.

## 1. Introduction

The competent authorities responsible for regulating the transport of radioactive materials around the world have demonstrated a commendable openness and a strong desire to be transparent with regard to this vital regulatory activity. A fundamentally important component of the regulatory function is the overview of the package design and shipment approval process. The challenge here is to provide an efficient package certification and revalidation process in a timely manner. This requires close co-operation between competent authorities and industry. Competent authority and industry are constantly striving to streamline and enhance the efficiency of this activity. Some aspects of the package design and shipment approval process are considered below and, where possible, enhancements to procedures and processes are proposed.

## 2. Package certification and revalidation

The technical arm of the competent authority is directly responsible for review and assessment activities associated with the package design and shipment approval process. They are experienced and knowledgeable in their respective areas of responsibility and have well-developed procedures to address many parts of the process.

This paper considers the following specific aspects of the approval processes giving an industry perspective:

- pre-transport licence application activities;
- package testing programmes;
- licence application guidance;
- technical reviews of the applications.

### 2.1 Pre-transport licence application activities

Often, in the past, the first contact of applicants with competent authorities was when they applied for an approval. It is now quite

common practice for competent authorities and industry to get in contact during the preliminary design stages in order to discuss the implementation of the relevant design principles and to establish both the approval procedure and the incumbent actions.

Most competent authorities and applicants have an established practice of early and active interaction with prospective applicants. This informal interaction, during the very early design review process and thereafter is beneficial in both assuring a quality application and in facilitating the final review process by addressing problems early in the design phase. Whilst all parties acknowledge the benefits of such early interaction, equally, all parties understand the effect that ad-hoc, un-programmed interactions have on scarce resources. Industry works with very demanding shipment schedules and relies on timely approvals. Staffing levels and financial resources available to regulatory bodies are important to their ability to fulfil their responsibilities in the area of the approval of package design in a predictable and reasonable time schedule.

### 2.2 Package testing

The impact design of packages is based upon a series of drop tests, which are considered to be the most onerous. The drop tests are performed to demonstrate that the containment of the package is not breached and that the package is protected from the effects of an impact such that the contents do not breach reactivity limits. The packages usually use drop testing as a fundamental part of their design justification. Such drop testing utilises, for example, one-third, full size model sections or even full size models of the package.

In general, the competent authority has an established practice of regularly observing physical testing of package designs. The competent authority reviews and influences proposed package-testing programmes. The discussions include potential use of scale models or prototype packages, attributes of the test facilities, and test details such as drop orientations.

In some cases, supplementing drop tests with finite element calculations may be seen as a reliable method of demonstrating structural integrity. However, it is also accepted that such analyses can become subjective due to a plethora of unknowns. This has led to protracted discussions and the inevitable delays to the delivery programme. Some of this subjectivity can be removed during the testing programme as the results of one test are used to influence the conditions of subsequent tests, with agreement from the regulator. This can only be achieved if suitably qualified and experienced staff are made available from both industry and the regulators during the testing programme.

### 2.3 Application guidance

It is the responsibility of the competent authority to determine that the designs of packages are assessed against all the relevant parts of the regulations. Many competent authorities have issued Applicant's Guides that are current and comprehensive in scope. The Applicant's Guides are a practical and useful tool. They are publicly available and include relevant administrative as well as technical aspects with respect to the information that is necessary for the submittal of an application for approval. Consistent approaches and consistent interpretation across the guides can expedite the approval and subsequent validation process.

## 2.4 Technical review of the application

The technical review is a co-ordinated review of, amongst other things, the mechanical engineering, criticality and quality assurance aspects of an application. Most competent authorities have procedures, at various stages of development, that provide an administrative guide for their assessors. From an industry perspective the review process, whilst complete and thorough, may be different from one competent authority to another. From an industry perspective, consistency in the review process is an essential efficiency component.

Of particular note here is multilateral approval and validation, and the importance of making a clear distinction between the two, to avoid an excessive or protracted review process.

## 3. Conclusion

Safe, efficient and reliable transport within the international transport safety regulatory regime is enhanced by the competent authorities and industry communicating and co-operating to the maximum extent throughout the regulation and review processes.

For further information, please contact:

WNTI  
7 Old Park Lane  
London W1K 1QR  
Tel: + 44 (0) 207 408 1944  
Fax: + 44 (0) 207 295 1964  
Email: [wnti@wnti.co.uk](mailto:wnti@wnti.co.uk)  
[www.wnti.co.uk](http://www.wnti.co.uk)