

## **APPROVALS PROCESS A CONSISTENT APPROACH BY INDUSTRY**

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### **Abstract**

The continued ability to transport radioactive material in the public domain is of key strategic importance to the long term viability of the industry. It is essential that all processes involving transporting packages containing radioactive material are carried out in compliance with all regulations and to a consistent high standard.

The assessment/approval process and documentation thereof for packages not requiring competent authority approval (self assessment package types) is a matter of interpretation of the IAEA regulations versus individual organisations documentation quality standards. This can cause some inconsistency within the industry and as a result confusion amongst users. The challenge is to agree and implement a consistent approach for the approval process for non CA approved packages. In the UK this challenge was taken up by the industry group Transport Container Standardisation Committee (TCSC).

International Nuclear Services is a member of the TCSC. The objective of the TCSC is to examine the requirements for the safe transport of radioactive material with a view to standardisation through developing guidance documents relating to radioactive materials transport. TCSC carried out research to identify all regulations and standards within the UK nuclear industry and the processes involved in the assessment of non CA approved packages. Attention was paid to both the graded approach and the IAEA regulatory requirements for such packages and as a result the following guidance document emerged during 2006.

### ***Approval of Radioactive Material Transport Packages which do not require Competent Authority Approval, TCSC 1078 – July 2006***

TCSC 1078 is a UK industry interpretation of the key IAEA terminology in respect of the approval process for non CA approved packages and has used the appropriate information from the UK competent authority applicants guide to promote consistency throughout. TCSC 1078 provides the user with guidance for the format and content of Design Safety Reports, Approval/Compliance Certificates and illustrates a change control system for changes to design or manufacture.

Suggestions are discussed for national implementation of the standard, thus paving the way for an eventual International standard for those IAEA packages that do not require competent authority approval.

## 1. INTRODUCTION

The use of radioactive materials and their associated transport are vital components to our everyday lives, therefore the continued ability to transport radioactive material in the public domain is essential. There has been a noticeable increase in the transport of Excepted Packages, Industrial Packages and Type A Packages, largely related to the decommissioning industry. Radioactive Material Transport is regulated by the IAEA “Regulations for the Safe Transport of Radioactive Material TS-R-1 2005 Edition” [1]. These regulations offer a number of package types that either require approval by the Competent Authority or that can be approved under the self assessment system, by appropriately qualified and experienced people. The following is a table illustrating the approval route for each package type.

<i>IAEA Package Type</i>	<i>Approval Route</i>
Excepted Package	Self assessment
Industrial Package Type 1 (Type IP-1)	Self assessment
Industrial Package Type 2 (Type IP-2)	Self assessment
Industrial Package Type 3 (Type IP-3)	Self assessment
Type A Package	Self assessment
Type H(M) & H(U)	Competent Authority
Type B(M) & B(U)	Competent Authority
Type C	Competent Authority
Note - All Fissile Packages require Competent Authority approval unless excepted by paragraph 672 [1] “Exceptions from the requirements of fissile packages”	

Table 1 – Package Type approval route

Table 1 above illustrates that the IAEA rely heavily on industry to design, assess, and approve such package types to a consistent high standard. The self assessment system deployed by IAEA saves the Nuclear/Radioactive industry significant time and costs when compared to other international systems for the assessment and approval of packaging. For example the United Nations UN [2] recommendations for the transport of dangerous goods state that all packagings for the transport of dangerous goods over limited quantities (other than class 7) be approved by a Competent Authority, when such packagings are only required to offer a very similar level of integrity to those classed as self assessment designs by IAEA.

The excellent safety record of the Nuclear Industry is an indication of industries vigilance towards compliance with the regulatory requirements for self assessment packagings. Nevertheless industry has an interest to both harmonise interpretation and continuously improve the standard of self assessment, to ensure the concept of self assessment remains in future editions of the regulations.

## 2. SELF ASSESSMENT – THE PACKAGE TYPES

The philosophy of the regulations is to provide comparable levels of safety to all package types. The IAEA graded approach results in self assessment package types varying considerably in regulatory requirements. In summary by relating the nature and amount of contents with graded package integrity requirements a uniform and adequate level of safety, that is commensurate with the inherent hazards of the contents, can be demonstrated. This IAEA system is based on three general severity levels;

### **Routine conditions of transport (incident free)**

It can be inferred from the regulations, by the exemption from any performance testing that Excepted Packages and Type IP-1 packages need only to demonstrate integrity under routine conditions of transport.

### **Normal conditions of transport (minor mishaps)**

Package types that are required to demonstrate integrity under normal conditions of transport only, are subject to differing performance tests dependent on package type, such packages are Type IP-2, Type IP-3 and Type A.

### **Accident condition of transport**

Package types that need to demonstrate integrity under the hypothetical accident conditions of transport performance tests, require Competent Authority Approval, hence are not discussed in this paper.

The above mentioned self assessment package designs can be anything from a very small cardboard box carrying a single test tube as an Excepted Package to non destructive testing NDT source packages as Type A to 80te packages designed to carry items from Nuclear decommissioning programmes as IP-2. This diversity can allude to many different interpretations of regulations and standards in documentary evidence.

## **3. SELF ASSESSMENT – THE PROCESS**

The transport of radioactive material by land, by air and by sea has been regulated by the IAEA since 1961 and the concept of competent authority approval for Type B packagings has existed since this first set of published regulations. Conversely since this date the IAEA has permitted the self assessment approach for a significant number of package types, the latest edition of the regulations TS-R-1 [1] permits self assessment for 3 package Types (see Table 1), increasing to 5 package types when the Industrial Packages are looked at in detail.

The self assessment process considerably varies as discussed in section 7. However the fundamental process of package assessment cannot follow any other pathway than the traditional approach that has been carried out by Competent Authorities for years. Thee main difference being Competent Authorities impose one system for all package types requiring Competent Authority approval, whereas industry uses the graded approach to determine the level of documentary evidence required as a function of the package type.

### **3.1 Common self assessment package stages of design and assessment**

Below is a summary of a particular design and approval staged process for Packagings designed to contain radioactive material;

Design stage	Process	Involvement
Stage 1	Functional Specification (requirements)	Design Authority
Stage 2	Concept (including baseline calculations, if required)	Designers Authority
Stage 3	Design (including analysis, if required)	Design & Approval Authority
Stage 4	Testing, (if, required)	Design & Approval Authority
Stage 5	Manufacturing Specification	Design Authority
Stage 6	Package Design Safety Report PDSR	Design Authority
Stage 7	Assessment and approval process	Approval Authority

For package types where testing is required to demonstrate integrity under Normal Conditions of Transport, the assessment process would be expected to start at stage 3 or 4 and stage 7 for designs where no testing is required. After testing stages (if required), for the approval process to commence a Package Design Safety Report PDSR and its associated documentation (for example Operating and Handling Instructions) is required by the approval authority. Approval is on the basis of appraisal of the PDSR which can demonstrate compliance with the regulations. Generally, some form of approval certificate will be issued by the “Approver” to signify acceptability of the design. Such certificate will include references to all the principle documentation required to operate the package.

#### **4. SELF ASSESSMENT - THE REGULATIONS**

Competent Authorities are responsible for assuring compliance with the regulations. Many Competent Authorities choose to carry out compliance assurance of self assessment package designs either through a systematic review of package designs on a sampling basis prioritised on risk or simply by National audit programmes. The degree with which Competent Authorities exercise this function varies considerably. In some member states Competent Authority intervention is minimal, but in others it can approach the same degree of involvement as for Competent Authority approved packages. For example, India has a requirement that all Type A packages are registered with their Competent Authority (Atomic Energy Regulation Board AERB), and in Russia, for certain self assessment package types, a full validation by their Competent Authority (Rosatom) is carried out.

The regulations do not impose any mandatory requirements for the approval process of self assessment package designs, only the graded approach system is implied. All responsibilities for compliance with the regulations are placed on the consignor of the package; this is where the inconsistencies begin, for example, larger companies with multiple consigning teams often choose to provide an *independent* internal approval service for self assessment package designs, and such service is then registered and audited by the Competent Authority. Other companies are not able to provide this level of independence in the process and often design, manufacture, approve and consign their own package designs against local procedures. These extremes can introduce significant variances in the standard of the package approval process.

#### **5. THE CHALLENGE OF CONSISTENCY**

Within the UK nuclear industry there is evidence of inconsistency in

- interpretation of the requirements for self assessment packages.
- processes for approving these package designs for use.
- standards of documentation to support the process.

Clearly industry would benefit from consistency in this area to encourage;

- national and international harmonisation in interpretation of regulatory requirements to avoid any conflicts regarding package design compliance.
- the development of the approval process across industry to satisfy expectations from Competent Authorities.
- standardisation of the documentation formats to create a uniform presentation of documentation, reducing the risks of increases in Competent Authority compliance audits for self assessment packages.

So the challenge became one of identifying those areas where consistency offers most benefit, then agreeing how this can be presented to the transport industry to obtain buy-in; it was then agreed that a guidance document would be appropriate. Taking into account potential commercial advantage it was agreed that the guidance document should not be authored by one single organisation; the Transport Container Standardisation Committee proved to be an effective independent solution. This committee and its terms of reference are discussed in the following section.

## **6. THE UK TRANSPORT CONTAINER STANDARDISATION COMMITTEE TCSC**

The TCSC was founded during the 1960's by the UK's leading organisations in the Nuclear industry. It is a self financing industry forum and concentrates on the practical aspects of container design and operation, bringing both safety and financial benefits to UK industry.

Over the years TCSC has developed into a widely recognised and highly respected UK industry committee and presently consists of a membership from twelve UK organisations. The terms of reference of the TCSC have remained relatively stable throughout its 30-year lifespan indicating the benefit to UK industry. In summary the terms of reference of the TCSC are to examine the requirements for the safe transport of radioactive materials with a view to standardisation and where either requested from the committee members or requested by industry, produce and maintain guidance in the form of TCSC standards. TCSC has published papers on topics of interest to industry and holds a library of such papers, for example: "The status of industry codes of practice and guidance" (a detailed study of the legal aspects of standards and codes of practice) and "Packaging tie-downs" (a report on experimental work by one of the members) etc.

### **TCSC Standards**

Currently there are eleven approved standards and three further standards under development. The range of standards and subjects covered are listed on the TCSC web site [www.tcsc.org](http://www.tcsc.org); a password is required for complete downloads. Consideration is being given for affiliate membership to obtain the latest revisions.

## **7. DEVELOPMENT OF TCSC 1078 STANDARD**

In 2006 the TCSC committee took on the task of developing a standard for UK industry the purpose being national harmonisation of the assessment and approval process for IAEA self assessment packages. This standard was titled "TCSC1078 Transport of Radioactive Material Code of Practice for the approval of radioactive material transport packages which do not require Competent Authority Approval".

The development of the guidance document TCSC1078 was addressed in two stages, stage one regulatory requirements and stage two demonstrable quality assurance.

## **Regulatory requirements for self assessment packages**

The regulations are brief but explicit in respect of in the approval and administrative requirements for packages not requiring Competent Authority approval. TS-R-1 quotes *“the consignor shall, on request, make available for inspection by the relevant competent authority, documentary evidence of the compliance of the package design with all applicable requirements”*

Five self assessment package types allude to 5 different sets of regulatory requirements and in addition the regulations list a range of alternative requirements for IP-2/3 Packages [para 624 – 628]. These varying regulatory requirements present significant challenges for a “harmonised approach”. TCSC decided that this task would need to be broken down further. The TCSC has under development guidance documents for,

- the requirements of ISO Containers as IP-2 packages ,
- the requirements for Excepted Packages,
- surface finishes standards for containers manufactured from stainless steel

## **Quality Assurance requirements of self assessment packages**

Requirements for quality assurance first appeared in the 1973 edition of the IAEA’s Transport regulations regarding **manufacture**. The 1985 edition of the regulations increased the requirements to cover quality assurance programmes for, design, manufacture, testing, documentation, use, maintenance and inspection.

In the spirit of the enhanced QA requirements TCSC initiated a review of the main components of the package design approval process. TCSC reviewed a number of Package Design Safety Reports (PDSRs) from a number of different organisations. In addition a review of the Package Design Modifications and Concession systems, including a suite of documentation templates to compliment such systems was reviewed.

The review further included a systematic evaluation of the documentary evidence prepared for the certification of self assessment packages (the auditable trail). Different standards/formats were presented both from the member organisations and their customers/suppliers.

### **7.3 Technical review of the UK self assessment approach – the findings.**

The need for some standardisation was obvious, in most cases compliance with regulations was not an issue, only differing standards of PDSR formats and assessment documentation formats, all with varying levels of content.

In respect to PDSR’s, for the many, creating anything new or different to the format of the UK Competent Authority applicants guide was unnecessary. Whereas the minority suggested that industry would benefit from a simple checklist approach as commonly found in US PDSRs for self assessment packages. It was clear that something was required in the middle of these two approaches.

## **8. TCSC 1078 GUIDANCE DOCUMENT**

TCSC 1078 is a comprehensive document and is designed to be used by industry in addressing the self assessment and approval process to promote consistency and assist

in compliance with the regulations. It includes all the fundamental back bones of an assessment and approval/appraisal system;

- Approval Process including documentation templates and contents guidance
- Packaging Design Modification and Concession process and documentation templates

### **8.1 TCSC1078 Approval Process**

In harmonisation with the UK Competent Authority Applicants Guide, the guidance document starts from an explanation of the assessment and approval process including a brief explanation of some key definitions followed by a template for a Package Design Safety Report (PDSR) and a template for a Package Approval Certificate.

The PDSR template as explained above is a condensed version of the Competent Authority Applicants guide split into only 7 sections with appropriate headed sub-sections with regulatory references. The sections headings are;

<i>Number</i>	<i>Section Title</i>
1	Introduction and supporting documentation list
2	Administration information
3	Specification of proposed radioactive contents
4	Specification of Packaging
5	Transport operations
6	Conformance with regulatory requirements
7	Quality Assurance

The TCSC formed a consensus that the above PDSR template both provides the user with a base line that can be used to demonstrate compliance if completed sufficiently, and when fully adopted will provide industry with a consistent controlled format that can be updated by TCSC as regulations develop or change.

For consistency, the Package Approval Certificate Template was again based on Competent Authority Certificates, again condensed as appropriate and sections added where industry has found itself developing, for example, colloquial names of packaging.

### **8.2 TCSC Packaging Design Modification and Concession**

The existing processes are such that self assessment package designs can be subject to design modifications and potentially the approval authority may not be informed of these changes. The UK Competent Authority system for design alterations was discussed as a solution, but considered to be onerous for self assessment package types.

TCSC 1078 includes a similar approach for modification control to that system adopted by the Competent Authorities. A documentation template for minor modifications to be communicated to the approval authority for such designs was created and attached to the guidance document. The process in summary consists of two categories of modification, i.e. major and minor. A major modification would require immediate revision to the PDSR and associated package approval certificate, whereas a minor modification would have no impact on safety and only information regarding the modification need be communicated.

## **9. CONCLUSION**

The key message to industry is that the approval process for self assessment packages (packages not requiring Competent Authority Approval) needs to evolve linearly with the Competent Authority approved package assessment processes. There is a requirement to improve the standard and consistency of assessment, without the risk of increasing the burden through more stringent regulations or even worse, the removal of the self assessment concept.

TCSC examined the regulations and standards within the UK nuclear industry and the processes involved in the design approval for self assessment packages; as a result a guidance document TCSC 1078 emerged during 2006.

TCSC 1078 is a UK industry interpretation of the key IAEA terminology in respect of the approval process for self assessment packages. TCSC 1078 provides the user with guidance for the format and the content of Package Design Safety Reports, Approval/Compliance Certificates and illustrates a change control system for management of changes during design, manufacture or operation.

## **REFERENCES**

- 1 TS-R-1), "Regulations for the Safe Transport of Radioactive Material", IAEA Safety Standards Series, (2005 edition).
- 2 Recommendations on the TRANSPORT OF DANGEROUS GOODS Modal Regulations, Fourteenth revised edition