ABSTRACT
In the framework of the Russian Research Reactor Fuel Return (RRRFR) Program US DOE and Russian organizations have developed the first commercial Type C cask having the purpose to ship by air research reactor spent nuclear fuel in conformity with the requirements of the IAEA TS-R-1/SSR-6 Regulations for the Safe Transport of Radioactive Materials. The TUK-145/C is based on the SKODA VPVR/M cask Type B package, incased in an energy absorbing container (EAC) that assures the containment tightness after an impact caused by an aircraft crash during the shipment of spent nuclear fuel.

Since the support documentation and administrative requirements for package design certification differ from country to country, after receiving the Russian certificate of approval for package design it was decided to proceed with the preparation of a single document (Reference Manual) containing all relevant design, fabrication, safety, maintenance, management system and other information that could serve for the multilateral approval of the TUK-145/C package design certificate in any country. For this purpose, the content of the Reference Manual was developed based on the IAEA, US, Russian and European requirements. Starting from the Russian technical documentation prepared for certification, the Reference Manual was then created.

This paper presents the TUK-145/C Reference Manual elaboration process, its content and the summary of differences between the support safety documentation and administrative requirements for package design certification of the assessed countries and organizations. The purpose of this work is to prepare a complete set of licensing documents for the TUK-145/C for potential further utilization. Proposals for using the existing TUK-145/C technology, as well as perspectives for its further development and utilization are also included in this paper.

EVOLUTION OF REQUIREMENTS FOR AIR SHIPMENT OF RADIOACTIVE MATERIALS
The main actor marking the evolution of the requirements for air shipments of radioactive materials was the necessity to ship plutonium either for military programs or as MOX fuel in civil programs. The early editions of the IAEA’s Regulations for the Safe Transport of Radioactive Materials (up until 1996) didn’t contain limitations for package designs destined for the transport of radioactive materials by air related to accident conditions. Since potential consequences of an air transport
accident are far more severe than of a land or a sea transport, regulatory restrictions appeared a lot earlier.
For example, in the United States, Public Law 94-79, enacted in August 1975 placed the following restriction on the Nuclear Regulatory Commission: "The Nuclear Regulatory Commission shall not license any shipments by air transport of Plutonium in any form, whether exports, imports, or domestic shipments, provided, however, that any plutonium in any form contained in a medical device designed for individual human application is not subject to this restriction. This restriction shall be in force until the Nuclear Regulatory Commission has certified to the Joint Committee on Atomic Energy of the Congress that a safe container has been developed and tested which will not rupture under crash and blast-testing equivalent to the crash and explosion of a high-flying aircraft" [1]. Accordingly, NRC has issued in 1978 the "Qualification Criteria to Certify a Package for Air Transport of Plutonium" (NUREG-0360) containing accident test requirements for packages, as summarized below [2]:

- Hard-Target Impact Test: The package is rocket propelled into a hard, essentially unyielding target at a speed of at least 422 ft/s (129 m/s) or at a free fall velocity, whichever is greater, at the orientation expected to result in maximum damage.
- Thermal Test: Cask is exposed to luminous flames from a pool of JP-4 or JP-5 aviation fuel for at least 60 minutes. Flames extending an average of 1-3 m (3-10 ft) past the cask in all horizontal directions. Cask positioned to result in maximum damage. Cask is then cooled naturally or by spraying water, whichever results in maximum damage. (Temperature of the fuel fire is 760-1 315 °C or 1 400-2 400 °F.)
- Water Immersion Test: Immersion under at least 1 m (3 ft) of water for at least 8 hours.
- Puncture Tearing Test: If the package has a mass less than 250 kg, a 250 kg mild steel probe, the shape of the frustum of a cone (12 in (30 cm) long, 8 in (20 cm) diameter at the base, and 1 in (2.5 cm) diameter at the tip) is to be dropped onto the package from a height of 3 m (10 ft), striking in the position expected to result in maximum damage at the conclusion of the test sequence. For packages having a mass of 250 kg or more, the probe is to be placed on a flat surface and the package dropped from a height of 3 m (10 ft) onto the probe.
- Slash Test: Cask to be hit near its center by the end of a structural steel angle section (at least 6 ft (2 m) in length with legs 5 in (13 cm) long and 1/2 in (1.3 cm) thick) falling from at least 150 ft (46 m). Then rotate 90 degrees and repeat.
- Static Compressive Test: 70 000 lb (32 t) applied to cask in the orientation expected to result in maximum damage. Force applied between flat steel surface and a straight solid steel bar.

In result, a Plutonium Air Transportable Package, Model PAT-1, has been developed by the Sandia Laboratories which met the NUREG-0360 requirements. The PAT-1 package design has been certified as capable of withstanding severe aircraft accidents in 1978. The package has been assessed for transport of up to 2.0 kg of PuO₂ having a maximum decay heat of 25 watts and the energy absorbing element was an outer assembly made of select, kiln-dried redwood to take advantage of redwood's high specific energy and fire resistant characteristics [3].

The IAEA-TECDOC-702 “The air transport of radioactive material in large quantities of with high activity” was issued in April 1993. Subsequently, the 1996 edition of the IAEA’s Regulations for the Safe Transport of Radioactive Materials included stricter requirements applicable to packages intended for transport by air. In particular, new requirements regarding the limitation of radioactivity content in a Type B package for non special form materials to 3000 A² where transported by air, subcriticality of a single package after a series of extended tests, as well as the Type C package...
capable of withstanding severe aircraft accidents were introduced. The later, 2005, 2009 and 2012 editions of the IAEA regulations confirmed the validity of those provisions [4].

INTRODUCTION TO TUK-145/C (TYPE C) PACKAGE DESIGN

The idea to develop a package for air shipments without restrictions on radioactive content activity (Type C package) developed after the completion of the first licensed shipment of spent fuel based on new regulations (not under special conditions) for the research reactor spent nuclear fuel (RR SNF) air shipment in TUK-19 casks (Type B) in 2009 from Romania to Russia, in the framework of the US National Nuclear Security Administration (NNSA) Global Threat Reduction Initiative (GTRI) and the Russian Research Reactor Fuel Return (RRRFR) Program. Since then 6 more similar RR SNF air shipments in TUK-19 casks were performed (from Libya (1 shipment), Uzbekistan (2 shipments) and Romania (3 more shipments) to Russia).

In 2009 the work on the Type C package development on the basis of SKODA VPVR/M cask for air shipment of RR SNF was started under the RRRFR program by order of the U.S. Department of Energy. The activities aimed to enhance safety of air shipments of radioactive material. Current requirements of Russian and international regulations for Type C packages do not impose any additional limits on activity of radioactive content but require maintaining the package tightness after testing on impact with a speed not less than 90 m/s and fire during one hour.

TUK-145/C (Type C) package [5] (Figure 1) consists of two main elements:

- an Energy Absorption Container (EAC) intended for absorption of dynamic acceleration in case of an air crash,
- a SKODA VPVR/M cask inside the EAC, that ensures radiation shielding and prevents a leakage or loss of radioactive contents under normal and accident conditions of transport.

The EAC is a titanium cylinder made of upper and lower halves similar in design and a welded body filled with energy-absorbing elements – hollow spheres made of titanium. The SKODA VPVR/M cask is placed into the inner cavity of the EAC. The main characteristics are presented in the Table 1.

![Fig. 1. TUK-145/C](image)
Table 1. Technical characteristics of TUK-145/C

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass of loaded TUK-145/C, kg</td>
<td>29 650</td>
</tr>
<tr>
<td>Mass of empty TUK-145/C, kg</td>
<td>29 200</td>
</tr>
<tr>
<td>Mass of EAC, kg</td>
<td>18 500</td>
</tr>
<tr>
<td>Maximal mass of SNF loading, kg</td>
<td>450</td>
</tr>
<tr>
<td>Number of cells for SFAs</td>
<td>36</td>
</tr>
<tr>
<td>Useful lifespan, years</td>
<td>30</td>
</tr>
<tr>
<td>Height, mm</td>
<td>3065</td>
</tr>
<tr>
<td>Width, mm</td>
<td>3168</td>
</tr>
<tr>
<td>Diameter, mm</td>
<td>2816</td>
</tr>
</tbody>
</table>

The EAC, which is fulfilling a function of dynamic protection in the case of an air accident, was developed to absorb the force of impact against a rigid target at the velocity of not less than 90 m/s up to the load levels that the SKODA VPVR/M cask body can endure in emergency situations during a land shipment. Two EAC were fabricated by the order of US DOE.

**TUK-145/C DESIGN AND SHIPMENT INTERNATIONAL LICENSING AND PERSPECTIVES FOR FURTHER UTILIZATION**

The international licensing of any packaging for radioactive materials transport is based on the initial certificate of approval for package design issued by the competent organization in the country of origin of the respective packaging. The first Russian certificate of approval no. RUS/3166/CF-96 for TUK-145/C package design was issued by the State Corporation for Atomic Energy ROSATOM in 2012. Several Russian types of RR spent fuel assemblies (SFA) (IRT-2M, IRT-3M, IRT-4M, VVR-M, VVR-M2, VVR-M5, VVR-M7, VVR-(S)M, S-36, EK-10, TVR-S) are included in this certificate, but other radioactive material can be also shipped by air in TUK-145/C provided that additional safety analyses are performed.

The air shipment organization of TUK-145/C by An-124-100/IL-76 aircraft is flexible and it depends on the available transport and loading infrastructure at the Consignor’s facility, and therefore the certificate of approval for its shipment can also vary. There are two shipment options available for the An-124-100 aircraft and one perspective option for IL-76 aircraft, as described below.

**Option 1: Combined Air and Road Shipment of TUK-145/C Loaded with SNF (An-124-100 aircraft)**

For this option a good road transport infrastructure between the Consignor’s facility and the expedition airport have to be in place for the safe shipment of the TUK-145/C loaded with the SKODA VPVR/M cask accommodating SFAs. As presented in Table 1 the weight of the loaded TUK-145/C is 29.65 t, at which the road conveyance’s weight shall be added.

In this case SKODA VPVR/M cask containing the SFAs is loaded in the EAC forming the TUK-145/C at the Consignor’s site and then is transported by road to the expedition airport using a special designed trailer and a truck. The TUK-145/C already fixed on the special trailer is then front loaded in the aircraft An-124-100 using the truck (Fig. 2).
The simplified shipment scheme applied in this case is presented in Figure 3.

It shall be noted that a single certificate of approval for combined road and air shipment of TUK-145/C is required in this case. For this option Russian certificate of approval no. RUS/3166/СF-96T (Rev.1) for TUK-145/C shipment was issued by the State Corporation for Atomic Energy ROSATOM in 2013 and recently validated by the Hungarian Atomic Energy Agency for future shipments.

**Option 2: Road Shipment of SKODA VPVR/M Cask and Air Shipment of TUK-145/C (An-124-100 aircraft)**

This option can be safely applied for an undeveloped road transport infrastructure between the Consignor’s facility and the expedition airport. In this case the SFAs containing SKODA VPVR/M
(as certified Type B cask) is transported in a specialized 20 ft ISO container by road to the expedition airport using appropriate standard semi-trailer and truck. The weight of a SNF loaded SKODA VPVR/M cask with mounted shock absorbers is less than 13 t, and together with the ISO container weights up to 20 t. At the airport the previously delivered EAC is then loaded with the SKODA VPVR/M cask forming the Type C TUK-145/C, and afterwards the package is front loaded in the aircraft An-124-100 using a special rolling system (Figure 4).

![Fig. 4. TUK-145/C loading in the An-124-100 aircraft using the special rolling system (Option 2)](image)

The simplified shipment scheme applied in this case is presented in Figure 5.
Fig.5. Simplified shipment scheme, Option 2, An-124-100/An-124-150 aircraft

It shall be noted that two certificates of approval for road shipment of SKODA VPVR/M and air shipment of TUK-145/C are required in this case. For this option two Russian certificates of approval nos. RUS/3065/B(U)F-96T (Rev.7) and RUS/3166/CF-96T (Rev.1) for SKODA VPVR/M road shipment and TUK-145/C air shipment respectively were issued by the State Corporation for Atomic Energy ROSATOM in 2012 and validated by the order of the Vietnam’s Ministry of Science and Technology in 2013. The first RR SNF air shipment in Type C package from Vietnam to Russia was completed in July 2013.

PERSPECTIVES FOR TUK-145/C FURTHER UTILIZATION

The TUK-145/C package can also be shipped in a smaller IL-76 aircraft in horizontal position using a special handling frame - Option 3 (Figure 6).

Fig.6. TUK-145/C loading in the IL-76 aircraft using the special handling frame (Option 3)

A synthesis of the three air shipment options presented above is included in Table 2.

Table 2. TUK-145/C air shipment options

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mass of 1 package with truck – 47 t</td>
<td>Mass of 1 package with base plate – 32.2 t</td>
<td>Mass of 1 package with frame – 32 t</td>
</tr>
<tr>
<td>Capacity – up to 2 TUK-145/C</td>
<td>Capacity – up to 3 TUK-145/C</td>
<td>Capacity – 1 TUK-145/C</td>
</tr>
<tr>
<td>Total cargo weight – 94 t (no base plate required)</td>
<td>Total cargo weight – 104 t (with base plate)</td>
<td>Total cargo weight – 38 t (with roller system)</td>
</tr>
</tbody>
</table>
As showed in this section, shipment organization options for the TUK-145/C package are various and design and shipment licensing in conformity with the IAEA Regulations for Safe Transport of Radioactive Materials can be efficiently assured provided that the safety of the shipments is justified accordingly.

TUK-145/C can be used for future shipments of:
- research reactor spent nuclear fuel;
- spent fuel assembly fragments of power-grade reactors for research;
- high-level radioactive waste for storage and disposal;
- encapsulated radionuclide sources;
- core of the Miniature Neutron Source Reactor for reprocessing;
- liquid spent nuclear fuel;
- for emergency shipments (during a war, extreme meteorological events, etc.).

The air shipment may help reaching difficult access places, improve the shipments schedule in big programs or when a limited fleet of transport packages can be used, assure better security in the cases of long routes, avoid dangerous goods transiting in the close proximity of communities or environmental protected zones etc.

**TUK-145/C REFERENCE MANUAL DEVELOPMENT**

TUK-145/C was used in July 2013 to ship HEU RR SNF from Vietnam to Russia and is planned to be used for similar shipments from Hungary and Uzbekistan. In anticipation of the perspectives for TUK-145/C further utilization taking into account the benefits of air shipment, the idea to develop a unified document (TUK-145/C package safety analysis report or “Reference Manual”) to make possible the design certification in any country was explored [6]. This necessity was brought up by the fact that the regulatory requirements regarding the content of package safety documentation and the administrative procedures for issuing certificates of approval for package design and shipment are not harmonized at the international level, even though the basic technical requirements for packages are very much similar in most of the countries, being based on the IAEA Regulations for the Safe Transport of Radioactive Materials.

The following regulations were taken into consideration in the process: IAEA Regulations for the Safe Transport of Radioactive Materials (TS-R-1/SSR-6), US NRC Regulatory Guides 7.9 (Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material) and 7.10 (Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material), Russian Safety Regulations for the Transport of Radioactive Materials NP-053-04 and the Administrative Regulation (approved by the order no. 527/2007), EU Technical Guides - Package Design Safety Report for the Transport of Radioactive Material (PDSR, 2009 and 2012 editions).

A correspondence table between the content by chapters of the TUK-145/C Reference Manual and the requirements of the listed regulations is presented in Table 3.
<table>
<thead>
<tr>
<th>Regulation or Guide</th>
<th>GENERAL INFORMATION</th>
<th>TUK-145/C PACKAGE DESCRIPTION</th>
<th>STRUCTURAL EVALUATION</th>
<th>THERMAL EVALUATION</th>
<th>CONTAINMENT</th>
<th>SHIELDING EVALUATION</th>
<th>CRITICALITY EVALUATION</th>
<th>PACKAGE OPERATIONS</th>
<th>ACCEPTANCE TESTS AND MAINTENANCE PROGRAM</th>
<th>QUALITY MANAGEMENT SYSTEM</th>
<th>APPENDIXES</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>809b, 809a</td>
<td>809c, 809f</td>
<td>809c, 809e, 809f</td>
<td>809 f</td>
<td>(RG 7.10)</td>
<td>809c, 809f/677b</td>
<td>809d</td>
<td>809i</td>
<td>809a-h</td>
<td>IAEA Regulations SSR-6</td>
<td></td>
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<tr>
<td>1.1</td>
<td>1.2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>7</td>
<td>8</td>
<td>-</td>
<td>At the end of each chapter.</td>
<td>US NRC Regulatory Guide 7.9</td>
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<td>11.2l</td>
<td>11.2a, 11.2b, 11.2g</td>
<td>11.2b, 11.2c, 11.2d, 11.2e, 11.2j, 11.2m</td>
<td>11.2c, 11.2d</td>
<td>11.2c, 11.2d, 11.2e</td>
<td>11.2f</td>
<td>11.2c</td>
<td>11.2k</td>
<td>11.2c</td>
<td>11.2o, 11.2g, 11.2n</td>
<td>Russian Administrative Regulation</td>
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<tr>
<td>1.2</td>
<td>1.2, 1.3, 1.5</td>
<td>1.4, 1.6, 2.1, 2.2.1</td>
<td>1.4, 2.1, 2.2.2</td>
<td>1.4, 2.1, 2.2.3</td>
<td>2.1, 2.2.5</td>
<td>1.7</td>
<td>1.7, 1.8</td>
<td>1.9</td>
<td>1.10</td>
<td>EU PDSR 2012</td>
<td></td>
</tr>
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<td></td>
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</tbody>
</table>
An analysis of the TUK-145/C Reference Manual content coverage of the mentioned regulations and short conclusions drawn up from this analysis is presented in Table 4.

### Table 4. Content comparison between the TUK-145/C Reference Manual and different requirements for the package design safety documentation content

<table>
<thead>
<tr>
<th></th>
<th>IAEA Regulations SSR-6</th>
<th>US NRC Regulatory Guide 7.9</th>
<th>Russian Administrative Regulation</th>
<th>EU PDSR 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage</td>
<td>100% Coverage</td>
<td>95% Coverage</td>
<td>100% Coverage</td>
<td>100% Coverage</td>
</tr>
<tr>
<td>Conclusions</td>
<td>Gives very little information on the content of the application and the level of details expected. Leaves space for interpretation.</td>
<td>Existence of supplementary requirements in comparison with other similar regulations.</td>
<td>Gives little information on the level of details expected. Based on multiple separate documents, rather than a unified package safety report.</td>
<td>Requirements formulated differently than in other similar regulations.</td>
</tr>
</tbody>
</table>

From the above presented information the following statements can be observed:

- The Reference Manual structure best complies with the requirements of the US NRC Regulatory Guide 7.9 since it was chosen as a model for its development. However, due to supplementary requirements existing in this Guide a full coverage was not achieved.
- The Russian Administrative Regulation implies the submittal of many separate documents containing the required information for the safety justification of the package. Taking into consideration that TUK-145/C safety documentation is built on this approach, the elaboration of a package safety report or Reference Manual (in our case) is difficult and time consuming. As a general conclusion it may be noted that certificate validation of Russian packages in other countries is difficult and time consuming because of the different structure of the safety documentation.
- The 2012 edition of the EU Technical Guide on PDSR has a clear and efficient structure that can be easily applied to any type of safety documentation (either a single safety report as in the US Guide, or multiple documents as in the Russian Administrative Regulation). This is why a very good correspondence with the Reference Manual’s information could be achieved. However, the formulation of the requirements differs from others since it requires a separate package performance characteristics assessment, which in other cases may be distributed in all the parts of the safety documentation (e.g. shielding performance – in shielding assessment, etc.). Nonetheless this adds a benefit since the PDSR can be easier assessed by the regulatory body than other safety documentation without this separate assessment.
- In comparison with the 3 national regulations and guides analyzed (US, Russian, EU), the IAEA SSR-6 contains the less volume of guidance and requirements on the application for a certificate of approval for package design and leaves much space for interpretation on the level of details that should be included by the applicant. For this reason new IAEA
guidance documents for the applicants and the regulators concerning package design and shipment approval documentation and review are welcomed.

**ANALYSIS OF DYNAMIC DEFORMATION OF TUK-145/C PACKAGE UPON ITS CLASH AGAINST SOFT SOILS AT A VELOCITY OF 90 M/S**

Supplementary analysis of dynamic deformation of TUK-145/C package upon its clash against soft soils at a velocity of 90 m/s was performed. Based on the analysis of the dynamic deformations of different types of soil 3 typical representative soils have been identified as follows:

- sand, 1.68g/cm³ density – the “softest” soil obstacle;
- sand clay, 2 g/cm³ density and 14% humidity – “medium”;
- mild clay, 1.97g/cm³ density – the most “rigid” soil obstacle.

Axial, side and corner (42°) drops of the TUK-145/C with the speed of 90 m/s onto soils were analyzed and the results were compared with those from the impact on an unyielding target. At the finish moment of the axial, side and corner drop simulation the TUK-145/C penetrated the soils at a 1.2 m, 0.9 m and 1.7 m depth respectively. The maximum levels of the total deformations in the EAC materials don’t exceed the design limit for their breaking. The joints situated in the immediate proximity of the impact zone were analyzed in more details. The bolts deform elastically. The maximum efforts localized on the joining bolts are significantly less than the bolt material flow limit (Figure 7).

![Fig. 7. TUK-145/C condition at the finish moment of the drop simulations in sand (a); field distribution of the total deformation intensity for TUK-145/C drops in mild clay (b); example of the effort intensity distribution on joins in the proximity of the impact (c)](image)

In Figure 8 the curves of changes in the SKODA VPVR/M body overload in time for the TUK-145/C clashes on 3 soils are presented in comparison with the curve corresponding to the impact on the unyielding target.
Fig. 8. Curves of changes in the SKODA VPVR/M body overload in time for the TUK-145/C drops on 3 soils and on the unyielding target: a – axial drop, b – side drop, c – corner drop

In all cases considered, the EAC ensures absorption of the impact on the SKODA VPVR/M cask and maintains its integrity and containment.

For the cases of the EAC clash against the soils, the acceleration rate on the elements of the SKODA VPVR/M cask is much lower than for the cases of the EAC clash against an unyielding target.

For the clashes against sand, sand clay and mild clay:

– the maximum acceleration rates on the SKODA VPVR/M cask body made up:
  – axial impact: 1000g, 1100g, 950g (1500g - for an unyielding target),
  – side impact: 850g, 900g, 880g (1600g - for an unyielding target),
  – corner impact: 400g, 420g, 360g (1000g - for an unyielding target),

– the maximum absorber travel (crumpling of the EAC absorbing elements in the direction of falling):
  – axial impact: 110, 140, 136 mm (460 mm – for an unyielding target),
  – side impact: 190, 220, 180 mm (650 mm – for an unyielding target),
  – corner impact: 220, 275, 270 mm (1100 mm – for an unyielding target).

CONCLUSIONS

The modern international and national regulatory frameworks are now sufficiently developed in comparison with the 1970s and efficiently assure the safety of spent nuclear fuel air shipments, in normal and emergency situations of transport. Complying with this framework, the first created Type C package for research reactor spent nuclear fuel shipments by air made it possible to achieve great progress in providing increased safety, security and schedule efficiency of such operations. A universal set of technical means was created, which includes:

– SKODA VPVR/M cask and auxiliary equipment that provides for spent fuel assemblies’ loading from the bottom, as well as from the top;
– special trucks and semitrailers for the TUK-145/C shipment, that can be transported by air;
– two EAC.

The flexible TUK-145/C technology and its international licensing possibilities can comply with the requirements for any future utilization in RR SNF shipments for research, reprocessing or storage, in research of failure causes of power reactors fuel fragments, high-level radioactive waste or sealed
radioactive sources shipments, Miniature Neutron Source Reactor shipments, liquid RR SNF, as well as for emergency shipments during war or terrorist threats or extreme meteorological events. In the case of air shipments and other long route radioactive material shipments involving transit of several countries a better international harmonization of the requirements for the applications on certificates of approval for package design and shipment and their review by regulatory bodies is highly needed in order to improve the efficiency of the radioactive materials transports regulatory process worldwide. This could be achieved by the development and adoption of new IAEA guidance documents for the applicants and the regulators concerning package design and shipment application documentation and review, based on the European Union PDSR model, which has successfully started the path of harmonization for EU countries.

REFERENCES