HARMONISATION OF TRANSPORT DOCUMENTS FOR B(U) and B(U)F PACKAGES: A FORATOM STUDY

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FORATOM

FORATOM, which is based in Brussels, is an association of the European nuclear industry dedicated to the promotion of the peaceful use of nuclear energy. The association comprises of twelve national nuclear forums namely: Austria, Belgium, Czech Republic, Finland, France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom. The membership of FORATOM represents major electricity producers, manufacturers of nuclear plant and components, suppliers of fuel cycle services, transportation companies, research facilities and consultants.

FORATOM has four main objectives:

- To promote and improve the perception of the nuclear industry with the institutions of the EU, that is the European Council, Commission, Economic and Social Affairs Committee and the European Parliament.
- To act as the voice of the nuclear industry in various European policy debates by articulating the opinion of the nuclear industry to European Institutions and the media.
- To collate and distribute relevant information from these EU bodies to our membership.
- To act as a technical and economical advisor to international institutions such as the IAEA, and to serve as a means of consolidating and channelling industry expertise on issues such as quality assurance and the handling, transport, treatment and storage of radioactive materials.

FORATOM is structured into working groups such as: the Civil Liability Working Group, the Strategy Working Group, the Quality Management Working Group and the Nuclear Transport Working Group. This group is responsible for this paper.

The Nuclear Transport Working Group was created at the request of the European Commission's DG XVII to help in the establishment of standardised regulations for the transport of radioactive materials between the EU Member States and to assist the European Commission, in particular within its « Standing Working Group on Safe Transport of Radioactive Materials ». By continually monitoring the development of nuclear transport issues in the various committees in the European Parliament (particularly Environment, Energy and Transport), FORATOM co-ordinates and supports its Members in contracting with the Commission on studies dealing with all the aspects of the transport of radioactive materials.

SUMMARY OF FORATOM STUDY FOR DG VII

Introduction

The study was initiated and funded by FORATOM with financial support from the European Commission (EC) Directorate General for Transport (DG VII). The study contributes to the objective of developing the necessary harmonisation throughout the European Union with respect to the adoption of international conventions, norms and standards to facilitate the creation of a single market. It develops a harmonisation of the transport documents and procedures for the transport of radioactive materials in Type B(U) and Type B(U)F packages. This includes a standardised format for Package Design Approval Certificates issued by Competent Authorities of Member States, Transport Safety Analysis Reports (TSAR) and international consignment notes as defined in the RID and ADR regulations.

The proposals made in this presentation reflect those of organisations represented in the FORATOM Working Group who are involved in the design of Type B(U)F packages and their transport on a world-wide basis.

The advantages provided by the recommendations made in this presentation are expected to increase the efficiency of the design processes, the Competent Authority approval processes and the day to day transport processes. These benefits should result in a decrease in the operating costs of the organisation involved together with an increase in the effectiveness of business planning.

To avoid the development of rules in a diverse manner at a national level within Member States, the European Commission has sought to promote alignment of Member States domestic legislation with internationally recognised transport agreements for the transport of dangerous goods:

- the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR),
- the Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID),

The first measures in this direction was the adoption of the Council Directives 94/55/EC of November 1994 and 96/49/EC of July 1996. All Member States have since transposed these Directives into their legislation.

The ADR and RID regulations state that the Competent Authority of the Member State in which the package design originated shall issue a Package Design Approval Certificate for Type B(U) and Type B(U)F packages. In addition, the regulations also require that the Competent Authority of each Member State through which Type B(U)F packages transit shall also issue a validation of this Certificate.

When applying for a Package Design Approval Certificate, the designer provides the Competent Authority with a Transport Safety Analysis Report (TSAR). This document defines, evaluates and justifies the package design to demonstrate its compliance with the requirements of the ADR and RID regulations.

The Package Design Approval Certificate is therefore the basic tool by which the users and the Competent Authorities check the conformity of a shipment with the requirements of the package design.

An effective harmonisation of the transport documents and procedures for the shipment of Type B(U) and Type B(U)F packages within the EU will have several benefits, namely:

- It would enable the safety of such packages to be demonstrated against a common format for the safety analysis that would raise the standard and quality of such documentation.
- The creation of a standard format for the regulatory documentation would increase understanding in the EU thereby raising levels of safety by increasing the clarity of information.
- It should facilitate the creation of a common methodology of approach used by the Competent Authorities within the EU thereby raising standards for the EU as a whole.
- It would create a consistent level of safety that would be demonstrable and measurable.
- It would increase the efficiency of activities related to the free transport of radioactive materials within the EU.
- It should create a consistent level of confidence in both the industry and the regulators.
- It should facilitate an increase in public acceptance of such transports within the EU.

Methodology

The methodology for this study was to obtain from the Competent Authorities and representatives of the nuclear industry (through the FORATOM Transport Working Group) of each EU Member State, a broad consensus on the format of a TSAR and Package Design Approval Certificate. In addition, consensus of opinion was also established concerning the philosophy and the implementation of these two key documents within the EU.

Work programme

An advisory Project Team was set up within FORATOM which defined the work programme at the start of the contract, namely:

(a) Establish and compare the practices in each Member State that has a prominent and significant sized nuclear industry base.

(b) Take into account the previous studies of Lafontaine and O'Sullivan (1)

(c) Establish how the various guidelines which concern the preparation of a TSAR and the Competent Authority approval of package designs of each Member State could be included in a model document.

(d) After discussion with the appropriate Authorities of the Member States, produce a Synthesis Report for presentation to the European Commission with recommendations

(e) Propose a similar exercise aimed at establishing integrated recommendations for international consignment of transport packages for radioactive materials (forms, procedures and authorisations).

Summary of regulatory guides in various member states

It was recognised that the majority of Type B(U) and Type B(U)F package designs used throughout the EU have been designed or are currently used in France, Germany and the UK. Consequently the requirements and/or guidelines used in these Member States were used as representative examples (Table 1). In addition the requirements used in the USA were also included to represent regulatory requirements of a controlled and regulated nuclear industry outside the EU.

STRUCTURE AND CONTENT OF TSAR

The content of the TSAR should reflect the overall objective of any package design, which is to protect persons, property and the environment from the effects of radiation during the transport of radioactive material. This protection is achieved by; the containment of the radioactive contents; the control of external radiation levels; the prevention of criticality; and the prevention of damage caused by heat.

The structure of the TSAR shall therefore lead the reader from details of the design, to the use and care of the packaging, to manufacturing issues. The structure shall also include the recommendations made in IAEA Safety Series n° 112 (Compliance assurance for the Safe Transport of Radioactive Material (Table 2) to create the following fourteen Chapters :

I General Information
II Quality Assurance Programme
III Compliance with RID/ADR Requirements
IV Description of the Radioactive Contents
V Structural Evaluation
VI Thermal Evaluation
VII Containment Evaluation
VIII Shielding Evaluation
IX Criticality Safety Evaluation
X Operating Procedures
XI Maintenance and Repair Requirements
XII Manufacturing process including document control and records
XIII Mode(s) of Transport
XIV Packaging Drawing List

Claims of adequacy of designs or design methods shall be made on a technical basis and supported by appropriate evaluation or description of actual tests. Definitions, as defined in the RID/ADR Regulations, shall be used throughout the TSAR to minimise ambiguity.

Appendices to each chapter of the TSAR shall include detailed information omitted from the main text for clarity. Photographs (colour or monochrome) should support all physical tests of components and packages; photocopies of photographs should be avoided.

All quantities, units and symbols stated in the TSAR shall be in accordance with ISO 31-3 to 31-13.

Information relating to the transport arrangements of the packages as required for Type B(U) packages shall not be included in the TSAR to minimise the need to revise the document should there be changes to the transport arrangements during the operational lifetime of the package.

Control of package design

The importance of the quality and effectiveness of the control measures adopted during the design of a package cannot be underestimated. It is vital that the design process is demonstrably controlled to provide the regulatory authorities and the users with the necessary high levels of confidence in the safety of the package design throughout its operational life. All design activities should therefore form a cohesive system with particular attention to the creation and control of a design specification, effective communication and reporting systems, project management skills and appropriate technical competencies in the various aspects of a package design.

Document control systems shall be in place to control the TSAR and also the individual calculations, reports, specifications and engineering drawings contained therein. This should ensure that each aspect of the technical evaluation of the TSAR relates to the same evolutionary step of the package design.

Quality Assurance information and benchmark calculations for the computer codes used for the design should be referenced in the TSAR.

For each of the fourteen chapters of the TSAR the study identifies in detail the scope of requirements of the TSAR including issues such as material specifications physical properties, standards for design methodology, performance limits and factors of safety adopted, non-conformance controls during manufacture and maintenance, etc.

Comparison between IAEA safety series n°6 and the TSAR

IAEA Safety Series n°6 - §§ 705-711	TSAR Chapter
(a) Description of the Radioactive Content	Chapter IV
(b) Package Design	Chapter V - IX
(c) Tests and Analysis	Chapter V - IX
(d) Utilisation Procedure and Maintenance	Chapter X - XI
(e) Pressure Evaluation	Chapter V
(f) Fissile Material	Chapter IX
(g) Transport Mode	Chapter XIII
(h) Quality Assurance	Chapter II
(I) Drawing of the Package	Chapter XIV

PROPOSED FORMAT FOR PACKAGE DESIGN APPROVAL CERTIFICATES

The Package Design Approval Certificates issued by the French, German and UK Competent Authorities show obvious similarities but their layout and composition are very different. In order to derive the format of the Certificate each aspect of the existing Certificate formats were evaluated and their positive aspects selected for consideration. The main aspects, which were considered to be positive and therefore included in the proposal of the study, were:

- Considering the multiplicity of international regulations and, in the case of a European model of the Certificate, the applicable national regulations, there is a need to classify the different rules by level and by mode of transport.
- The possibility of establishing a common correlation between the Certificate, its revision status and the information given to the Competent Authority by the applicant.
- The need to provide a well-defined area in the Certificate.

- The need to provide a sufficiently complete description of the packaging and its contents.
- For validation Certificates, a unique validation reference together with a definitive reference to the original Certificate.
- Group together under a separate heading (Administrative Section: Chapter B), the main requirements of IAEA Safety Series n°6.
- Separate the Administrative Section from the Technical Section of the Certificate when the Certificate is issued for the first time in the country of the applicant (package design approval certificate).
- To identify the Quality Assurance systems which relate to the design of the package, and that which relates to the use, maintenance and repair of the packaging in the Administrative Section.
- To identify European standards and norms concerning the methodology used to compile the Package Design Approval / Validation Certificate.

Based upon these basic principles, an EU format for a Package Design Approval Certificate was proposed. The first page of this proposal is shown in Table 2. Abstracts of the guidelines explaining the contents of each numbered component of the Certificate are also included.

CONCLUSION

The results of this study should be considered as the beginning of a long-term process. The initial step of harmonising administrative documents, will require detailed discussions and agreement between representatives of the Competent Authorities of all EU Member States and the nuclear industry involved in the design, licensing and use of Type B(U) and Type B(U)F packages. The creation and use of an EU format for TSAR and Package Design Approval Certificates will significantly increase the efficiency of the approval processes of the Competent Authorities within the EU. This in turn will increase the efficiency of the transport of radioactive material industry within the European Union.

The success of the proposed harmonisation of regulatory documents will also depend upon the close liaison and co-operation between Competent Authorities. It is therefore proposed to establish a forum, which enables the Competent Authorities to meet and discuss on a regular basis the issues relating to the interpretation of the regulations, and the methodologies and philosophies of approach used to assess the various package designs. This will in time create a common understanding at a working level between the Competent Authorities thereby enabling guidelines for applicants to be produced in each member State of a consistent standard. This in turn will then create a more consistent quality and format of the Transport Safety Analysis Reports for the various package designs in use.

REFERENCES

I. Lafontaine, Study Contract No. 4.102/E/91-110
O'Sullivan,Study Contract No. 4102/E/91-10.

TABLE 1: SPECIFIC REQUIREMENTS OR GUIDELINES FOR TSAR AND PACKAGE DESIGN APPROVAL CERTIFICATE OF TRANSPORT PACKAGES

	GERMANY			FRANCE			UK			USA		
	Name of the document	Authority in charge of the application of the document	Mandatory (M) or not	Name of the document	Authority responsible for the application of the document	Mandatory (M) or not	Name of the document	Authority responsible for the application of the document	Mandatory (M) or not	Name of the document	Authority responsible for the application of the document	Mandatory (M) or not
TRANSPORT SAFETY ANALYSIS REPORT												
Transport Safety Analysis Report				N° 106a	IPSN	NM	DTp/RMT-D/001 (1992)	DETR	M	Regulatory guide 7.9 (1980)	NRC	M
				Type B packaging design safety analysis guidelines			Guide to applications for competent authority approval			Standard format and content of part 71 applications for approval of packaging for RAM		
Maintenance Operating Procedure										ANSI N67-9.1976	ANSI	NM
										Guide for writing operating manuals for radioactive materials packaging		
Manufacture	TRU 001 (1987)	BAM	M									
	Technical guide for the supervision of the manufacture of packagings											
QA & QC rules	TRV 006 (1991)	BAM	M									
	QA and QC guide for packagings for the transport of radioactive materials											
Modification Procedure												
PACKAGE APPROVAL												
Package Approval	R003 (1991)	BfS	M									
	Guide for the approval of the package design											
Shipment Approval							DTp/RMT-D/001 (1992)	DETR	M			
							Guide to applications for competent authority approval					
Special Arrangements										ANSI N14-10.2 (1973)	ANSI	NM
										Guide for obtaining special permit for RAM shipments		
Package Validation	R003	BfS	M									
Indexing, prolongation, extension, change of issue of the certificate				EASE/PRO n° 1 (1995)	IPSN	NM						
				Procedure defining the indexing rules of all the pages of package approvals and special arrangements								

TABLE 2: PACKAGE DESIGN APPROVAL CERTIFICATE FORMAT AND GUIDELINE

	1	Reference No. : Revision : Page :
2	Competent Authority	
	Seal of the Administration	
3	**TITLE OF THE DOCUMENT**	
4	Certified Item :	
5	Applicable Regulations & Codes : International : Road : Rail : Sea : Air : National : Others :	
1	System of Revision : The reference on the certificate shall correspond to the appropriate identification mark as described in § 724 of IAEA Safety Series No. 6. The IAEA proposal, explained in § 725 c), would be followed by all the Member States. A revision index for the technical part of the certificate, different from that of the administrative part, is possible and must appear if it is the case in Item 13.	
2	At the request of the RTSG, a TECDOC identifying the applicable rules and procedures for the transport of radioactive material in each IAEA Member State and the Competent Authorities will be issued soon. It will in particular clarify the administrative procedures for the EU Member States for the different documents for radioactive transport issued. The complete address of the Competent Authority references in this TECDOC would be mentioned in Item No. 13.	
3	Two different titles would be possible : - "Certificate of Approval of Package Design type '...' for the Carriage of Radioactive Materials". - "Certificate of Validation of Approval of Package Design type '...' for the Carriage of Radioactive Materials". As mentioned in § 724 of the IAEA Safety Series No. 6, this model of certificate would cover the package design AF, B(U), B(U)F, B(M), B(M)F, IF, special form radioactive material and the shipment of the above mentioned packages. This is a very important point because a validation and an approval are not identical. In case of validation, the reference to the original certificate must be given; A Certificate of Validation shall make specific reference to the original package design approval certificate.	
4	The applicants or the users of a package often use an abbreviation identifying the package design. The daily management of certificates would be facilitated by mentioning this synonym at the beginning of the Certificate. This commercial name will not supplant the identification mark of the Certificate and the item number of the Transport Safety Analysis Report (TSAR) (see Item No. 8).	
5	The list of applicable regulations may be long and not easily readable and therefore the list shall be segmented into three parts : international regulations, international regulations relating to mode of transport and national regulations.	